Failure Mode and Effect Analysis

FMEA from Theory to Execution

Second Edition
Revised and Expanded

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ASQ Quality Press
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List of FMEA Samples
Found in Appendix D
On CD

All samples are real and represent a variety of different industries. Due to their proprietary nature, changes were made to eliminate company identification. Some of the FMEAs are still being developed and do not have all the columns filled or are only partly presented.

System FMEA
   Example 1 Sample of a generic system FMEA
   Example 2 Fidd Quad LSD

Design FMEA
   Example 3 Throttle body machine
   Example 4 Package/layout
   Example 5 Armature

Product Design and Development FMEA
   Example 6 Cooling fan assembly

Process FMEA
   Example 7 Nitride etch
   Example 8 Slit base laminate
   Example 9 GDS assembly

Service FMEA
   Example 10 Complaint diagnosis

FTA Development
   Example 11 FTA development of an air pumping system

Machine FMEA
   Example 12 Machine FMEA: modular oven
In the past 100 years or so, the United States has been the envy of the world. This country has been the leader in almost every major innovation people have made. The historical trend has been positive indeed. But what about the future? Should the status quo be retained? Is there anything to worry about? Can the leadership for tomorrow be guaranteed by following past successes?

Yes, indeed the United States wants to be among the leaders; it wants to be better; its citizens want to work smart and be efficient. But with leadership and general betterment comes change—change in behavior and technology. The old ways served workers well but not anymore. The following saying describes the situation best.

*If you always do what you always did, you will always get what you always got.*

What the United States has is not good enough anymore as world competition increases. The United States must improve or it will be left behind to those who will pursue technological and quality improvements for their products and/or services. Stated in simple terms: This country must change.

As with any transformation, this change brings uncertainty and risk. The recognition that all well-managed companies are interested in preventing or at least minimizing risk in their operations is the concept of risk management analysis. Bass (1986) showed this concern of risk in Figure I.1. The requirements for performing such analysis may be extensive and demanding. The elimination, control, or reduction of risk is a total commitment by the entire organization, and it is more often than not the responsibility of the engineering department.
The focus of identifying and/or analyzing the risks may be due to a variety of reasons, such as customer requests, continual improvement philosophy, and competition. This is shown in Figure I.2.

The risk analysis has a fundamental purpose of answering the following two questions (Stamatis 1989, 1991, 1992):

1. What can go wrong?
2. If something does go wrong, what is the probability of it happening, and what is (are) the consequence(s)?

To answer these questions, problems used to be examined. Of course, by focusing on problems it was assumed that somebody was to blame, and action was taken.

Today, that paradigm has changed. The focus is on prevention. A comparison of the shift in thinking follows.

This book addresses the issue of risk elimination by focusing on the failure mode and effect analysis (FMEA). FMEA is a specific methodology to evaluate a system, design, process, or service for possible ways in which failures (problems, errors, risks, concerns) can occur.

<table>
<thead>
<tr>
<th>Old way</th>
<th>New way</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solution of problems</td>
<td>Prevention of problems</td>
</tr>
<tr>
<td>Monitoring of waste</td>
<td>Elimination of waste</td>
</tr>
<tr>
<td>Quantification of reliability</td>
<td>Reduction of unreliability</td>
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</tbody>
</table>
For each of the failures identified (whether known or potential), an estimate is made of its occurrence, severity, and detection. At that point, an evaluation is made of the necessary action to be taken, planned, or ignored. The emphasis is to minimize the probability of failure or to minimize the effect of failure.

This simple but straightforward approach can be technical (quantitative) or nontechnical (qualitative). In either case, the focus is on the risk one is willing to take. By definition, the FMEA becomes a systematic technique using engineering knowledge, reliability, and organizational development techniques; in other words, teams to optimize the system, design, process, product, and/or service (Stamatis 1991a).

The complication of the approach always depends on the complexity of the problem as defined by the following (Juran and Gryna 1980):

1. Safety—Injury is the most serious of all failure effects. In fact, in some cases it is of unquestionable priority. At this point it must be handled either with a hazard analysis and/or failure mode and critical analysis (FMCA).

2. Effects on downtime—What problems are affecting yield? How is that effect being monitored? What type of testing is available? Is the testing appropriate? How are repairs made? Are the repairs appropriate? Is preventive maintenance part of quality planning? Can the repairs be made while the machine is off-line or should they be made while the machine is operating? Is corrective action actively pursued?

3. Repair planning—Repair time; maintainability; repair costs; repair tools; recommendation(s) for changes in specifications in fit, form, and function. The Shingo (Poka-Yoke) approach, design of experiments (DOE), or design for manufacturability (DFM) may be considered for this problem.

4. Access—What hardware items must be removed to gain access to the failed component? This area will be of great importance as environmental

Figure I.2  Pressures leading to overall perception of risks.

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4. Access—What hardware items must be removed to gain access to the failed component? This area will be of great importance as environmental
laws and regulations are introduced and/or changed to reflect world conditions for disassembly, removal, and disposal.

To carry this methodology to its proper conclusion there are at least four prerequisites that must be understood and followed.

1. *All problems are not the same.* Not all problems are equally important. This is perhaps the most fundamental concept in the entire FMEA methodology. Unless a priority of problems (as a concept) is recognized, workers are likely to be contenders for chasing fires. They will respond to the loudest request and/or the problem of the moment. (In other words, they will manage by emergency.) In no uncertain terms, workers must recognize and believe in the principle of the vital few as opposed to the trivial many (Pareto principle). The FMEA will help identify this priority.

2. *The customer must be known.* Before one undertakes the responsibility of conducting an FMEA it is imperative that the customer be defined. Traditionally, the definition of customer is thought of as the end user. That, however, may be a simplified approach; indeed a definition that may not apply to the problem. A customer also may be viewed as the subsequent or downstream operation as well as a service operation (Ford 1992). In some cases, the customer may be the operation itself.

This is important because when using the term *customer* from an FMEA perspective, the definition plays a major role in addressing problems and their solutions. For example, as a general rule, in the design FMEA the customer is viewed as the end user, but in the process FMEA the customer is viewed as the next operation in line.

This next operation may be the end user, but it does not have to be. After the customer has been defined as external, intermediate, internal, or self, it cannot be changed (at least for the problem at hand) without some surprise ramifications. Those ramifications will affect the definition and consequences of the problem.

3. *The function must be known.* It is imperative that the function, purpose, and objective of what is to be accomplished be known. Otherwise the result is wasting time, and the effort is focused on redefining the problem based on situations. If necessary, the extra time must be taken to ensure that everyone concerned understands the function, purpose, and objective of what is to be accomplished.

4. *One must be prevention oriented.* Unless continual improvement is the force that drives the FMEA, the efforts of conducting an FMEA will be static. The FMEA will be conducted only to satisfy customers and/or market requirements to the letter rather than the spirit of the requirements. (Unfortunately, this is a common problem in implementation of an FMEA program). This is a myopic perspective and as such the spirit of improvement will be lost. The emphasis will be on speed—“Let us get it done, as soon as
possible and move to the next one.” Remember, there is a correlation between time and quality. The following diagram shows the relationship.

![Diagram showing the relationship between fast, cheap, and quality](image)

The moral of the diagram is that it is impossible to have all three factors at the same time. A company must decide which type of product it wants. After the decision is made, it develops that niche in the market. The television commercial for Paul Masson’s wines exemplifies the notion of quality versus time versus price: “We will sell no wine before its time.”

The push for this continual improvement makes the FMEA a dynamic document, changing as the system, design, process, product, and/or service changes with the intent always to make a better system, design, process, product, and/or service. Therefore, all FMEAs are living documents.

**WHY CONDUCT AN FMEA?**

The propensity of managers and engineers to minimize the risk in a particular system, design, process, and/or service has forced an examination of reliability engineering, not only to minimize the risk, but also to define that risk whenever possible. Some of the forces for defining risks were shown in Figure I.2.

These risks can be measured by reliability engineering and/or statistical analysis. Because of their complexity, however, the FMEA has extracted the basic principles without the technical mathematics. (See the CD: Appendix A for specific formulae and techniques.) It also has provided a tool that anybody committed to continual improvement can utilize.

Statistical process control (SPC) is another tool that provides the impetus for implementation of an FMEA, especially for a process and service FMEA. SPC provides information about the process in regard to changes. These changes are called common and special causes. From an FMEA perspective, the common causes may be considered as failures that are the result of inherent failure mechanisms; as such, they can affect the entire population. In this case, the common cause may raise additional questions
and/or concerns so that further examination of the system or design may be in order (Denson 1992).

Conversely, special causes are considered as failures that result from part defects and/or manufacturing problems; they can affect a relatively small population. In this case, there is cause for examining the process (Denson 1992).

Customer requisition strongly influences the motivation to perform an FMEA. For example, all major automobile companies in their supplier certification standards even before the international standards (such as, Ford—Q101, General Motors—Targets for Excellence, Chrysler—Pentastar) required an FMEA program for their suppliers (Chrysler 1986; Ford 1992; General Motors 1988). The same is true with other industries (such as semiconductor, computer, government, aerospace, and medical device). Through product liability, courts may also require some substantiation as to what level of reliability products and/or services perform (Bass 1986).

International standards such as the ISO 9000 series may define the program of documentation in design (Stamatis 1992; see also Chapter 13). For example, the product liability directive of the European Commission (EC) 1985 stipulates that manufacturers of a product will be held liable, regardless of fault or negligence, if a person is harmed or an object is damaged by a faulty or defective product. (This includes exporters into the European Union [EU] market.) This liability directive essentially reverses the burden of proof of fault from the injured to the producer. For more details see Chapters 13 and 14. (Hagigh 1992; Kolka, Link, and Scott 1992; Kolka and Scott 1992; Linville 1992). In addition, ISO/TS 16949 Section 7 (2002-03-01) is abundantly clear of the FMEA requirement.

Other benefits of conducting an FMEA include the following:

- Helps define the most significant opportunity for achieving fundamental differentiation (Peters 1992). After all, there is only one organization that can distinguish itself as the cheapest in town. The rest have to depend on other attributes.

- Improves the quality, reliability, and safety of the products or service. (Table I.1 shows that even 99.9 percent is not good enough in certain situations.)

- Helps select alternatives (in system, design, process, and service) with high reliability and high safety potential during the early phases (Blanchard 1986).

- Improves the company’s image and competitiveness.

- Helps increase customer satisfaction.
Reduces product development time and costs.

Helps select the optimal system design.

Helps determine the redundancy of the system.

Helps identify diagnostic procedures.

Establishes a priority for design improvement actions.

Helps identify critical and or significant characteristics.

Helps in the analysis of new manufacturing and or assembly process.

Helps in the analysis of tasks, sequence, and or service.

Helps establish the forum for defect prevention.

Helps error identification and prevention.

Helps define the corrective action.

Ensures that all conceivable failures and their effects on operational success have been considered.

Lists potential failures and identifies the relative magnitude of their effects.

Provides the basis for the test program during development and final validation of the system, design, process, or service.
• Develops early criteria for manufacturing, process, assembly, and service (Kececioglu 1991).
• Provides historical documentation for future reference to aid in the analysis of field failures and consideration of design, process, and service changes.
• Provides a forum for recommending and tracking risk-reducing actions.
• Major technical advances.
• Demanding customer requirements.
• Intense shareholder pressure.
• Global consolidation of alliances.
• Continuing price and margin pressures.
• Increasing sophistication of customers.
• Economic challenges with design innovations/modifications.

The most important reason for conducting an FMEA is the need to improve. To receive all or some of the benefits of an FMEA program, the need to improve must be ingrained in the organization’s culture. If not, the FMEA program will not succeed. Therefore, a successful FMEA is both a company and a supplier requirement for world-class quality. Specifically, any FMEA can help in the following areas:

• Superior competitive advantage
  – Best in class value
  – Quality performance
  – Sustainable cost advantage
  – Flawless launch

• Superior organizational capability
  – Brings best of class design
  – Breakthrough technology
  – Moves fast

• Superior culture
  – “Can do” attitude
  – Obsesses with continual improvement
  – Team spirit
  – Saying “no” the right way
Change rarely comes in the form of a whirlwind, despite the currently popular notion to the contrary. Change is not “creative destruction,” like we’ve been told. Change that expects us to throw out everything we were and start over isn’t change at all, but a convulsion. A hiccup. The Internet did not change everything. Broadband did not change everything. September 11th did not change everything. Nor did Enron, WorldCom, or any other company. Nor will tomorrow’s horror, tomorrow’s amazing breakthrough, or tomorrow’s scandal.

If you follow the cataclysmic theory of change, you will reap a whirlwind indeed. There is a different theory of change that no one talks about, but is much more significant for the wise professional. In the coastlines of any country, state, or territory one can see it every day. The waves may crash against the rocks, but they are a distraction. The real action is the tide. When the tide changes, huge forces are put in motion that cannot be halted. (If you doubt the power of the tide, look at the suburbs of any fair-sized town anywhere. A piece of farmland on the edge of most towns is worth its weight in gold. And why? Because it’s where the affluent middle class wants to bunk down every night.)

Or consider the change being wrought on health care by boomers. Or the change in our concepts of service or of travel. If you get these change-of-the-tide changes right, you will become very rich. It is that simple. Target got it right, but Kmart didn’t. Disney got it right, but Columbia didn’t. Marriott got it right, but Howard Johnson didn’t. GE got it right, but Westinghouse didn’t. Boeing got it right, but McDonnell Douglass didn’t.

And now you will get it right. Just ignore the wind and waves. Watch the tide. What is the tide? Since the early 1980s, the world of quality has been bombarded with the concept of “continual improvement.” For most of
us, this concept has been focused on “prevention” as opposed to “appraisal.” Yet, many companies have chosen to disregard this change as a “fad” and a “passing attitude.” As a result, we have seen programs on Statistical Process Control (SPC), Total Quality Management (TQM), Six Sigma, Lean manufacturing, Quality Function Deployment (QFD), and many more come and go, with some effect but nothing really substantial. In other words, we have been treating them as “whirlwinds” rather than “tides.”

Since 1995, when the first edition of the Failure Mode and Effect Analysis (FMEA), was published by Quality Press, much has changed. However, the quest for excellence continues to drag for many reasons.

To be sure, I am not trying to diminish the importance of the great efforts that many organizations have implemented in their organizations in reducing failures and improving customer satisfaction. For example, in the automotive industry a 10 percent improvement compared to 2001 has been noted by J. D. Power and Associates. This 10 percent is the largest improvement for the industry since 1997. However, that is still not good enough!

J. D. Power also released data based on 65,000 new vehicle buyers and lessees after the 90 days of ownership and targeted 135 potential problems, that was published in the Wall Street Journal with the following data: Toyota had 107 problems per 100 vehicles; Honda had 113; GM averaged 130. Many such examples do exist in many industries. However, there are many more companies that do suffer many losses due to mistakes that could have been avoided if a thorough FMEA was conducted. Some examples are:

**Company:** Marrone Pasta Corporation, Carmel, NY.—Bad labeling.  
(For more information on this case, the reader is encouraged to contact the USDA Meat and Poultry Hotline at 1-800-535-4555.)

**Affected products:** Pasta Del Mondo chicken ravioli.

**Reason:** Contains undeclared eggs, which could be dangerous if eaten by someone allergic to eggs.

**Number recalled:** 3,150 pounds

**Company:** Candle-lite, Cincinnati, Ohio.—Unsafe design. (For more information on this case the reader is encouraged to contact The Consumer Product Safety Commission.)

**Affected products:** Ceramic potpourri simmering pots.

**Reason:** Flames from the tea light candles inside can flare out the side ventilation holes, possibly causing burns.

**Number recalled:** 80,000

**Note:** The pots were sold under the Martha Stewart Everyday Brand.
Company: In-Sink-Erator, Racine, Wisconsin.—Defective materials. (For more information on this case the reader is encouraged to contact the Consumer Product Safety Commission.)

Affected products: Half-gallon instant hot water dispensers.

Reason: Water can leak from the metal holding tank, wet insulating material, and cause electrical arcing and heat build-up.

Number recalled: 252,000

Note: Tanks were sold under the brand names In-Sink-Erator, ISE, Steamin’ Hot, Emerson, Dayton, ACE, Kenmore, and Kohler.

Our intent in this edition is to bring the reader up-to-date and to focus on some minor changes, as well as additions, in the process of doing an FMEA. Specifically, we have replaced the ISO chapter with the new information as relates to the ISO 9000:2000, added a new chapter on FMEA and Six Sigma, and a new chapter on machine FMEA. Also, we have added an expanded chapter on the automotive industry and the requirements of the ISO/TS19649. We also have added a chapter on robustness and the linkages of FMEA to boundary diagram, p diagram, interfacing diagram, and the characteristic matrix.

Yet another major change in this addition is the inclusion of a CD to cover all the appendices and added information. We believe that the reader will find it quite helpful. The CD has all the appendices from the first edition but also includes some very current examples of p diagrams, interfacing diagrams, robustness, and a template for an FMEA facilitator to guide him or her through the questioning process. Furthermore, through an example it follows the application of the FMEA methodology from a boundary diagram to a process FMEA.

In addition this edition incorporates:

- New definitions from the SAE J1739 September 2000 revision
- Recognition that environment and attribute FMEA may be an option
- Updated glossary

As in the first edition, we have tried to make each of the chapters and appendices independent of each other. Therefore, the reader may find some overlap in the discussion of each type of the FMEA. This overlap is by design, as we have tried to demonstrate that the FMEA methodology—no matter where it starts—is a connecting thread. That thread is emphasized through the linkages of the FMEA in Chapter 17 and Appendices H and I on the CD with several examples. To be sure, if one does all the steps, they will indeed have an excellent design—but not a perfect design, as perfection
belongs in the domain of God. On the other hand, if all the steps are not followed then there is a possibility that marginal success may follow.

A final point. Figure 2.6 shows the relationship of the four types of the FMEA. However, Chapter 9 is devoted to machine FMEA, and in Chapter 14 we make references to environmental and attribute FMEA. This is not an oversight on our part, rather the fundamental issues of machine, environmental, and attribute FMEA is nothing more that a variation of design FMEA. Consequently, they do not appear on Figure 2.6. There is no contradiction and there should not be any confusion about it.
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This chapter addresses the fundamentals of product liability, theories of recovery, and defenses and bars to recovery. The intent is to give the engineer some understanding of law and establish the need for FMEA. This is not an attempt to exhaust the topic, or to offer legal advice.

A LEGAL APPROACH TO LIABILITY

Product liability laws are complex and continue to cover the products and services that enter commerce. By addressing the fundamentals of the legal ramifications of product liability and examining other basic issues regarding liability, the need for conducting an FMEA should be quite obvious.

Who Is Responsible for Safe Products?

Product liability applies to those in the business of manufacturing products that enter the stream of commerce—placing the product in the marketing cycle (Armstrong Rubber Co. v Urquidez, 570 SW2d 3741 [Texas 1978]). Liability includes demonstration, lease, a free sample, or sale of the product. (A product under construction or for internal use is not considered to be in the stream of commerce.)

Specifically, product liability (negligence or strict liability) may be considered in the following industries (Bass 1986, 1991; Pozgar 1993).

Special note: The intent of this chapter is not to interpret the law of liability but to establish the rationale and need to perform the FMEA.
• All services, because negligence principles are applicable.

• Software, because there is the potential for personal injury, property damage, or business loss. From a liability perspective the primary issue is not whether software is liable, but whether or not it is a service or a product. If it proves that it is a service, the principles of negligence will apply. If it is considered as a product, the strict liability will apply.

• Engineers and architects, because they provide a service (La Rosa v Scientific Design Co., 402 F2d 937 [3d Cir 1968]).

• Medical products and drugs; depending on how the court views the usage of the product, it may be considered either as a strict liability (Johnson v Sears, Roebuck and Co., 355 F Supp 1065 [ED Wis 1973]) or negligence (Carmichael v Reitz, 17 Cal App 3d 958, 95 Cal Rptr 381 [1971]).

• Component suppliers, because they are held liable under the theories of strict liability, warranty, and negligence (City of Franklin v Badger Ford Truck Sales, Inc., 58 Wis 2d 641, 207 NW2d 866 [1973]).

• Insurance companies, because they have been found liable for negligent inspections performed by their loss control engineers. This may involve furnaces, utilities, buildings, or machinery (Evans v Liberty Mutual Insurance Co., 398 F2d 665 [3d Cir 1968]).

• Testing laboratories, because they have been found liable for negligent tests performed at their facilities (Hemstead v General Fire Extinguisher Corp., 269 F Supp 109 [D Del 1967]).

• Franchisors or trademark licensors may be held for strict liability if they have extended strict tort liability to franchisors or trademark licensors who sell the right to use their trade name, or even processes, to others who actually supply the product (Connelly v Uniroyal, Inc., 75 Ill 2d 393, 389 NE2d 155 [1979], revg 55 Ill App 3d 530, 13 Ill Dec 162, 370 Ne2d 1189 [1977]).

• Bailors and lessors of goods; strict liability may be extended to bailors and lessors of goods as well as those who sell goods (Price v Shell Oil Co., 2 Cal 3d 245, 466 P2d 722, 85 Cal Rptr 178 [1970]).

• Sellers of used products, because they have been found liable for negligence, warranty, and strict liability (Turner v International Harvester Co., 133 NJ Super 277, 336 A2d 62, 69 [1975]).
• Landlords, because they have been found liable under negligence (Sargent v Ross, 113 NH 388, 308 A 2d 528 [1973]).

• Engineers, because they have been found liable under negligence. Engineers are held responsible, however, when it can be proved that their negligence resulted in the plaintiff’s injury (Gagre v Bertran, 43 Cal 2d 481 [1954]).

• Rebuilders, because they have been found liable under strict liability, just as with manufacturers of complete machines (Michalko v Cooke Color & Chemical Corp., 91 NJ 386, 451 A2d 179 [1982]).

Although this list is not exhaustive, the message should be clear that everything one individual or organization does (product or service) can be an issue of liability and negligence. By performing the FMEA at the appropriate stage, the liability and negligence may be minimized, and if punitive damages are not completely eliminated, they will be minimized.

WHAT IS PRODUCT LIABILITY?

The term product liability often stands for a variety of meanings; however, the term in law is defined as the liability of a seller or manufacturer for damages caused by its allegedly defective product. Product liability action can be based on a number of legal theories, including negligence, strict liability, fraud, misrepresentation, warranty, and so on. To more fully understand the legal concepts, one must familiarize oneself with some of the basic theories.

Theories of Recovery

Although several legal theories may be used in a product’s liability action, the three most commonly used are: negligence, warranties, and strict liability in tort.

Negligence Action. Negligence law (failing to act as a reasonable and prudent person would in like or similar circumstances) was developed approximately 200 years ago. Before that, all wrongdoers had to pay for any damages that they directly caused. Consequently, a type of no-fault concept would hold the person directly causing the harm to be liable for such harm. Negligence law developed as a protection for the defendant and required more than proof of a mere direct injury. Negligence includes the concept
that an individual may not be liable for the direct or indirect harm he or she causes unless he or she has acted unreasonably. The modern view of negligence consists of the following four elements.

1. Duty
2. Breach
3. Causation
4. Damages

An individual who is harmed by someone must be able to show all four elements. If any one is missing, there is no case.

The duty element of negligence requires that a person owes to another to conduct him or herself in a particular manner. A person may owe a duty that is created by statute or a local ordinance. For example, a person must drive according to the motor vehicle laws, or construct safe buildings, or build certain items with specific codes so as not to create dangerous conditions to the public.

Duty may be established by the courts, such as exercising reasonable care to protect and warn persons of dangers on one’s property. For example, in medicine, doctors have a duty to practice within the accepted standard of care; engineers have a duty to design and manufacture a safe product.

Duty is measured by the reasonable person under like or similar circumstances and can be created in many different ways based on the facts of a particular case. Therefore, the objective hypothetical reasonable person is the standard by which the law measures the duty of all defendants in a negligence action. If no duty is found, the negligence issue fails and the defendant will not be liable even if he or she caused the damages to the injured party (called the plaintiff).

If a duty is found to exist, then the plaintiff must also show that the defendant breached that duty. In other words, one asks whether the defendant fulfilled the duty to act or not to act in a reasonable manner. Breach of duty is the failure (any failure) to perform or conduct oneself in a particular manner when one is obligated to do so.

The negligent conduct must have been a cause of the injury, and the injury is a natural and probable result of the negligent conduct. “Did the negligent conduct cause the injury to another?” This is the fundamental question of causation and, as such, it has become one of the most philosophical areas of negligence. Because this is a tricky area of defense, defendants will argue that the injured party also was negligent and may have been 40 percent responsible for his or her own injury.
Causation can be divided into two basic elements: (1) the but for test, and (2) proximate or legal cause test. The but for test merely asks the question: “But for the defendant’s conduct, would the accident or injury have occurred?” Obviously, the but for test is very broad and cannot be used alone to sufficiently narrow the possibilities to find responsible parties to an action. For example, but for Joe and Jane the defendant would not have been born; thus, almost all responsibility could be attributed to some past, direct happenings. Negligence law includes only those causes that have been a proximate or legal cause in producing the damage to the plaintiff. Proximate cause is measured by the substantial factor test, which includes only causes that have been a substantial factor in producing the plaintiff’s damages. What constitutes a substantial factor will vary from case to case, but such flexibility is necessary because of the wide variety of situations brought as negligence actions.

Generally, damages are determined by asking how has the injured party suffered physically, mentally, financially, or otherwise. (Many forget this piece of the puzzle.) If there is a suit for negligent acts of another, the plaintiff must be able to demonstrate in court that harm has occurred. If a person was hurt by a product, run over by a truck, slipped and fell, used a defective product, or received improper care from a physician, or wrong instructions in the course of using a product, it may be that there was clear negligent conduct. The person suing must show that he or she was harmed even if the wrongdoer admits his or her negligence.

If the defendant has breached his or her duty, and this breach caused the harm or damages, then he or she may be found liable. Engineers who work with exactitude may have some difficulty with apparent vagueness of the elements of negligence; however, this vagueness is necessary because negligence law covers almost any conceivable situation. No one correct answer is possible when one considers the almost infinite variety of situations that occur in day-to-day activities. The variable conduct of human beings, however, by observance of social norms, can be considered either reasonable or unreasonable. This is the essence of negligence.

Warranties. Warranty law, a hybrid of both contract and tort law, developed before negligence. Warranties can be either expressed or implied. Thus, if the seller of a product states that the product will perform in a certain manner, and the product fails to live up to those expressed representations, then the seller may be found liable. Through custom, it gradually became common for certain products to be expected to perform in a certain manner, and if the product failed to do so, the user was deprived of his or her reasonable expectations. Under these conditions, the seller could be found liable for warranties, which by implication accompanied the product. The warranty types of actions have now been codified in almost all jurisdictions (states and
territories), and can be found in the Uniform Commercial Code (UCC). The UCC generally involves commercial situations; however, it also may be used in personal injury actions. The expressed warranty is found in UCC S2-316, whereas the implied warranties are found in UCC S2-314 (implied warranty of merchantability), and UCC S2-315 (implied warranty of fitness for a particular purpose).

**Strict Liability in Tort.** As negligence law developed, the concept of no-fault method of recovery retained some vitality. Negligence law developed as a protection for the defendant, especially newly developing industries and railroads at the time of the industrial revolution. Thus, if the defendant caused injury to the plaintiff, but acted reasonably, he or she was not liable. There were certain types of conduct, however, that the law considered so hazardous or unsafe that the older no-fault concept law was retained to establish liability. Thus, one who used dynamite (no matter how reasonably) was held liable for the injury caused by the dynamite. In addition, food that was unwholesome or deleterious was considered a product to which negligence should not apply. The restaurant that served unwholesome food was strictly liable for the damages caused by such food. This type of liability was called strict liability, absolute liability, or no-fault liability because, no matter how reasonably he or she acted, the defendant could be held liable if his or her deleterious food or dynamite caused injury.

As negligence law developed and the industrial revolution moved into the twentieth century, the production and marketing of all products began to expand and involve more complex situations. In the nineteenth century the sale and exchange of goods and products was, more or less, on a one-to-one basis. In this instance the buyer or user, familiar with the product, would inspect the product for defects. Furthermore, the nineteenth century exchange of goods did not involve mass advertising and extremely complicated products. Therefore, it was assumed and expected that a buyer could and would inspect for defects and accept or reject the product upon delivery. This may have been acceptable practice for products such as the rake, plow, or saddle; however, with the advent of mass production, complicated machinery, and Madison Avenue advertising, a modern consumer was neither capable of nor expected to inspect products such as his or her automobile, blender, or combine. In addition, the manner of production changed to such an extent that it became impossible for a plaintiff to prove negligence.

Although nineteenth century buyers could show with some reasonable certainty that the cobbler’s conduct was unreasonable when he failed to properly nail shoes, it was almost impossible for the twentieth century consumers to discover the exact point in the chain of production where the vehicle or product became defective and how the defendant’s conduct was
unreasonable. With greater public reliance upon products being reasonably safe, without inspection, the almost impossible problems of proving who was responsible for unreasonable conduct, and what conduct in the manufacturing process was unreasonable, resulted in more injured consumers not being recompensed for injuries that truly were caused by defective products.

In recognition of the serious problems caused by the requirements of negligence law, the courts began to allow recovery under a theory of strict liability in tort. Beginning in 1963 in California with Greenman v Yuba Power Products, Inc., 59 Cal 2d 57, 377 P2d 897, 27 Cal Rptr 697 (1963), the courts allowed recovery without showing a defect was caused by unreasonable conduct. The requirement changed. Now, the plaintiff must show that the product was defective, and that the defect caused him or her injury. Thus, the emphasis changed from the showing of unreasonable conduct that created the defect to one of merely showing a defect, regardless of how or what caused the defect in the product. If the plaintiff could show that the product left the manufacturer’s or seller’s hands in a defective condition, and that the defect caused the plaintiff injury, he or she could recover.

From 1963 until the present, almost all jurisdictions in the United States have adopted strict liability in product liability actions. The generally accepted version of strict liability is found in the American Law Institute’s Restatement (Second) of Torts S402A (1965), which states:

(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his or her property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if:
   (a) the seller is engaged in the business of selling such a product, and
   (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

(2) The rule stated in Subsection (1) applies although:
   (a) the seller has exercised all possible care in the preparation and sale of his or her product, and
   (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

Although one can examine in detail the language of S402A, the major elements consist of:

1. A defect/unreasonably dangerous
2. Causation
3. Damages
WHAT IS A PRODUCT?

Historically, a product was a chattel, defined as an article of personal property which was not land. The courts, however, recently have allowed recovery under a product liability theory for homes, rental apartments, and sometimes, condominiums. The term product also can include the product’s packaging or container; some courts have included electricity as a product.

Because the product definition by the courts is so broad, one may wonder, how can the court define the defect and what are some of the conditions that will indeed define the defect (if in fact, there is such a requirement)?

In order to understand the defect requirement one must understand how the legal system defines defects, how it views the types of defects, and whether or not there is a difference between design, manufacturing, and service.

Defects

In the scientific and realistic sense, nothing is perfect (Bass 1986, 1991). All products and/or services have flaws. From a legal perspective, defects are defined based on user expectation, manufacturer representation, and foreseeability. The test for defect is safe performance under foreseeable conditions of use.

The law generally agrees that perfect safety usually is not technologically possible or if it is possible, it costs too much. Therefore, a defect is more likely to be discussed under a customer expectation test or a risk-benefit test (Bass 1986, 1991).

Types of Defects

A product presents a reasonable risk and is not defective when:

- The product meets the ordinary customer’s expectations.
- Risks are reduced to the greatest extent possible by design or safety features (Peters 1992).
- The product contains adequate warnings that a risk is associated with the product.
- The user is given enough information to decide whether or not to accept the risk.
- The benefits cannot be obtained in a less risky way.
- It is not economically feasible to reduce the severity.
- Evaluating the product as a whole, the benefits outweigh the risks.
Products may be defined as defective because they:

- Deviate from the intended condition by the manufacturer
- Are unsafe, due to design defects, even though they are produced perfectly
- Are incapable of meeting their implied or expressed claims of performance
- Are dangerous because they lack adequate warnings and instructions

**Design Defects**

A design defect is a defect that affects an entire line of products (Bass 1986; Omdahl 1988; ASQC 1983). It may be a result of trade-off analysis, cost-benefit analysis, and/or customer’s requirements. A design defect occurs when a product does not adequately protect against risks of injury, fails to perform intended functions safely, does not protect adequately against the danger against which it was supposed to guard, creates unreasonably dangerous side effects, or fails to minimize avoidable consequences in the event of an accident.

**Manufacturing Defects**

A manufacturing defect exists when the product does not meet the manufacturer’s own specifications (Bass 1986; Omdahl 1988; ASQC 1983). This can be because:

- The raw materials or components used in making the product may contain unacceptable flaws.
- There are assembly mistakes.

The major issue in manufacturing defect cases is whether the defect is due to a mistake in design, manufacturing, normal wear, normal tear, or misuse.

**Service Defects**

A service defect exists when the service does not meet the defined criteria of the design and/or the customer. The FMEA can and does provide the method for analysis of known and potential problems in all of the system, design, process, and service phases. (Remember, although the law describes defects,
in modern quality thinking one should substitute the term nonconformity in its place.

**THE DEFECT REQUIREMENT**

The major consideration of S402A is the defect requirement. In fact, negligence, strict liability, and implied warranties all require at least three of the same elements that the plaintiff must prove to sustain his or her case: (1) defect, (2) causation, and (3) damages. The major difference between negligence law and strict liability and warranties is that in negligence the plaintiff must prove unreasonable conduct that causes the defect or injury, whereas in strict liability and implied warranties all the plaintiff has to prove is the existence of the defect itself. In strict liability actions there are three basic types of defects that may render the defendant liable. They are:

1. Manufacturing defects
2. Design defects
3. A failure to adequately instruct on usage and a failure to warn of dangers in the product

A manufacturing defect exists when the product comes off the production line in a condition different from what the manufacturer intended. Thus, a rectangular cover plate that was intended to have a total of four holes, one at each corner for bolts, would contain a manufacturing defect if it had only three holes. In other words, the product that has a manufacturing defect is different than the other products that come off the production line.

A design defect is when a product is designed such that there are unreasonable dangers in the product as designed. Thus, a designer might design a rectangular plate with only three holes in the plate where it is to be fixed with bolts, but because of the design, the plate might fail due to lack of sufficient bolts fixing the plate in place. Here it is clear that there is no manufacturing defect because the plate comes off the production line as intended (like all others), but is maldesigned.

If a product is to be used in a specified manner, the manufacturer has the obligation to give sufficient instruction to the person who is to use the product. If the manufacturer fails to give instructions or gives inadequate instructions, and the consumer uses the product in a forbidden manner and is injured, the consumer may recover because of the lack of instructions.

Finally, a product can be perfectly manufactured, have no design defect, and may contain adequate instructions on usage, but still be defective. This
is true if the manufacturer fails to warn about the dangers that may be involved in proper usage.

The Parties

Defendant—Seller and Stream of Commerce. It is assumed that the manufacturer of the product may be a defendant in a product liability action. But what about other parties such as assemblers and component part manufacturers? Can they be sellers? In *Suvada v White Motor Co.*, 210 NE 2d 182 (Ill 1965), the defendant Bendix-Westinghouse Automotive Air Brake Company was held liable for a defective brake system installed in a tractor by White Motor Company.

Although White Motor Company did not make a change in the brake system, White also was liable to the plaintiff for the defective brake. There are numerous cases where the assembler of a defective component part is liable to the plaintiff even though he or she did nothing to the component part nor could have discovered the defect.

The law has developed in such a way that any party that comes into contact in the commercial stream may be held strictly liable for the defective product. Thus, wholesalers, retailers, and distributors have been held liable and some courts have held used-goods dealers and lessors of defective products liable under a strict liability theory. A famous Indiana case stated the following:

“Liability under 402A will attach to anyone who places such a product in the stream of commerce by sale, lease, bailment or other means.” *Gilbert v Stone City Construction Co.*, 357 NE 2d 738 (Ind Ct App 1976).

The Plaintiff—The User. Recovery will be allowed for the consumer or user of the defective product. Since privity has been eliminated in all but a few commercial cases, it is not necessary that the user be the actual purchaser of the product. The plaintiff may be a neighbor who borrows a lawn mower and is injured by it, or he or she may be the employee using the punch press. What about the bystander or onlooker? Can the person walking on the sidewalk and struck by the rock thrown from an unshielded lawn mower recover? In strict liability actions, all jurisdictions that have discussed the issue allow the bystander or onlooker to recover.

Defenses and Bars to Recovery

There are many factors that may bar a plaintiff even though he or she can show that a defective product caused him or her injury, and there are several
defenses or bars to liability that question the elements of defect, duty, or causation. Remember that a plaintiff may bring his or her action based upon multiple theories, and that a valid defense under one theory may not be a defense under another theory. For example, contributory negligence is a defense in negligence actions, but is not a defense in strict liability actions. Thus, one should note the context of which defense or bar to recovery applies to each legal theory.

**Privity.** Since medieval times, a seller or manufacturer could be held liable for a breach of warranty, but only to the immediate buyer. In the mid-nineteenth century this same concept (called privity) was extended to negligence cases. Thus, a buyer of a defective product could not recover unless he or she could show some type of contractual nexus between him or herself and the seller. In 1916, in the case of *MacPherson v Buick Motor Co.*, 111 NE 1050 (NY 1916), the privity concept was eliminated in negligence actions and within the next 50 years all jurisdictions followed the *MacPherson* rule.

It is now well accepted in negligence and strict liability cases that no privity is required. In some jurisdictions privity may still be required in UCC cases that have their basis in contract law and do not involve personal injuries.

**Contributory Negligence.** As the nineteenth century common law concept of negligence developed, a complete defense evolved which consisted of the plaintiff’s own negligence contributing to his or her injury (called *contributory negligence*). Thus, if the plaintiff was contributorily negligent, and such contributory negligence was a substantial factor in bringing about his or her own harm, the plaintiff was barred from recovery. As a fault concept, this was compatible with nineteenth century logic—a wrongdoer should not recover. Contributory negligence, however, was greatly criticized on many grounds, including the concept that although a person had contributed somewhat (say, theoretically 5 percent) to his or her own injury, he or she should not be completely deprived of recovery when the defendant was the major wrongdoer (say, 95 percent).

In strict liability actions (including warranty actions), fault of either the defendant or the plaintiff is not a factor. In other words, the unreasonable conduct of the defendant in creating the defective product is not a consideration, nor is the unreasonable conduct of the plaintiff in contributing to his or her own injury. Thus, in strict liability actions, contributory negligence is not a defense (*Farmer v School District*, 171 Wash 278, 17 P 2d 899).

**Assumption of Risk.** The second major defense in negligence actions is assumption of the risk (sometimes called incurred risk). Assumption of the
risk is based upon consent. Consent is measured upon a subjective standard. If the plaintiff consents, either expressly or impliedly, then he or she cannot complain of his or her injury. Consent consists of four major elements:

1. Knowledge
2. Understanding
3. Appreciation
4. Voluntariness

Thus, the plaintiff must have actual knowledge (subjective) of the risk, understand the consequences (subjective) of the risk, appreciate the extent (subjective) of the risk, and voluntarily enter said risk. All four elements must be complied with before anyone is said to consent. For example, for something to be done voluntarily, the person making the choice must be given reasonable and viable alternatives or he/she cannot be said to have voluntarily undertaken the risk.

In many situations all four elements of assumption of risk may be met, yet the plaintiff may still have acted reasonably in his or her choice (reasonable assumption of risk). In other situations the plaintiff may have consented to an unreasonable risk; thus, his or her consent becomes unreasonable based upon objective standards (unreasonable assumption of risk).

In negligence law either reasonable or unreasonable assumption of risk is a defense. In strict liability (or warranty) cases, however, only unreasonable assumption of risk is considered a defense.

**Misuse.** The misuse of a product is said to be a defense or bar to plaintiff’s recovery. Misuse has been used interchangeably with abnormal use and unintended use. Misuse was first used in the context of how the manufacturer subjectively intended the product to be used. This concept was extremely narrow, however, and misuse was gradually broadened to require the manufacturer to objectively anticipate or foresee greater use of the product. In this expanded, foreseeability concept, the manufacturer was required to objectively anticipate the uses of the product in the environment in which the product was placed. Thus, unusual but foreseeable uses would not be considered a misuse of the product.

Misuse also was considered part of the defense of contributory negligence or assumption of risk. In other instances, misuse was considered a part of the defect requirement or of causation. This chameleon character of misuse proved to be confusing to everyone.

Misuse, if it has independent existence as a bar to plaintiff’s recovery, depends upon reasonable foreseeability. If the use of the product is not
foreseeable, then such unforeseeable use may bar the plaintiff’s recovery. Foreseeability of use, however, is not restricted to the manner of use that a manufacturer desires, but may include all objectively foreseeable uses of a particular product in a particular environment. The ingestion of furniture polish by young children is hardly the intended use of furniture polish. But what would be more reasonably foreseeable than young children consuming bottles of red liquid that look like cherry cola?

**Comparative Fault.** After heavy criticism of both contributory negligence and assumption of risk as complete bars to recovery, almost all jurisdictions have adopted some form of comparative fault or comparative negligence. In such jurisdictions the contributory negligence and assumption of risk of the plaintiff are weighed against the fault of the defendant, and the plaintiff is allowed recovery based upon a percentage comparison. Sometimes misuse is also included in such percentage comparison. There are three major types of comparative negligence:

1. **49 percent to 51 percent.** In some jurisdictions the plaintiff is allowed to recover as long as his or her fault or negligence is less than that of the defendant. If the plaintiff’s fault is equal to or greater than that of the defendant, he or she cannot recover.

2. **50 percent to 50 percent.** In some jurisdictions, if the plaintiff’s conduct or negligence is equal to or less than the negligence of the defendant, then he or she may recover.

3. **Pure comparative fault.** In a growing number of jurisdictions, the plaintiff is allowed to recover, and his or her damages are to be reduced by the proportion of his or her contributory fault, whether it is 1 percent or 99 percent. Thus, a plaintiff who is 65 percent at fault is still allowed to recover 35 percent of the costs of his or her injury.

In negligence actions, comparative fault seems appropriate, but in strict liability actions, the fault of either party is irrelevant. It would seem that comparative fault would not be appropriate in strict liability cases since this would bring contributory negligence back as a defense. Despite the incompatibility of the theories, a growing number of courts have allowed the comparison of all forms of plaintiff’s conduct (contributory negligence and assumption of risk) to apply comparative fault in strict liability actions.

**State of the Art.** It has been said that state of the art is not a defense to liability under any theory of recovery, but is merely an explanation of what is being done by a particular industry at a particular time. In recent years,
however, several states have enacted legislation that does have a defense called state of the art. The real problem is defining state of the art.

State of the art has been used to mean many different things. At one end of the spectrum of meanings is custom and practice in the industry; at the other end of the spectrum is that state of the art is the cumulation of all conceivable knowledge relating to a product at any given point in time. The case law has discussed both ends of the spectrum and quite a bit in between.

If used in a legal context, state of the art does not mean the custom or standards of a particular industry. See *Cantu v John Deer Co.*, 24 Wash App 701, 603 P2d 839 at 840 (1979).

The generally accepted state of the art definition is: whatever is technologically feasible and economically feasible at the time of either the manufacture of the product or at the time of the accident. Thus, to be in conformance with the state of the art, the manufacturer or seller must consider what is feasible, not what is being done. An entire industry could be acting in a substandard manner in producing a particular product, and it is no defense to say that no one is using a particular guard or safety device as long as it was feasible to include such guard or safety device with the product. The primary reason for the rejection of any particular custom or usage of any industry as a complete defense is the court’s lack of trust in self-imposed standards, and the court’s recognition that any such self-regulatory standard will probably provide only a minimum of protection and safety for the consumer or user.

State of the art does not mean that the seller must do the impossible or perform the impractical. For instance, a $500 product may not necessarily have to include a $1000 guarding device to make it safer because this would not be economically feasible. A $500 product may have to include a $10 guard, however, if such guard could reduce injuries to the user.

Technological feasibility does not require prescience; however, any technology that could reasonably be incorporated with a product and that could reduce injuries or improve safety may be required. State of the art does not require that a manufacturer use certain safety items; however, if injury or damage results from the lack of such safety items or design, the manufacturer may have to pay for said injuries.

Recently, New Jersey decided that state of the art was not an acceptable defense to strict liability in tort. *Beshada v Johns-Manville Products Corp.*, 90 NJ 191, 447 A2d 539 (1982).

The effects of customer satisfaction because of a defect (nonconformance) in design, manufacturing, or service may cause the customer to sue. But what is the legal process to sue? The next section addresses this problem.
THE LEGAL PROCESS

The focus of this section is on the legal process as it relates to design and manufacturing. It is an attempt to give a sense of understanding of the legal process for those who design and manufacture a product. This is not an exhaustive legal review; however, the short summary should establish the ground for the engineer and/or those around the design process to take preventive measures to avoid legal action.

A Cursory View of the Legal Process*

A lawsuit begins when a person (corporations, as well, are considered as persons for legal purposes) whose body or property is injured (or damaged or destroyed) alleges that the injury was caused by the acts of another and files a complaint. The person asserting the complaint is the plaintiff and it is brought against the defendant.

Implicit in such a complaint must be the existence of duty (or responsibility) that would make the defendant liable to the plaintiff, if the plaintiff can prove his or her case. In addition to a duty, the plaintiff also must assert that there is cause of action (a legal theory or principle) that would permit the plaintiff to recover damages (money, return, or restoration of property, or whatever may be appropriate to restore the plaintiff to the condition existing before the injury).

For example, a product manufacturer has a duty to use reasonable care in the design and manufacture of a product and this duty extends to all persons who can reasonably be expected to use or come in contact with the product. But the law does not impose a legal duty on a stranger to give aid to a person on a street corner who may be suffering a heart attack and requests help.

Although a legal duty may exist, a cause of action may not exist. A person suffering bad dreams after seeing a foreign object in a soft drink bottle, but not consuming the beverage, may not have a cause of action in that the harm suffered (in other words, the bad dreams) may not be legally compensable, even though the bottler has violated a legal duty by inserting foreign objects in the bottles along with the drink.

To avoid stale claims, the plaintiff must file the complaint within the period of the statute of limitations (generally between one and six years) after the alleged injury has occurred or after the plaintiff should have known of the injury. After the plaintiff files the complaint, the defendant

*This legal review is based on Product Liability and the Engineer by J. F. Vargo and A. S. Weinstein. SAE publication #82002. (Warrendale, Penn.: Society of Automotive Engineers.) It is used here with their permission.
must answer within a specified time period. The answer, as one might expect, generally denies all of the allegations and will also assert affirmative defenses. That is, the defendant will state that if there was an injury it was due to the plaintiff’s own behavior which fell short of an appropriate legal standard (for example, contributory negligence, assumption of the risk, misuse, abuse). After the paper sparring is completed, the period of discovery begins. Each side of the litigation can submit interrogatories (questions) to the other attempting to learn facts that can assist in formulating the issues and defenses.

In addition, each party can depose the other party’s witnesses or other persons who may have information pertaining to the case. The deposition is a legally formal session at which the deponent, under oath, answers questions posed by the attorney or the opposing side. The proceedings are recorded and transcribed. The transcript may be used at trial if the witness cannot be present or to impeach the witness if the testimony at trial differs materially from that given at the deposition.

The plaintiff has the right to request a trial by jury, or may decide to let the judge alone decide the case, in which instance the judge also serves as the jury. The roles of the judge and jury are totally different. The judge (often referred to as “the court”) is to decide the issues and points of law and instruct the jury on the legal principles within which the case is to be decided. The jury is to focus on the factual evidence as brought out by the witnesses under questioning by the attorneys and by any physical evidence introduced by both sides. The jury is to weigh this factual evidence and decide whether the plaintiff has proved the allegations within the legal framework described by the judge.

For example, assume that the plaintiff was injured by an exploding soft drink bottle. If the legal principle asserted is that of negligence, the plaintiff must prove that the bottler was at fault in shipping a bottle that either had a flaw in the glass or was overcarbonated and caused the explosion. The plaintiff must therefore prove to the satisfaction of the jury that if the bottler had used reasonable inspection or control procedures the problem would have been discovered. The defendant bottler would counter by attempting to show that there were no reasonable inspection or control techniques that would have uncovered the problem or alternatively, that it was the plaintiff’s misuse or abuse of the bottle in handling it that caused it to explode.

The jury is instructed, under a negligence theory, that it must measure the fault of both sides by using a reasonable person standard. That is, the jury decides whether or not a reasonable person, under the same or similar circumstances as the plaintiff and defendant in their respective situations in their case, would have acted in the same way. If the jury finds that the bottler was acting reasonably in not uncovering the problem, then the bottler was not
negligent and the plaintiff cannot recover for the injuries suffered. On the other hand, the jury may decide that it was the combination of the negligences of the defendant and the contributory negligence of the plaintiff that caused the injury. Today a significant number of state courts (if not most) ask the jury to compare the relative degree of fault of the plaintiff and defendant and to reduce any award by the percentage of the plaintiff’s fault.

The complaining party, the plaintiff, has the burden of proof in the trial. That is, the plaintiff, who presents his or her case first must introduce sufficient evidence to convince the judge that, if the jury believed all of the evidence to that point, the jury would find the defendant liable. If so, the plaintiff has made out a prima facie case and the trial goes on, with the defendant then introducing evidence to refute the plaintiff’s contentions as well as the evidence necessary to prove the asserted affirmative defenses.

If the defendant makes a motion, after the plaintiff has rested his or her case (in other words, has introduced all of the evidence supporting the allegations in the complaint), asserting that a prima facie case has not been made out and the judge agrees, the judge will grant a directed verdict for the defendant. The trial is ended at that point with the plaintiff losing, because of not having submitted sufficient evidence to make out a case against the defendant.

This first stage of a lawsuit can end even before the trial begins by either party making a motion for summary judgment after the complaint and reply have been filed (collectively termed the pleadings) together with any supporting affidavits. If the judge agrees with a party making the motion that there is really no dispute over the crucial material facts, that side can prevail as a matter of law. Alternatively, the judge can wait until the very end of the trial, but before the jury retires to consider its verdict, and grant a directed verdict in favor of either party. Further, the judge may believe that all of the evidence (after both plaintiff and defendant have rested their respective cases) so overwhelmingly favors one side or the other that if the jury’s verdict does not agree with the judge’s belief, the judge can reverse the jury’s verdict through a JNOV (that is, a judgment notwithstanding the verdict) and find for the losing side.

After the trial court has made a final judgment as a result of a summary judgment, directed verdict, jury verdict, or JNOV, the losing side has the right to appeal that loss to the appropriate appellate court and is called the appellant (or petitioner). The appeal asserts that a substantial error(s) of law (not fact) has been made by the judge and that the error(s) resulted in that side losing. If the appellate court agrees, it can order a new trial or can reinstate the original jury verdict if the trial judge had entered a JNOV. Of course, the winning side, the appellee (or respondent), argues to the appellate court that the trial judge had not made an error or that the
error was harmless and the original ruling should stand. The appellate process only involves the submission of the appropriate paperwork and perhaps a brief oral argument by the attorneys in front of a panel of the appellate judges. There is no jury.

A lawsuit of the nature considered here usually is brought in the appropriate court in the plaintiff’s state. If there is *diversity of citizenship* (that is, if the plaintiff and defendant are residents of different states), however, the lawsuit can be filed in the appropriate U.S. District Court, a court system established by Congress, having its own trial and appellate courts. A corporation is considered to be a resident of both the state in which it is incorporated and the state in which it principally conducts its business (which could be either the location of corporate management headquarters or the location of the principal manufacturing facilities, if the two are not located in the same state).

The legal theories or principles of law that form the matrix of any lawsuit arise from two sources. First, there are the legislative enactments such as the traffic laws, criminal laws, the UCC, antipollution laws, and so on. Generally separate and distinct from these *statutory laws* is the *common law*, created by the courts as they articulate principles to adjudicate disputes. The common law, developed and expanded over the last 200 years from the English common law, is perhaps more firmly established than statutory enactments, which can change because of the view of a new legislature.

The courts, sensitive to the potential disruption of common law that could arbitrarily be altered by one judge in one court, have established the policy of *stare decisis*, which means an adherence to precedent. Once a principle of law has been laid down applicable to a certain set of facts, the court will adhere to that principle and apply it to all future cases involving substantially the same factual setting, unless they later find that the principle is no longer sound social policy.

Finally, the U.S. legal system is premised on the adversary process where the attorney’s role is to present his or her client’s case in the most favorable light and to cast significant doubt on the believability of the opposing party’s evidence. Because the principal evidence is presented orally by witnesses under *direct examination* by the attorney of the party calling that witness, the opposing party’s attorney attempts to discredit either the testimony or the witness or both through *cross examination*. Both direct and cross examination are simply the series of questions by the attorneys and answers by the witnesses from which the jury is to judge the believability of the answers and the credibility of the witness. Ultimately, justice is determined by the jury reaching a verdict through secret deliberation of the factual evidence it has heard and seen as applied to the law given by the judge in his or her charge to them.
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A failure mode and effect analysis (FMEA) is an engineering technique used to define, identify, and eliminate known and/or potential failures, problems, errors, and so on from the system, design, process, and/or service before they reach the customer (Ömdahl 1988; ASQC 1983).

The analysis of the evaluation may take two courses of action. First, using historical data, there may be analysis of similar data for similar products and/or services, warranty data, customer complaints, and any other appropriate information available, to define failures. Second, inferential statistics, mathematical modeling, simulations, concurrent engineering, and reliability engineering may be used to identify and define the failures (Stamatis 1989, 1991a, 1992).

Using an FMEA does not mean that one approach is better than the other, or that one is more accurate than the other. Both can be efficient, accurate, and correct if done properly and appropriately.

This chapter focuses on generic concerns of what the FMEA is, what it can do, what it means, how it is conducted, and how it compares with other tools available.

Any FMEA conducted properly and appropriately will provide the practitioner with useful information that can reduce the risk (work) load in the system, design, process, and service. This is because it is a logical and progressive potential failure analysis method (technique) that allows the task to be performed more effectively. FMEA is one of the most important early preventive actions in system, design, process, or service which will prevent failures and errors from occurring and reaching the customer (Kececioglu 1991).
This early warning and preventive technique provides the designer with a methodical way of studying the causes and effects of failures before the system, design, process, or service is finalized. In essence, the FMEA provides a systematic method of examining all the ways in which a failure can occur. For each failure, an estimate is made of its effect on the total system, design, process, or service, of its seriousness, of its occurrence (frequency), and its detection.

The FMEA will identify corrective actions required to prevent failures from reaching the customer, thereby assuring the highest durability, quality, and reliability possible in a product or service.

A good FMEA:

• Identifies known and potential failure modes
• Identifies the causes and effects of each failure mode
• Prioritizes the identified failure modes according to the risk priority number (RPN)—the product of frequency of occurrence, severity, and detection
• Provides for problem follow-up and corrective action

CRITICAL OR SIGNIFICANT CHARACTERISTICS OR KEY INDICATORS

To achieve customer satisfaction, the quality of the products and services must be the number one priority. The mission is to improve customer satisfaction through never-ending improvement (eliminate or reduce failures, errors, cost, mistakes, and so forth) in quality. To support that objective, a company may employ many measures of quality. These measures (sometimes called indicators, critical, or significant characteristics) are numerous and in some cases not widely known. For further explanation see the CD: Appendix B, Table B.4.

The key for selecting these characteristics is the ability to detect quality concerns before the product reaches the hands of the customer, or on their ability to measure customer dissatisfaction with the product or service. The ideal place for the identification of these characteristics is the design phase of the project. The definitions that are used in relation to the FMEA follow:

**Critical characteristics**—Those characteristics that can affect compliance with governmental regulations or safe product or service operation. These characteristics must be identified in the drawings and/or procedures,
as well as on the FMEA form. Stamatis (1992) has pointed out that generally the critical characteristics are defined by:

- The courts—through product liability
- Regulatory agencies—through formal laws and/or regulations
- Industrial standards—through generally accepted practices in the industry
- Customer requisition—through their wants, needs, and expectations
- Internal engineering requirements—through historical data or leading edge technology, or experience with product or service

**Significant characteristics**—Quality features of a process or product or service on which data should be collected. These characteristics are identified by a consensus of the customer and supplier as well as the FMEA team.

When a supplier’s proprietary design is being used, it is imperative that the supplier and customer’s quality planning team jointly identify the internal characteristics that will affect quality requirements and customer expectations. In the case of the service FMEA, the customer’s voice may be heard through a survey, Quality Function Deployment (QFD) study, or even benchmarking.

The content of the design FMEA and process FMEA should be used to identify appropriate significant product, process, or service characteristics (Ford 1992, 2000). Figure 2.1 shows how Ford Motor Company views the FMEA in relation to the other tools available for an optimum design.

All significant characteristics should be designated and agreed upon during the feasibility stage.

**Key characteristics**—Measurement indicators that provide rapid feedback to the process and thus provide an opportunity to immediately correct quality issues. They also provide problem definition at the source, as well as quantitative and qualitative measures of customer dissatisfaction with quality issues.

There are three types of key characteristics used in the FMEA:

1. *Leading characteristic*—A measure of quality that can be assessed and analyzed prior to shipment of product or service to the customer
2. *Intermediate characteristic*—A measure of quality that can be assessed and analyzed after shipment or delivery of the product or service, but prior to placing the product or service in the hands of the customer
3. *Lagging characteristic*—A measure of quality that can be assessed and analyzed to measure customer satisfaction, long after the product or service has been built, and/or delivered

**When Is the FMEA Started?**

By definition the FMEA is a methodology to maximize the satisfaction of the customer by eliminating and/or reducing known or potential problems. To do this the FMEA must begin as early as possible, even though all the facts and information are not known yet. The FMEA focuses on the motto:

*Do the best you can, with what you have.*

Is there a really best time to start? Yes. One should start an FMEA as soon as some information is known (usually through a QFD). Practitioners should not wait for all the information. If they do, they will never perform an FMEA because they will never have all the data or information. Certainly, with the preliminary information, some system constraints or design definitions may develop. This early notion of preparing the FMEA is illustrated in Figure 2.1. Specifically, an FMEA program should start:

- When new systems, designs, products, processes, or services are designed
- When existing systems, designs, products, processes, or services are about to change regardless of reason
- When new applications are found for the existing conditions of the systems, designs, products, processes, or service
- When improvements are considered for the existing systems, designs, products, processes, or services

Remember that the issue of the FMEA is to help map the road to continual improvement. As such, the FMEA may start at any point between system conception and manufacturing or service delivered. This road map is shown in Figure 2.2.

After the FMEA begins, it becomes a living document and is never really complete. It is a true dynamic tool of improvement (as opposed to static) because regardless of the beginning phase, it will use information to improve the system, design, product, process, or service. It is continually updated as often as necessary. The evolution of design is shown in Figure 2.3.
Figure 21  FMEA interrelationships.  
Courtesy of Ford Motor Co. Used by permission.
When Is the FMEA Complete?

Is there a time when the FMEA may be considered finished or complete? Yes. Only when the system, design, product, process, or service is considered complete and/or discontinued.

Specifically, the system FMEA may be considered finished when all the hardware has been defined and the design is declared frozen. The design FMEA may be considered finished when a release date for production has been set. The process FMEA may be considered finished when all operations have been identified and evaluated and all critical and significant characteristics have been addressed in the control plan. The service FMEA may be considered finished when the design of the system and individual tasks have been defined and evaluated, and all critical and significant characteristics have been addressed in the control plan.

It is important to note the following: Even though a finished or completed FMEA is defined as such based on circumstances, at any point it may be opened for a review, evaluation, and/or improvement of the system, design, product, process, or service as long as the system, design, product, process, or service is currently in existence.

Can the FMEA be discarded? If so, how? When? The strict answer to the question is yes. Depending on the relationship between the organization and the customer or supplier, however, different guidelines exist. There are no definite and universal guidelines other than specific rules in specific organizations and industries. For example, in the nuclear industry the retention
record is from cradle to grave, but in some automotive guidelines the FMEA should be kept as long as the product is produced. (As a general rule, the FMEA should be available for the entire product life.)
Who Conducts the FMEA?

The FMEA is a team function and cannot be done on an individual basis. The team must be defined as appropriate for a specific project and cannot serve as the universal or company FMEA team. The knowledge that is required for the specific problem is unique to that problem. Therefore, the makeup of the team must be cross-functional and multidisciplined for each FMEA (Stamatis 1991b). For more detailed information see Chapter 4.

Under no circumstances should any FMEA be done with a single individual (in other words, design or process engineer). An individual may fill out the FMEA form properly, but there will be built-in biases based on the single perspective of the individual conducting that FMEA.

If time constraints do not allow for a full team discussion, the recommendation (reluctantly) is to allow the leader of the FMEA team to present some of the failures in the team’s presence, and follow with a full discussion.

Under no circumstances should the enumeration of failures be done privately by anyone with the expectation that the team will at a later time discuss the discrepancies. That will never happen. The format for such an exercise is shown in Figure 2.4.

Interpretation of the FMEA

The essence of the FMEA is to identify and prevent known and potential problems from reaching the customer. To do that one has made some assumptions, one of which is that problems have different priorities. Thus, finding that priority is important and the thrust of the methodology.

There are three components that help define the priority of failures:

- Occurrence (O)
- Severity (S)
- Detection (D)

Occurrence is the frequency of the failure. Severity is the seriousness (effects) of the failure. Detection is the ability to detect the failure before it reaches the customer.

There are many ways to define the value of these components. The usual way is to use numerical scales (called risk criteria guidelines). These guidelines can be qualitative and/or quantitative.

If the guideline is qualitative, it must follow theoretical (expected) behavior of the component. For example, in the case of the occurrence the expected behavior is normality. This behavior is expected because frequencies over time behave in a normal fashion. Thus, the guideline should follow
### Type of FMEA: __________________
Prepared by: __________________

### Others involved: __________________
Responsibility: __________________

### FMEA date: ____________
Page _____ of _____ pages

| System/ design/ process/ service function | Potential failure mode | Potential effect(s) of failure | Potential cause(s) of failure | Detection method | O | C | S | E | V | D | E | T | R | P | N | Recommended action | Responsibility and completion date | Action results |
|------------------------------------------|------------------------|-------------------------------|-----------------------------|-----------------|---|---|---|---|---|---|---|---|---|---|-------------------|---------------------------|---------------|
| Engineer Team                            | Engineer with selective team |

**Figure 2.4** An alternate FMEA construction.*

*Not recommended for general use. Use only when time contraints do not allow full FMEA development.
the normal distribution. In the case of severity, the expected behavior is log-normal. This behavior is expected because the failures that occurred should be of the nuisance category as opposed to critical or catastrophic. Thus, the guideline should follow a distribution that skews to the right (positively skewed). In the case of the detection, the expected behavior is that of a discrete distribution. This is expected because there is more concern if the failure is found by the customer as opposed to finding the failure within the organization. Therefore, there is a discrete outcome (internal organization versus customer) in the detection. Thus, the guideline should follow a distribution with a gap between the values. Figure 2.5 shows these distributions.

If the guideline is quantitative, it must be specific. It must follow actual data, statistical process control data, historical data, and/or similar or surrogate data for the evaluation. The guideline does not have to follow the theoretical behavior. If it does, it is strictly coincidence. Table 2.1 displays some of the guidelines for the selection guideline. On the CD, Appendix F includes examples of actual evaluation criteria.

The ranking for the criteria can have any value. There is no standard for such value; however, there are two very common rankings used in all industries today. One is the ranking based on 1 to 5 scale and the second, a 1 to 10 scale.

The ranking of 1 to 5 is limited in nature, but offers expediency and ease of interpretation. It does not provide for sensitivity (accuracy) of specific quantification, because it reflects a uniform distribution. The ranking of 1 to 10 is used widely and, in fact, is highly recommended because it provides ease of interpretation, accuracy, and precision in the quantification of the ranking. Examples of both rankings are in Appendix F. Rankings of higher than 1 to 10 scales are not recommended (even though they can be very precise and accurate) because they are difficult to interpret and lose their effectiveness.

The priority of the problems is articulated via the RPN. This number is a product of the occurrence, severity, and detection. The value by itself should be used only to rank order and concerns of the system, design, product, process, and service. All RPNs have no other value or meaning (Ford 1992, 2000).

The threshold of pursuing failures/problems is an RPN equal to or greater than 50 based on a 95 percent confidence and a 1 to 10 guideline scale. By no means is this a standard or a universal number. It can and does change with the scale chosen and the statistical confidence the engineer wants. Of course, there is no limit to pursuing all failures, if that is the goal. At that point the order is determined by the magnitude of the RPN for each of the failures. (The high RPN failures are addressed first, then the lower, and so on until all failures have been resolved.) To undertake an analysis of
Figure 2.5 Different distributions.
Table 21 Criteria for selecting ratings.

<table>
<thead>
<tr>
<th>If</th>
<th>Then use</th>
<th>Select</th>
</tr>
</thead>
<tbody>
<tr>
<td>The system is similar to others or historical data exist</td>
<td>Statistical data from either historical or surrogate systems: Reliability data, actual distribution, mathematical modeling, simulation</td>
<td>Actual data and/or C&lt;sub&gt;pk&lt;/sub&gt;</td>
</tr>
<tr>
<td>Failure history is available with the system itself or similar, or surrogate parts</td>
<td>Historical data based on reliability, system, actual distributions, mathematical modeling, simulation, cumulative data, and/or fraction defectives</td>
<td>Actual data and/or cumulative number of failures</td>
</tr>
<tr>
<td>The system is new and/or no quantification for any data is available</td>
<td>Team judgment</td>
<td>Subjective criteria. Use team consensus and be conservative</td>
</tr>
<tr>
<td>The design is similar to others or historical data exist</td>
<td>Statistical data from either historical or surrogate systems: Reliability data, actual distribution, mathematical modeling, simulation</td>
<td>Actual data and/or C&lt;sub&gt;pk&lt;/sub&gt;</td>
</tr>
<tr>
<td>Failure history is available with the design itself or similar, or surrogate parts</td>
<td>Historical data based on reliability, system, actual distributions, mathematical modeling, simulation, cumulative data, and/or fraction defectives</td>
<td>Actual data and/or cumulative number of failures</td>
</tr>
<tr>
<td>The design is new and/or no quantification for any data is available</td>
<td>Team judgment</td>
<td>Subjective criteria. Use team consensus and be conservative</td>
</tr>
</tbody>
</table>

(Continued)
### Table 21 Criteria for selecting ratings. (Continued)

<table>
<thead>
<tr>
<th>If</th>
<th>Then use</th>
<th>Select</th>
</tr>
</thead>
<tbody>
<tr>
<td>The process is under statistical process control (SPC)</td>
<td>Statistical data: reliability data, process capability, actual distribution, mathematical modeling, simulation</td>
<td>Actual data or ( C_{pk} )</td>
</tr>
<tr>
<td>The process is similar to others or historical data exist</td>
<td>Statistical data from either historical or surrogate systems: reliability data, process capability, actual distribution, mathematical modeling, simulation</td>
<td>Actual data or ( C_{pk} )</td>
</tr>
<tr>
<td>Failure history is available with the design itself or similar, or surrogate parts</td>
<td>Historical data based on reliability, process, actual distributions, mathematical modeling, simulation, cumulative data, and/or fraction defectives</td>
<td>Actual data and/or cumulative number of failures</td>
</tr>
<tr>
<td>The process is new and/or no quantification for any data is available</td>
<td>Team judgment</td>
<td>Subjective criteria. Use team consensus and be conservative</td>
</tr>
<tr>
<td>The service is under statistical process control (SPC)</td>
<td>Statistical data: simulation</td>
<td>Actual data or ( C_{pk} )</td>
</tr>
<tr>
<td>The service is similar to others or historical data exist</td>
<td>Statistical data from either historical or surrogate systems: reliability data (queue modeling), process capability, actual distribution, mathematical modeling, simulation</td>
<td>Actual data or ( C_{pk} )</td>
</tr>
<tr>
<td>Failure history is available with the design itself or similar, or surrogate parts</td>
<td>Historical data based on reliability, process, actual distributions, mathematical modeling, simulation, cumulative data, and/or fraction defectives</td>
<td>Actual data and/or cumulative number of failures</td>
</tr>
<tr>
<td>The service is new and/or no quantification for any data is available</td>
<td>Team judgment</td>
<td>Subjective criteria. Use team consensus and be conservative</td>
</tr>
</tbody>
</table>
all problems at the same time is not recommended and is contrary to the philosophy of the FMEA.

The threshold can be changed for any given statistical confidence and/or scale. For example, say 99 percent of all failures must be addressed for a very critical system, design, product, process, and/or service on a guideline scale of 1 to 10. What is the threshold? The maximum number possible for the RPN is 1000 \((10 \times 10 \times 10)\) from occurrence, severity, and detection. Ninety-nine percent of 1000 is 990. Now subtract 1000 \(-\) 990 \(=\) 10. Therefore, the threshold of examining the failures would be anything equal or greater than a 10 RPN. If the statistical confidence is 90 percent with a scale of 1 to 10, then the threshold becomes 100, and so on.

If the scale is 1 to 5, then the threshold changes accordingly. The method is the same; however, the total number now is 125 instead of 1000. Thus, in a 90 percent, 95 percent, and 99 percent confidence the RPN of concern is 13, 7, and 2, respectively. (Special warning: In some of the automotive companies, a threshold is not acceptable. Rather, the severity, criticality, and the RPN are used in that order for a successful evaluation. More on this, see Chapter 14).

After the RPN has been determined, the evaluation begins based on the definition of the risk. Usually this risk is defined by the team as minor, moderate, high, and critical. It may be changed to reflect different situations.

• Under minor risk, no action is taken.
• Under moderate risk, some action may take place.
• Under high risk, definite action will take place. (Selective validation and evaluation may be required.)
• Under critical risk, definite actions will take place and extensive changes are required in the system, design, product, process, and/or service.

If there are more than two failures with the same RPN, then first address the failure with high severity, and then detection. Severity is approached first because it deals with the effects of the failure. Detection is used over the occurrence because it is customer dependent, which is more important than just the frequencies of the failure.

An example of extreme cases when corrective action must be taken is shown in the following design ratings.
### Assessment rating | Causes of failure | Action taken
---|---|---
O | S | D | Ideal situation (goal) | No action (N/A)
1 | 1 | 1 | Assured mastery | N/A
1 | 1 | 10 | Failure does not reach user | N/A
1 | 10 | 1 | Failure reaches user | Yes
1 | 10 | 10 | Frequent fails, detectable, costly | Yes
10 | 1 | 1 | Frequent fails, reaches the user | Yes
10 | 1 | 10 | Frequent fails w/major impact | Yes
10 | 10 | 1 | Trouble! | Yes, Yes, Yes, Yes, Yes

Again, a typical example of actions which will influence the design FMEA risk evaluation follows:

### Corrective actions | O | S | D
---|---|---|---
Redesign the product | Y | Y | Y
Improve current control | N | N | Y
Change material parts | Y | N | Y
Change the application | Y | Y | Y
Change the field environment | Y | Y | Y
Improve reliability program | Y | N | Y
Improve employee training | N | N | Y
Implement FMEA program | Y | Y | Y
Implement SPC program | N | N | N
Improve quality plan | N | N | N

(Y=Yes, N=No)

For a process, extreme cases where corrective action must be taken include the following process ratings:

### Assessment rating | Causes of failure | Action taken
---|---|---
O | S | D | Ideal situation (goal) | No action (N/A)
1 | 1 | 1 | Assured mastery | N/A
1 | 1 | 10 | Failure does not reach user | N/A
1 | 10 | 1 | Failure reaches user | Yes
1 | 10 | 10 | Frequent fails, detectable, costly | Yes
10 | 1 | 1 | Frequent fails, reaches the user | Yes
10 | 1 | 10 | Frequent fails w/major impact | Yes
10 | 10 | 1 | Trouble! | Yes, Yes, Yes, Yes, Yes

Another example of actions that will influence the process FMEA risk evaluation follows:
Corrective actions | O | S | D
---|---|---|---
Redesign the process | Y | M | Y
Redesign the product | M | M | M
Improve current control | N | N | N
Change material parts | M | N | M
Change the application | N | M | M
Change the field environment | N | M | N
Improve reliability program | Y | N | Y
Improve employee training | M | N | Y
Implement FMEA program | Y | Y | Y
Implement SPC program | Y | N | Y
Improve quality plan | Y | N | Y

(Y=Yes, M=Maybe, N=No)

The Process of Conducting an FMEA

To conduct an FMEA effectively one must follow a systematic approach. The recommended approach is an eight-step method that facilitates the system, design, product, process, and service FMEA.

1. **Select the team and brainstorm**—Make sure the appropriate individuals are going to participate. The team must be crossfunctional and multidisciplined and the team members must be willing to contribute (Stamatis 1991b).

   After the team has been identified and is in place, the team tries to prioritize the opportunities of improvement. Is the concern in a system, design, product, process, or service? What kind of problems are there and/or what kind are anticipated with a particular situation? Is the customer and/or supplier involved or is continual improvement being pursued independently? If the customer and/or supplier has identified specific failures, then the job is much easier because direction has already been given. On the other hand, if continual improvement is being independently pursued, the brainstorm, affinity diagram, storybook method, and/or a cause-and-effect diagram may prove to be the best tools to identify some direction.

2. **Functional block diagram and/or process flowchart**—For system and design FMEAs the functional block diagram is applicable. For the process and service FMEAs the process flowchart is applicable. The idea is to make sure that everyone is on the same wavelength. Does everyone understand the system, design, process, and/or service? Does everyone understand the problems associated with the system, design, process, and/or service?
The functional block diagram focuses the discussion on the system and design while the process flowchart focuses the discussion on the process and service. Both of these tools also provide an overview and a working model of the relationships and interactions of the systems, subsystems, components, processes, assemblies, and/or services and help in the understanding of the system, design, product, process, and/or service.

3. *Prioritize*—After the team understands the problem, the actual analysis begins. Frequent questions are: What part is important? Where should the team begin?

Sometimes, this step is completely bypassed because the prioritization is de facto. The customer has identified the priority, or due to warranty cost or some other input the determination has been made by the management to start at a given point.

4. *Data collection*—This is where the team begins to collect the data of the failures and categorizes them appropriately. At this point the team begins to fill in the FMEA form. The failures identified are the failure modes of the FMEA.

5. *Analysis*—Now the data are utilized for a resolution. Remember, the reason for the data is to gain information that is used to gain knowledge. Ultimately, that knowledge contributes to the decision. This flow can be shown as follows:

   Data -----> Information -----> Knowledge -----> Decision

   ---->>> Flow >>>----->

The analysis may be qualitative or quantitative. The team may use brainstorming, cause-and-effect analysis, QFD, DOE, Statistical Process Control (SPC), another FMEA, mathematical modeling, simulation, reliability analysis, and anything else that team members think is suitable.

Information from this step will be used to fill in the columns of the FMEA form in relationship to the effects of the failure, existing controls, and discussing the estimation of severity, occurrence, and detection.

6. *Results*—The theme here is *data driven*. Based on the analysis, results are derived.

The information from this step will be used to quantify the severity, occurrence, detection, and RPN. The appropriate columns of the FMEA will be completed.
7. **Confirm/evaluate/measure**—After the results have been recorded, it is time to confirm, evaluate, and measure the success or failure. This evaluation takes the form of three basic questions:

- Is the situation better than before?
- Is the situation worse than before?
- Is the situation the same as before?

The information from this step will be used to recommend actions and to see the results of those actions in the corresponding columns of the FMEA form.

8. **Do it all over again**—Regardless of how step 7 is answered, the team must pursue improvement all over again because of the underlying philosophy of FMEA, which is continual improvement.

The long-term goal is to completely eliminate every single failure. The short-term goal is to minimize the failures if not eliminate them. Of course, the perseverance for those goals has to be taken into consideration in relationship to the needs of the organization, costs, customers, and competition.

**How Long Should the FMEA Be and How Much Time Should It Take?**

Conducting an FMEA is a time-consuming exercise, but if one evaluates all alternatives, it is evident that it is worthwhile. Regarding the eight steps, the majority of the time is spent on the first three steps. Identifying the problem, understanding the problem, and prioritizing the analysis accounts for approximately 60 percent to 80 percent of the total time. The remainder of the time is spent in actual analysis.

There are no specific length or time limits for any FMEA. The length and time is defined by the conditions, objectives, and complexity of the project at hand.

An appropriate FMEA may be one-quarter of a page that took only one-half hour to complete. Conversely, an FMEA with 164 pages and six months (five persons meeting twice a week for three hours per meeting) of work does not guarantee completion.

Often an FMEA is performed on commodity items. In these situations, it is acceptable to perform group FMEAs on similar or identical items and then address the out-of-the-ordinary conditions as separate items. Examples of this include washers (fasteners), screws, springs, and O-rings. They all have some inherent common characteristics that can be addressed together; however, they all have some special attributes that should be addressed separately.
What Happens After Completion of the FMEA?

Generally there are seven steps that the team must follow (Stamatis 1993).

1. **Review the FMEA**—Make sure that the function, purpose, and objective have been met. Make sure that all the loose ends have been addressed and the appropriate action has been recommended and/or implemented. Some helpful hints for this review follow.
   - Is the problem identification specific?
   - Was a root cause, an effect, or a symptom identified?
   - Is the corrective action measurable?
   - Is the corrective action proactive?
   - Is the use of terminology current and consistent?
   - Is the corrective action realistic and sustainable?

2. **Highlight the high-risk areas**—A visual inspection of the critical column, the severity column, and the RPN column generally will identify the high-risk areas. In the critical column, the high-risk item may be identified as such; in the severity column the high-risk item usually will have a number higher or equal to 7; and in the RPN column usually a number higher or equal to 100 (on a 1 to 10 scale) will indicate that there might be a high-risk item.

3. **Identify the critical, significant, and major characteristics**—Upon completion of the FMEA, a visual check of the RPN and critical columns should identify the critical, significant, and major characteristics. Make sure that there is a direct correlation between the critical column and the effects of the failure and the severity columns. Great care should be taken when reviewing the RPN because these numbers will indicate whether or not action should be taken.

4. **Ensure that a control plan exists and is being followed**—As previously mentioned, the idea of performing an FMEA is to eliminate and/or reduce known and potential failures before they reach the customer. In this step, make sure that all critical, significant, and major characteristics have a documented plan for controlling, improving, and/or handling changes. The control plan is the map that will allow practitioners to make the product and/or service acceptable to the customer. Although the FMEA identifies the vital signs of the process and/or service, the control plan monitors those vital signs of the process and/or service.
5. **Conduct capability studies**—After the control plan is in place and statistical control has been established, a potential capability or a long capability must be performed.

6. **Work on processes which have a Process Capability Index (Cpk) less than or equal to 1.33**—Although the 1.33 generally is accepted as the minimum goal, be aware that some companies require a $C_{pk} = 1.67$ (Ford Motor Co.) or even a $C_{pk} = 2.00$ (Motorola). The point is to continually improve the process by eliminating variation. Produce everything around the target.

7. **Work on processes which have $C_{pk}$ greater than or equal to 1.33**—After the minimum standard is reached in step 5, try to go beyond that standard for further improvement. Reduce variation and try to reach or exceed a $C_{pk}$ greater than or equal to 2.00. Remember, all standards are minimum performance. Consequently, continual improvement dictates that one should, at all times, try to exceed all standards, including all $C_{pk}$ targets.

## THE FOUR TYPES OF FMEAS

Generally, it is accepted that there are four types of FMEAs. In Figure 2.6 the relationships of the four FMEAs are shown with their respective focus and objective. The four types are:

1. **System FMEA** (sometimes this is called a concept FMEA)—Used to analyze systems and subsystems in the early concept and design stage. A system FMEA focuses on potential failure modes between the functions of the system caused by system deficiencies. It includes the interactions between systems and elements of the system.

   The output of the system (concept) FMEA is:
   - A potential list of failure modes ranked by the RPN
   - A potential list of system functions that could detect potential failure modes
   - A potential list of design actions to eliminate failure modes, safety issues, and reduce the occurrence

   The benefits of the system FMEA are that it:
   - Helps select the optimum system design alternative
   - Helps in determining redundancy
   - Helps in defining the basis for system level diagnostic procedures
• Increases the likelihood that potential problems will be considered
• Identifies potential system failures and their interaction with other systems or subsystems

2. Design FMEA—Used to analyze products before they are released to manufacturing. A design FMEA focuses on failure modes caused by design deficiencies. (Note that a variation of the design FMEA is the machine FMEA, the environmental and attribute FMEA, which are covered separately in Chapters 9 and 14 respectively.)

The output of the design FMEA is:

• A potential list of failure modes ranked by the RPN
• A potential list of critical and/or significant characteristics

**Figure 2.6** Types of FMEAs.
• A potential list of design actions to eliminate failure modes, safety issues, and reduce the occurrence

• A potential list of parameters for appropriate testing, inspection, and/or detection methods

• A potential list of recommended actions for the critical and significant characteristics

The benefits of the design FMEA are that it:

• Establishes a priority for design improvement actions

• Documents the rationale for changes

• Provides information to help through product design verification and testing

• Helps identify the critical or significant characteristics

• Assists in the evaluation of design requirements and alternatives

• Helps identify and eliminate potential safety concerns

• Helps identify product failure early in the product development phase

3. Process FMEA—Used to analyze manufacturing and assembly processes. A process FMEA focuses on failure modes caused by process or assembly deficiencies.

The output of the process FMEA is:

• A potential list of failure modes ranked by the RPN

• A potential list of critical and/or significant characteristics

• A potential list of recommended actions to address the critical and significant characteristics

The benefits of the process FMEA are that it:

• Identifies process deficiencies and offers a corrective action plan

• Identifies the critical and/or significant characteristics and helps in developing control plans

• Establishes a priority of corrective actions

• Assists in the analysis of the manufacturing or assembly process

• Documents the rationale for changes
4. Service FMEA—Used to analyze services before they reach the customer. A service FMEA focuses on failure modes (tasks, errors, mistakes) caused by system or process deficiencies.

The output of the service FMEA is:

- A potential list of errors ranked by the RPN
- A potential list of critical or significant tasks, or processes
- A potential list of bottleneck processes or tasks
- A potential list to eliminate the errors
- A potential list of monitoring system/process functions

The benefits of the service FMEA are that it:

- Assists in the analysis of job flow
- Assists in the analysis of the system and/or process
- Identifies task deficiencies
- Identifies critical or significant tasks and helps in the development of control plans
- Establishes a priority for improvement actions
- Documents the rationale for changes

**Guidelines for Process and Service Control**

Specifically, with a process and/or service, the flow for control using an FMEA follows.

1. *Select the process and/or service*—The necessary changes and/or improvements must be identified. The goal of the undertaking must also be defined.

2. *Conduct the FMEA*—After the goal and expectations of the process and/or service are established, the FMEA should be pursued.

3. *Conduct a measurement system analysis*—Make sure the measurement system is appropriate and applicable to the process and/or service.

4. *Conduct process potential study*—A short-term (cursory) capability study (sometimes a feasibility study) must be performed to identify whether or not the process and/or service is doable and appropriate.
5. **Develop control plan**—Make sure that a road map exists to identify and prescribe critical processes/services. For a basic control system, see CD Figure H.2.

6. **Train operators in control methods**—It is imperative that all operators have the appropriate training. Without it, they cannot be expected to know what they have to do. It is management’s responsibility to identify and provide the appropriate training.

7. **Implement control plan**—Just because the documentation exists, it does not imply that it is being followed. It is imperative that the control plan be followed at all times if improvement is expected. With an implemented control plan there is a better chance for consistency and reduction of variation than without it.

8. **Determine long-term capability**—Know whether or not the organization can produce and/or service what it says it can produce and/or service. The only way to know for sure is through a capability study.

9. **Review the process and/or service for continual improvement**—Always be cognizant of changes. Because changes occur, one must be vigilant to make sure that the changes are for a true improvement rather than something different.

10. **Develop an audit system**—The switch from inspection (which is product oriented), to audit system (which is system oriented), must be implemented in the organization if continual improvement is really a concern. Only with audits can one demonstrate true quality orientation. Inspection, by definition, focuses on sorting quality (good versus bad). On the other hand, audits by definition focus on the systems that are in place to produce/service good quality.

11. **Institute improvement actions**—The focus in any organization is to improve. This is done by constantly evaluating current and future activities and implementing those activities that will make the process/services better.

   It is this need for improvement that generates the interest for an FMEA. It is the FMEA that will contribute to the improvement by eliminating known and/or potential failures from the process/service. As a consequence, variation is minimized and improvements realized.
RELATIONSHIPS OF FMEA AND OTHER TOOLS

Fault Tree Analysis

FTA is a deductive analytical technique of reliability and safety analysis and generally is used for complex dynamic systems. It provides an objective basis for analysis and justification for changes and additions (Blanchard 1986).

FTA was developed in 1961 by Bell Telephone Company. Later on, the Boeing company modified the concept to the point that now the FTA is widely used in many fields and industries.

As it is used today, the FTA is a model that logically and graphically represents the various combinations of possible events, both faulty and normal, occurring in a system that leads to the top undesired event. It uses a tree to show the cause-and-effect relationships between a single, undesired event (failure) and the various contributing causes. The tree shows the logical branches from the single failure at the top of the tree, to the root cause(s) at the bottom of the tree. Standard logic symbols are used.

After the tree has been constructed and the root cause(s) identified, the corrective actions required to prevent or control the causes can be determined. Usually probabilities are associated with the undesired failure.

The FTA always supplements the FMEA and not the other way around. In general, its application may be in a system or subsystem environment with a focus on identifying the root factors that could cause a failure and their interdependent relationships. The benefits of using FTA are that it:

- Helps in visualizing the analysis
- Helps identify the reliability of higher-order (level) assemblies or the system
- Determines the probability of occurrence for each of the root causes
- Provides documented evidence of compliance with safety requirements
- Assesses the impact of design changes and alternatives
- Provides options for qualitative, as well as quantitative, system reliability analysis
- Allows the analyst to concentrate on one particular system failure at a time
• Provides the analyst with insight into system behavior
• Isolates critical safety failures
• Identifies ways that failure of the product can lead to an accident

Figures 2.7 and 2.8 show the elements of the FTA. Figure 2.9 shows how the FTA can be used with the FMEA, and Figure 2.10 shows an example of an FTA diagram.

**General Rules of Construction for FTA**

When constructing a fault tree, the scope of the analysis may need to be reduced in order to make it more manageable. This can be accomplished by using a block diagram such as the reliability block diagram for the system and equipment. A separate fault tree can then be constructed for each block. Conversely, a success tree could also be constructed for each block in order to identify what must occur for the block to be a success.

Therefore, once the top-level “fault event” has been defined, there is a series of steps that should be followed by the Product Development or the FMEA team in order to properly analyze and construct the fault tree.

**Step 1**: Define the system and any assumptions to be used in the analysis. Also, define what constitutes a failure (that is, limit, parametric shift, functionality, and so on).

**Step 2**: If needed to simplify the scope of the analysis, develop a simple block diagram of the system showing input, output, and interfaces.

**Step 3**: Identify and list the top-level “fault events” to be analyzed. If required, develop a separate fault tree for each top-level event, depending upon how the top-level event is defined and the specificity of the event or scope of study.

**Step 4**: Using the fault tree symbols presented earlier and a “logic tree format,” identify all of the contributing causes to the top-level event. In other words, using deductive reasoning, identify what events could cause the top-level event to occur.

**Step 5**: Thinking of the causes of step 4 as intermediate effects, continue the logic tree by identifying causes for the intermediate effects.

**Step 6**: Develop the fault tree to the lowest level of detail needed for the analysis—typically with basic or undeveloped events.
<table>
<thead>
<tr>
<th>Name of gate</th>
<th>Symbol of gate</th>
<th>Input–output relationship</th>
</tr>
</thead>
<tbody>
<tr>
<td>AND gate</td>
<td><img src="image" alt="AND gate symbol" /></td>
<td>The output event occurs if all of the $n$ input events occur.</td>
</tr>
<tr>
<td>OR gate</td>
<td><img src="image" alt="OR gate symbol" /></td>
<td>The output event occurs if at least one of the $n$ input events occurs.</td>
</tr>
<tr>
<td>$m$-out-of-$n$ voting gate</td>
<td><img src="image" alt="m-out-of-n voting gate symbol" /></td>
<td>The output event occurs if $m$ or more out of $n$ input events occur.</td>
</tr>
<tr>
<td>Priority AND gate</td>
<td><img src="image" alt="Priority AND gate symbol" /></td>
<td>The output event occurs if all input events occur in a certain order.</td>
</tr>
<tr>
<td>Exclusive OR gate</td>
<td><img src="image" alt="Exclusive OR gate symbol" /></td>
<td>The output event occurs if only one of the input events occurs.</td>
</tr>
<tr>
<td>Inhibit gate</td>
<td><img src="image" alt="Inhibit gate symbol" /></td>
<td>The input event causes the output event only if the conditional event occurs.</td>
</tr>
</tbody>
</table>

**Figure 2.7** Fault tree gate symbols.
Step 7: Once completed, analyze the fault tree in order to understand the logic and the “interrelations” of the various fault paths, and to gain insight into the unique modes of product faults. Additionally, this analysis process should focus on those faults that, potentially, appear most likely to occur.

Step 8: Determine where corrective action is dictated or a design change is required to eliminate fault paths wherever possible, or

<table>
<thead>
<tr>
<th>Symbol of event</th>
<th>Meaning of symbol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Circle</td>
<td>Basic event</td>
</tr>
<tr>
<td>Diamond</td>
<td>Undeveloped event</td>
</tr>
<tr>
<td>Oval</td>
<td>Conditional event</td>
</tr>
<tr>
<td>House</td>
<td>Trigger event</td>
</tr>
<tr>
<td>Rectangle</td>
<td>Resultant event</td>
</tr>
<tr>
<td>Triangle</td>
<td>Transfer-in and transfer-out events</td>
</tr>
</tbody>
</table>

Figure 2.8 Fault tree event symbols.
identify any control(s) that could keep the fault from possibly occurring.

**Step 9:** Document the analysis process and then follow up to ensure that all appropriate action(s) have been taken.

Once the appropriate logic gates, symbols, and event descriptions have been developed, the next level of complexity in FTA involves the calculation of the probability of occurrence of the top-level events. In order to do this, the probability of occurrence values for the lowest-level events are required.

Probability Equation: \[ P(\text{System Fault}) = 1 - \left( [1 - P(1)] [1 - P(2)] [1 - P(3)] \right) \]

Where \( p(\text{ }) \) = Probability of Event Occurrence

When the probability of occurrence of the lowest-level events has been determined, the probability of occurrence of the top-level events can be calculated by using Boolean algebra probability techniques. In most cases, it

![FTA and FMEA (possible specific failures)]
will be more convenient to use computer software to perform these calculations. One such computer program is the FaultrEase program. An alternative approach to calculating the probability of occurrence of the top-level event is to convert the fault tree to its equivalent reliability block diagram.

To do the conversion when using a fault tree, an OR Gate corresponds to a series reliability block diagram, an AND Gate corresponds to a parallel reliability block diagram. Recall that the Reliability Equation for a system is:

$$R_{sys} = R_1 \times R_2 \times R_3$$

Where: $R_1$ = Reliability of Element 1 = $1 - P$ (Element 1 Fault) and $R_{sys}$ = System Reliability = $1 - P$ (System Fault)

On the other hand, $P$ (System Fault) $P(1) \times P(2) \times P(3)$; Where $P (\cdot)$ = Probability of Event Occurrence

To convert then to a parallel reliability block diagram, recall that the reliability equation is

$$R_{sys} = 1 - [(1 - R_1)(1 - R_2)(1 - R_3)]$$

Where: $R_1$ = Reliability of Element 1 = $1 - P$ (Element 1 Fault) and $R_{sys}$ = System Reliability = $1 - P$ (System Fault)
The following example demonstrates these principles:

Using the formula for reliability of a parallel system,

$$R_{sys} = 1 - [(1-R3)(1-R1 \times R2)]$$

where \(R_{1\&2} = \text{Reliability of Elements 1 and 2 in series.}\)

Therefore,

$$R_{sys} = 1 - [(1-R3) (1-R1 \times R2)]$$

$$= 1 - [(1-.99)(1-(.999)(.998))]$$

$$= 1 - [(.01)(1.997002)]$$

$$= 1 - .0002998$$

$$= 0.9997002$$

Probability of damage, \(P(D) = 1 - R_{sys} = .0002998\) or approximately .0003.

If, on the other hand, we use the reliability block diagram for the system reliability, we can find the same answer as follows:
Therefore the $R_{sys} = 0.99997$

$P(D) = \text{Probability of failure} = 1 - R_{sys} = 0.00003$

By using the reliability block diagram, the system reliability is: $R_{sys} = 0.99997$. The probability of potential engine damage due to insufficient oil pressure, $P(D)$, can be found by subtracting $R_{sys}$ from 1.

$$P(D) = 1 - R_{sys} = 1 - 0.99997 = 0.00003$$

This agrees with the values of $P(D)$ obtained when using the fault tree probability equations.

One can see that this sort of analysis enables both the product development and the FMEA team to determine the:

- Overall likelihood of the undesired top-level event
- Combination of input events most likely leading to the undesired top-level event
- Single event contributing most to this combination
- Most likely path(s) leading through the fault tree to the top-level event where redundancy or system reconfiguration would improve the system reliability

A final point for the FTA is the notion about success trees. They complement fault trees and they help in identifying contributors to robust function(s). The FTA identifies possible causes of failure. Conversely, if we wish to design an Ideal Function, we may represent relationships by a success tree. A success tree is the complement or “dual” of the fault tree and focuses on what must happen for the top-level event be a success.

Therefore, a fault tree can be converted to a success tree by: Changing each OR Gate to an AND Gate and Changing each AND Gate to an OR Gate. (Obviously, appropriately rewording statements within the blocks to their respective complements [success statements instead of fault statements] must be made.) For a successful conversion the same methodology and appropriate logic symbols as the fault tree are used to arrive at a success tree.

This success tree/reliability block diagram relationship follows from the fact that for a system success, the series reliability block diagram requires that Block 1 AND Block 2 AND Block 3 all be successes. Thus, the success tree AND Gate corresponds to a series reliability block diagram. And the success tree OR Gate corresponds to a parallel block diagram.

The benefit of a success tree is that it helps in the Quantitative evaluation of a reliability prediction by using the same procedure as for fault trees. The top-level probability of occurrence of a success tree is probability of
success, which by definition is Reliability, $R$. Due to this fact, a success tree can be used as a reliability prediction model.

If a success tree has been developed for a product and the probability of occurrence has been determined for each cause, the reliability of the product can be determined by calculating the top-level probability of success.

**Task Analysis**

After the system has been defined and allocated, the specific tasks that must be performed are analyzed. A task analysis defines:

- The stimulus initiating the task
- The equipment used to perform the task
- The task feedback
- The required response of the human
- The characteristics of the task output, including performance requirements

**Process Flowchart**

This is the sequence of flow in the operations among processes and personnel using standard symbols for each of the processes. The symbols are:

<table>
<thead>
<tr>
<th>Activity/operations</th>
<th>Inspection</th>
<th>Flow/movement</th>
<th>Delay</th>
<th>Inventory storage</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Activity" /></td>
<td><img src="image" alt="Inspection" /></td>
<td><img src="image" alt="Flow/movement" /></td>
<td><img src="image" alt="Delay" /></td>
<td><img src="image" alt="Inventory storage" /></td>
</tr>
</tbody>
</table>

The process flowchart is used primarily in the process FMEA and service FMEA.

**Functional Flow Diagrams or Block Diagrams**

Block diagrams illustrate the physical or functional relationships as well as interfaces within a system or assembly under analysis. They are used as a
mechanism for portraying system design requirements in a pictorial manner, illustrating series-parallel relationships, the hierarchy of system functions, and functional interfaces.

The types of block diagrams used in FMEA are:

- **System**—For identifying the relationships between major components and subsystems
- **Detail**—For identifying the relationships between each part within an assembly or subsystem
- **Reliability**—For identifying the series dependence or independence of major components, subsystems, or detail parts in achieving required functions

Block diagrams are not intended to illustrate all the functional relationships which must be considered in the FMEA. They should be made as simple and explicit as possible. An example of a block diagram and logic diagram is shown in Figure 2.11.

**System level diagrams** are generated for components or large systems which are made up of several assemblies or subsystems. **Detail level diagrams** are generated to define the logical flow and interrelationships of individual components and/or tasks.

**Reliability level** diagrams generally are used at the system level to illustrate the dependence or independence of the systems, or components contributing to the specific functions (General Motors 1988). They also are used to support predictions of successful functioning for specified operating or usage periods.

**Sketches, Layouts, Schematics**

These diagrams present a picture of how the product or process is proposed to look (General Motors 1988). The purpose of using these diagrams is to gain a better understanding of the system being studied by the analysis team. Using this information, the team can gain more objective information regarding:

- The general size—The relative size of the component and the process operation.
- The overall space involved—How the system fits within the total system. Specifically, information about accessibility and serviceability are of concern.
### Reliability block diagram

| A | B |

| A | B | A | B |

| A | B | C | A | B | C |

| A | B | C | A | B | C |

| A | B | C | A | B | C |

| A | B | C | A | B | C |

| A | B | C | A | B | C |

| A | B | C | A | B | C |

### Logic diagram

- A
- B

- A
- B

- A
- B

- A
- B

### Figure 2.11

Block diagrams and logic diagrams.

- The number of items—What is the quantity of bolts, nuts, and so on, or the number of fixtures and/or tools in an operation.

Figures 2.12, 2.13, 2.14 show examples of a schematic diagram, functional diagram, and a sketch layout diagram.

### Need and Feasibility Analysis

A feasibility analysis often is conducted as part of, or an extension to, a preliminary market analysis to:

- Define system operational requirements
- Develop a system maintenance concept
• Identify a system configuration that is feasible within the constraints of available technology and resources

The feasibility analysis uses product design and process failure mode effects analysis as its primary tools (Ford 1992, 2000).

**Failure Mode Analysis**

FMA is a systematic approach to quantify the failure modes, failure rate, and root causes of known failures. Usually, the FMA is based on historical information such as warranty, service, field, and process data (Omdahl 1988). In a sense, the FMA is a diagnostic tool because it concerns itself with only known and/or occurred failures.

The FMA is used to identify the operation, failure modes, rates, and critical design parameters of existing hardware or processes. Because of the ability to utilize historical data and known failures, the FMA is used primarily on current production as opposed to the FMEA which is used on changed and/or new designs, processes, and/or services.
The rocketborne photoflash unit will operate successfully and within specified tolerance limits.

- Capacitor C1 is not open when timer S2A closes
- Capacitor C2 is not open when time S2A closes
- Capacitor C1 does not short between pre-launch checkout and moment S1A closes
- Capacitor C2 does not short between pre-launch checkout and moment S2A closes
- Switch S1E1 is not open when timer S1A closes
- Switch S1E2 is not open when timer S2A closes
- Diode CR1 is not open when timer S2A closes
- Diode CR2 is not open when timer S2A closes
- Diode CR1 does not short before timer S2A closes
- Diode CR2 does not short before timer S2A closes
- Inertial starter M1 operates successfully
- Timer mechanism M2 operates successfully
- Timer mechanism M2 is accurate enough to close timer S2A at specified time
- Timer S2A closes at specified time
- Photoflash bulb ignitor is not shorted when timer S2A closes
- Photoflash bulb gas seal is not broken when timer contact S2A closes
- Photoflash bulb is capable of delivering its specified light intensity for specified time

Success

**Figure 213** Reliability functional diagram.
Figure 2.14 Sketch layout diagram.
Both the Failure Mode Analysis (FMA) and the FMEA deal with failure modes and causes. The FMA usually is done first, however, and the information gained is fed into the FMEA.

Control Plan

A control plan is a written summary of the producer’s quality planning actions for a specific process, product, and/or service. The control plan lists all process parameters and design characteristics considered important to customer satisfaction and which require specific quality planning actions (Chrysler 1986; Ford 1992, 2000; General Motors 1988; ISO/TS 19649; AIAG 2001). The control plan describes the action(s) and reaction(s) required to ensure the process is maintained in a state of statistical control (as agreed upon between customer and supplier).

It is the FMEA that identifies the critical and significant characteristics, and therefore the starting point, for initiating a control plan. It can never be the other way around. A typical control plan may include:

- A listing of critical and significant characteristics
- Sample sizes and frequency of evaluation
- Method of evaluation
- Reaction and/or corrective action

An example of a control plan is shown in Figure 2.15. Figure 2.16 shows a different format of a control plan.

Process Potential Study (PPS)

The PPS is the experimental part of new product introduction. It consists of implementing the control plan, which has been developed through the defined process and evaluates the results through statistical capability studies. If the desired capability is not achieved, changes in the control plan are agreed upon and the study repeated. This process may include a design of experiments to determine optimum process parameters.

Failure Mode and Critical Analysis

FMCA is a systematic approach to quantify the failure modes, rates, and root cause(s) from a criticality perspective. It is similar to the FMEA in all other respects (Bass 1986). The FMCA analysis is used primarily with government
### Control plan

**Flowchart**

<table>
<thead>
<tr>
<th>Critical characteristic</th>
<th>Sample size</th>
<th>Sample frequency</th>
<th>Inspection procedure</th>
<th>Report document</th>
<th>Additional requirements</th>
<th>Miscellaneous information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Start</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Incoming inspection</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Storage</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Press</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Bake oven</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Finish</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Pack</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Flowchart Critical characteristic**

- Grain size
- Density
- Impact test
- Cracks, chips, spots, stains, pits
- Insulation

**Sample size**

- Gram
- 1
- 100
- 1 box

**Sample frequency**

- 1/lot
- 1 Hr
- 1/batch
- 4 Hrs

**Inspection procedure**

- ASTM No
- SAE No
- ASTM No
- Visual
- No

**Report document**

- Lab report
- X chart
- Inspect sheet
- U chart
- Status sheet

**Additional requirements**

**Miscellaneous information**

---

**Figure 2.15** An example of a typical control plan.
**Process control plan**

<table>
<thead>
<tr>
<th>Process flow</th>
<th>Controlling parameters</th>
<th>Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operation number</td>
<td>Process name</td>
<td>Manufacturing equipment/tooing identification</td>
</tr>
</tbody>
</table>

Prepared by: _____________________________ Date: __________ Page _____ of _____ pages

**Figure 216** A different format of a control plan.
contracts based on the MIL-STD-1629A where the identification of critical, major, and minor characteristics is important.

One of the most important contributions of the FMCA is the fact that by focusing on criticality one can identify the so-called single point failure modes. A single point failure mode is a single human error or hardware failure that can result in an accident (Motorola 1992).

On the CD, Appendix D, an example of a design and process FMCA is shown with explanations.

Safety Hazard Analysis; Fault Hazard Analysis; Operating Hazard Analysis; Preliminary Hazard Analysis

These are methods to define hazards during operation, transportation, between products and systems, and to users. All of them supplement the FMEA and cannot take its place (Bass 1986).

Design of Experiments (DOE)

DOE is a very special way of conducting an experiment or a study. Certain independent variables are changed to a predefined plan, and the effects are determined on the dependent variable (Stamatis 1991c, 2003).

DOE is used in reliability testing and can identify the primary factors causing an undesired event. The optimum use of DOE in FMEA application(s) is when there is a concern about several independent variables and/or an interaction effect of the causal factors.

The question of whether or not to use the classical approach as opposed to the Taguchi approach in the experimentation process is always an interesting discussion. It is the opinion of the author that the Taguchi experimentation in the early stages of development and/or manufacturing may produce faster and just-as-correct results as the classical approach. As the experimenter closes in on the design and/or process and more precise evaluation is demanded, the classical approach has the edge. Again, from the FMEA perspective, the difference is minor and as long as the analyst is comfortable with either one, the results should not matter that much.

Quality Function Deployment (QFD)

QFD is a systematic methodology that brings together the various factions within the corporation (in a planned manner) and causes them to focus on the voice of the customer. The voice of the customer from a QFD perspective is to correctly interpret the needs, wants, and expectations of the customer.
By addressing the planning process with a specific objective, QFD can help identify weaknesses and strengths. It encourages a comprehensive, holistic approach to product development (Clausing and Simpson 1990; Stamatis 1990, 2003).

The implementation of QFD can provide the following benefits:

- **Strategic benefits**
  - Reduced cost
  - Fewer engineering changes
  - Shorter cycle time
  - Larger market share
  - Reduce process variation

- **Operational benefits**
  - Ties together other quality technologies
  - Enhances communications
  - Identifies conflicting requirements
  - Preserves information for the future

QFD is a tool that translates the customers’ requirements, part characteristics, manufacturing operations, and production requirements. Each step is interrelated and tracked through the house of quality until and when all concerns have been resolved.

QFD and FMEA have a lot in common. They both aim at continual improvement; they both focus on elimination of failures; they both look for satisfied customers.

Because of this overlap, one may think that they may be used interchangeably. That is not so. The QFD must be performed first and, based on the results, the system FMEA will follow and so forth.

Figures 2.17, 2.18, and 2.19 show the relationship of the FMEA and QFD. Specifically, in Figure 2.17 the QFD is shown as the impetus for planning. Figure 2.18 illustrates the different phases of QFD. In Figure 2.19 the production planning matrix is shown. Using the total points of the operation evaluation as a guide, the team will identify the most appropriate points for an analysis using the FMEA. In this example, a process FMEA should be performed for the part position, die bottoming, and at least the ram cornering pressure. The same principle can be used for a design FMEA.
Chapter Two

Planning tools

Quality improvement tools

Monitoring tools

- Quality function deployment
- Pareto analysis
- Pat
- Failure mode & effects analysis
- Root cause analysis
- Fishbone diagrams
- Taguchi
- Process model
- Statistical process control

Figure 2.17 QFD—the impetus for planning.

Figure 2.18 The four phases of QFD.
## Figure 2.19 The production planning matrix.

<table>
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<tr>
<th>Flow diagram</th>
<th>Process elements</th>
<th>Critical process parameters</th>
<th>Critical process parameter values</th>
<th>Process capability</th>
<th>Operation evaluation</th>
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<th>Operation information</th>
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Brainstorming; Cause-and-Effect Diagram; Kepnor and Tregoe Method

These are techniques that can be used in the FMEA process as a supplement to identify root causes. The Kepnor and Tregoe method is also known as the “is” and “is not” method. An example of this methodology is shown on the CD, Appendix I.

WHO IS RESPONSIBLE AND CONTROLS THE FMEA?

The responsibility for the system FMEA is with the system engineer, who makes sure that the FMEA is up to date and properly distributed. The distribution is a control document and should be treated as such.

Minimum distribution should be to product engineering, design engineering, and quality assurance.

The responsibility for the design FMEA is with the design engineer, who makes sure that the FMEA is up to date and properly distributed. The distribution is a control document and should be treated as such. Minimum distribution should be to design engineering, manufacturing, product engineering, and quality assurance.

The responsibility for the process FMEA is with the system engineer, who makes sure that the FMEA is up to date and properly distributed. The distribution is a control document and should be treated as such. Minimum distribution should be to manufacturing, design engineering, and quality assurance.

The responsibility for the service FMEA is with the department manager for that service, who makes sure that the FMEA is up to date and properly distributed. The distribution is a control document and should be treated as such. Minimum distribution should be to managers of the affected area, supervisors of the affected area, marketing department, and quality assurance.

Special Considerations

The FMEA can and should be used with any problem in any organization. Its simplicity and its forward methodology tends itself to more than just problems for system, design, manufacturing, and service. It can be used by itself or in conjunction with other tools to help identify and/or remove problems in areas such as safety, repair planning, access, effect on downtime, and others.
It is a great disservice for a tool such as the FMEA to be used in a narrow application solely in manufacturing areas. FMEA is widely applicable.

**FMEA and Computer Software**

Although all FMEAs are nothing more than spreadsheets, it is not necessary to have a software package to do an FMEA. On the other hand, an FMEA software application will reduce clerical errors in the data input process and will facilitate the correction and updating of the FMEA. Furthermore, some also facilitate the linkages between several documents. There are several available software packages in the market. The two most commonly used are:

1. Formuser* By Engineered Work Systems, Inc.
2. FMEAPLUS* By Ford Motor Co.

**WARNINGS!!!**

Anyone who is involved in performing a failure mode and effect analysis must be always conscious of the fact that the work may turn out to be “busy work” rather than “value work.” This is so because it is very tempting to choose a path that leads to “analysis paralysis” of the item concerned. A typical example is shown in Figure 2.20. The now famous cartoon drawn in 1972 by J. N. Devin demonstrates in tongue and cheek fashion what can happen if one carries the “what if” game too far.

A second warning in performing an FMEA—at any level—is to be aware of the propensity to stagnate in the name of the following:

1. We have never done it that way.
2. We are not ready for that yet.
3. We are doing all right without it.
4. We tried it once and it did not work.
5. It costs too much.
6. That is not our responsibility.
7. It would not work around here anyway.

*Formuser and FMEAPLUS are registered trademarks of Engineered Work Systems and Ford Motor Co., respectively.*
A third and final warning deals with those individuals who will be doing System (concept), Service and or Attribute FMEA. The warning is in reference to forecasting techniques. Some of the most commonly used forecasting techniques are explained in detail and include examples. Others, those that are relatively sophisticated (and require comparatively extensive formulae), have only been briefly described and mentioned for suitable applications. In case you’re interested in examining any of these techniques in greater detail, see any statistics book or Stamatis (2003, 2003a). First, let’s take a look at the quantitative techniques.

**QUANTITATIVE TECHNIQUES**

There are three major classifications:

1. Time series analysis and projections.
2. Regression analysis
3. Econometrics
All of these techniques use past history as a basis for projections. In this section we are going to give brief explanations of them—but it doesn’t make much sense for one to do those without the aid of a computer. There are a number of packaged personal computer programs which can do the manipulation of the data, in a matter of minutes. Included is a brief description of several programs to consider.

The reason the techniques are explained here is to clarify, for the most part, what type of analysis is being performed by the various software packages.

**Time Series Analysis and Projections**

Essentially, time series analysis and projections are forecasts derived solely by extrapolations of past historical data. The underlying rationale for this method is that past data represent actual causal relationships. And, in some cases, this representation may be valid. Such instances would be where industry change (supplier relationships, products demanded, and so on) is only gradual. But the reliability of the method decreases as change increases.

There are a couple advantages worth considering when doing a time series study. They are:

- Very accurate in projecting future activity if past relationships (for example, demand, competition) follow past trends
- Easy to do and require little time

On the other hand, there are also some limitations. They are:

- Valid only if past relationships remain constant. Forecasts may be in error if there are:
  - New products
  - New competitive moves
  - New governmental restrictions/relaxations
  - Changes in market segment (for example, diminishing number of “members,” members who switch to substitute products)

In general, the forecasts derived from time series analysis and projections are suspect if the products/services are in an industry that is subject to structural changes, for example, discontinuous events. There are a number of techniques in this general category. Five will be discussed here.
Simple Trend Line Extrapolation (Linear): This technique is the easiest of all to use. All that needs to be done, is to plot past activity, establish a trend line, and then project future sales on basis of trend line. Here’s an example:

Suppose activity “a” for the past five years were as follows (in 1,000 units with T=0 being the current year)

<table>
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<th>Year</th>
<th>Activity</th>
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<tr>
<td>T24</td>
<td>95</td>
</tr>
<tr>
<td>T23</td>
<td>90</td>
</tr>
<tr>
<td>T22</td>
<td>95</td>
</tr>
<tr>
<td>T21</td>
<td>105</td>
</tr>
<tr>
<td>T20</td>
<td>110</td>
</tr>
</tbody>
</table>

To develop a trend-line, two basic techniques can be used: graphical and/or mathematical.

Graphical. Plot the activity/data on graph paper. Put unit sales on the vertical axis and years on the horizontal. Next, draw a line which is consistent (visually) with the dots (do not show the actual plot). The projected activity for T+1 are 113 units, or T+5 are 133.

Mathematical (Least Squares). The formula is as follows:

\[ y = a + bx \]

where,

\[ a = \frac{\sum y}{n} - b \left( \frac{\sum x}{n} \right) \]

\[ b = \frac{\sum xy - \frac{\sum x(\sum y)}{n}}{\sum x^2 - \frac{(\sum x)^2}{n}} \]

and \( y = \) activity for a given time period (year, month)

\( x = \) year (with T−4 =1, T−3 = 2…T−0 =5)

\( a = \) intercept on y axis

\( b = \) slope of trend line

\( n = \) number of periods

Using the same activity data (as with the graphic solution),
Therefore the activity data function looks as

\[ Y_i = 85.5 + 4.5x_i \]

Where \( Y_i \) = activity forecast for period \( i \)

Now that we have the relationship function we can forecast the activity for any period. For example: To forecast the activity “\( a \)” for period 6 for \( X \) we get: \( Y_6 = (4.5 \times 6) + 85.5 = 112.50 \). Notice that the mathematical approach is very comparable with the graphical approach. In this case, recall that the graphical approach indicated 113.00. Remember, the mathematical approach is more accurate in interpreting the correct trends. This is why for concept, service, and attribute the time series may be of use to the practitioner—especially when they define the requirements. For period \( T+5 \) (using 10 for \( X \)) the forecast is 130.5, and so on.

Through the use of decomposition analysis, long-term trends, cyclical, and seasonal fluctuations can be detected. These pattern fluctuations can be incorporated into future projections. For example, governmental statistics, such as housing starts, are usually reported adjusted for seasonal variations.

Moving Average: A good technique to use to remove random events that may cause distortions, but only if (1) your time horizon for forecasting is for only several months and (2) your activity(ies) are not subject to trend; seasonal or cyclical patterns during the forecast period.
This method consists of averaging past activities. As the most recent month’s activities figures become available, they are used. This makes the average “move” through time. (A good tool for warranty analysis.)

The moving average can also be used to remove seasonality. Simply choose the same number of results that would comprise a seasonal pattern (for example, if there is an annual seasonal pattern use 12 months’ results). This removes the forecast’s error since results for each period are included in the average. There are two basic methods for forecasting with the moving average approach: unadjusted and weighted.

**Unadjusted Moving Average:** The formula for the forecast of the next period is the summation of previous periods’ activities divided by the number of previous periods taken into consideration.

Therefore, using the same data as used in the trend line examples, the forecast for:

\[
T + 1 = \frac{95 + 90 + 95 + 105 + 110}{5} = 99
\]

This forecast for the next year (99) does not seem realistic, because the moving average ignores the positive upward trend in the activity(ies). This method assumes each year the same weight of 20 percent. Comparing results of unadjusted moving average with the graphical and least square method, we see immediately the disadvantages of the moving average method. If your activities show a trend or if cyclical or seasonal patterns exist, the unadjusted moving average method should not be used.

**Weighted Moving Average:** This technique is better suited when a trend is present. For example, assume that you believe that the more recent periods should receive the greater weight and that the sum of the years’ digits would best represent reality. Of course, this method of adjustment is not the only suitable one. Any method may be used as long as it is consistent with reality. To arrive then at a forecast, first determine the sum of the periods using \(n(n+1)/2\). Now let’s suppose there are five months, \(n = 5\), the sum of the months = 15. Now, proceed as follows:

<table>
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<td>6.7</td>
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<td>2/15</td>
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</tr>
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<td>95</td>
<td>3/15</td>
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<td></td>
<td>96.6</td>
</tr>
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Therefore, the activity forecast for T+1 is the sum of the weighted sales, 96.6. One can see that the weighted average technique does give you more flexibility in determining which periods should receive the greater weight. However, unless a rationale exists for adjusting the weights, and use of moving averages is desired, use the unadjusted method.

**Exponential Smoothing**: This forecasting approach, as with other time series methods, uses past activities to forecast future activities. Exponential smoothing is most useful when frequent forecasts are needed for making for a large number of products/services for short periods of time. Specific advantages of the exponential smoothing approach are:

- Once the model is set up, all that is needed is to carry forward only a very limited amount of data.
- Calculations are quick and simple.
- Trend, seasonal, and cyclical patterns can be incorporated in the model.

The major disadvantage is that setting up the exponential model is rather difficult. However, this job is made considerably easier by using a computer program.

**Regression Analysis**: Regression analysis derives forecasts by determining relationships between activities and those factors which create demand. In simple regression analysis only one factor is used in predicting (variable) activities. Through regression analysis one can determine the weights that will be applied to the past values of a variable. To forecast the variable, apply the appropriate weight. (In the example on trend line extrapolation, the least squares was simple regression analysis: past activity data was used to predict future activities.) In some cases, marketing and product development forecasts require more than a single variable. If a marketing manager wants to forecast next year’s customer’s expectations, he or she would consider not only past industry sales but such independent variables (predictors) as industry promotional expenditures, trends, inflation, and so on.

To set up a regression model, one must experiment with a number of different independent variables which are believed have been significant in predicting activities in the past. This is done through regression analysis. Stepwise regression analysis will give the predictive values of each of the independent variables. The coefficient of determination \( R^2 \) will also give the predictive accuracy of the model. The correlation coefficient can also be used to measure the goodness of fit if there is only one predictor in the
equation. Continuing with the example, through regression analysis the following model was established based on the general model:

\[ Y_t = a + bX_1 + cX_2 + dX_3 + \ldots + e_t, \]

where
- \( Y_t \) = predicted activity in year \( t \)
- \( a \) = intercept (constant)
- \( b, c, d \) are coefficients of independent variables \( X_1, X_2, X_3, \ldots \) etc.
- \( e_t \) = error term or difference between 100 percent explanation and explanation provided by independent variables \( X_1, X_2, X_3 \ldots \) etc.

Now, plugging in the coefficients (found through regression analysis):

\[ Y_t = -16.64 + .756X_1 + .64X_2 + 2X_3 - 20X_4, \]

\( Y_t \) = yearly activity in thousands of dollars for period \( t \)
\( X_1 \) = yearly activity (lagged one year) in thousands of dollars
\( X_2 \) = yearly promotional expenditure (in forecasting year) in thousands of dollars
\( X_3 \) = year (\( T_4=0, T_3=1, T_2=2, T_1=3, T_0=4, T_5=5 \))
\( X_4 \) = expected inflation rate in percentages in forecasting year

This model helped explain 95 percent of the yearly variation in the “\( a \)” activity of company XYZ for the past five years (error term accounts for 5 percent). To use the “\( a \)” activity (say sales, for example) forecasting equation for \( T+1(X_j) \), it would be necessary to insert figures for the four independent variables. Sales of \( T \) (last year sales) should be put in \( X_1 \) (110); promotional expenditure in \( T+1 \) in \( X_2 \), (-20); the numbered year corresponding to \( T+1 \) (-5) in \( X_3 \) and the \( T+1 \) estimated inflation rate in \( X_4 \) (.06). The results are then: Sales forecast \( T+1 = 16.64 + (.756 \times 110) + (.64 \times 10) + (2 \times 5) - (20 \times .06) = 115 \).

To forecast 5 years ahead (sales forecast for \( T+5 \)):

Sales forecast \( T+5 = 16.64 + (.756 \times \text{Sales forecast } T+4 + (.64 \times \text{Planned Promotional expenditure } T+5) + (2 \times 10) - (2.0 \times \text{Expected Inflation Rate } T+5). \) With this equation there are several explanations that need to be addressed. First of all note that \( X_1 \), the yearly sales (lagged one year) is replaced by sales forecast of the previous year (in this case year \( T+4 \)). The reason is simple, since what is being predicted is 5 years ahead (\( T+10 \)), actual sales for the previous year (\( T+4 \)) is not available; therefore sales forecast of previous year (\( T+4 \)) has to be used. It becomes then obvious that in order to determine sales forecast for 5 years ahead (\( T+5 \)), the whole sequence needs to be gone over again. Sales forecasts for \( T+1, T+2, T+3 \) and \( T+4 \) are needed. Second, in order to calculate sales forecast \( T+5 \), it is also mandatory that promotional expenditures for \( T+5 \) are estimated.
Normally this figure will be based on trend in historical data and company policy. Third, the inflation rate for year T+5 will come from your most likely scenario.

Some final comments about the model:

- Activity forecast depends on the independent variables $X_1$, $X_2$, $X_3$, and $X_4$. The value for $X_1$ and $X_2$ can be manipulated (in our hypothetical example of sales, sales forecast figures and promotional expenditures are not fixed). By varying the value of these variables, different sales forecasts will be obtained. This might help in determining the optimal level.

- Sales forecasts for 1, 2, 3, 4, or 5 years ahead can be updated when actual sales data become available. For instance, a forecast for T+5 is now based on the forecast of sales in T+4. As soon as actual sales of T+4 become available (normally at the end of year T+4) this figure may be plugged into the model. In case actual sales T+4 differ from forecasted sales T+4, the T+5 sales forecast will also be different from the original estimate.

Some of the basic advantages and limitations of this technique:

**Advantages**

- The forecast is more than a “rear-view-mirror” approach. What is being forecasted is the value of variables which create a specific activity for the product.

- Regression analysis is extremely useful when lead-lag relationships can be established between the variables—causal factors. This may be introduced through QFD, Kano model, Benchmarking, and so on.

- The variables, and their coefficients, can be varied to determine how sensitive the forecast is to possible errors in the forecasted values and the coefficients of the variables. Since variables must be identified and “quantified,” usually one learns a lot. It forces one to think—concretely—about what creates demand for specific products/services.

**Limitations**

- One still has to rely on past history to determine, quantitatively, variables and their coefficients. In this sense a “rear-view-mirror” approach is still being used.
• Cause and effect must go only one way—from causal factor to the dependent variable. In other words, the dependent variable must not affect the causal factor(s). For example, in some industries the amount spent on advertising and sales promotion is determined by past sales—or on the sales forecast. In such an industry, projected advertising and sales budgets could not be used as independent variables.

• It may be as difficult to forecast the independent variable(s) as the dependent variable. There is the old “saw” of how to determine the exact weight of a pig when you don’t have a scale: Get a beam and suspend it over a fence. Put a basket on each end. Put the pig in one basket and fill the other basket with stones. When the beam balances, guess the weight of the stones. Then you will know the exact weight of the pig.

Typical software packages: There are many software packages that can do all the above techniques. Some examples are MINITAB, SPSS, and SAS.

**QUALITATIVE TECHNIQUES**

All FMEAs are somewhat subjective by definition. However, they do provide a sound outcome of minimizing and sometimes eliminating catastrophic failures or failures that could affect the customer’s satisfaction. Since the overall methodology is a compound product, it stands to reason that some qualitative tools and/or techniques are utilized for optimum results. Five major qualitative techniques are mentioned here:

1. Jury of Executive Opinion
2. Jury of Expert Opinion
3. Sales Force Composite
4. Survey of Buyers’ Intentions (Industrial)
5. Survey of Buyers’ Intentions (Consumers)

In general, these are better suited for forecasting situations where the past is not a good indicator of future sales. However, all of these techniques are often subject to two major types of bias:

1. Law of Overriding Negativism: Negative factors are usually given excessive weights.
2. Law of Current Situations: Projections are unduly influenced by conditions of the present.

**Jury of Executive Opinion**

Jury of executive opinion is getting the forecasts of a number of the firm’s executives. Usually views of executives from diverse functional areas such as sales, purchasing, finance, production, and engineering will be solicited to broaden the judgment base of the forecast. These opinions may be gathered in a number of ways. For example, starting with an extremely informal approach and moving to the more structured procedures: (1) one person soliciting opinions through casual encounters and then consolidating these opinions, (2) a group of executives arriving at a consensus during a meeting, (3) have a group of executives submit forecasts and supporting reasons, then have a committee of executives examine these forecasts and supporting reasons and then arrive at a final forecast.

**Advantages**

- Quick
- Management often extremely knowledgeable
- Management is involved, therefore forecasts more likely to be used
- May be only feasible method
- Good for history-less situations
- Forecasts usually based on current situation

**Limitations**

- Purely subjective
- Management may not be knowledgeable
- “Inbred” thinking most likely to prevail
- Tendency to average different opinions
- May be biased by group effects
Jury of Expert Opinion

Similar to jury of executive opinion, only forecasts are made by one or more well-informed “experts” outside of the company. If several outside experts are used, a jury of executives may decide on a compromise forecast.

Advantages

• Quick (sometimes)
• Inexpensive (sometimes)
• Non biased opinions; avoidance of inbred beliefs and “boss-pleasing” (sometimes)
• A number of viewpoints can be evaluated
• Good for history-less situations

Limitations

• May be purely subjective
• Sometimes expert doesn’t understand specific industry, market segments, and competitive group
• Good opinions and bad opinions may be given equal weight

Sales Force Composite

The sales force composite method relies on the views of salespersons to forecast industry sales. Salespersons estimate sales for their sales areas, these are then combined to get the total forecast of industry sales. (A very strong warning: This generally is not a good way of forecasting. In fact it is very unreliable, especially if the sales force only has the input to product development.)

Here’s an example: A sales manager decided to use forecasts of his ten salespersons to predict future sales. Each salesperson had to come up with 3 figures for (a) each customer and (b) his/her entire geographic territory. These 3 figures for customers and geographic areas consisted of the most likely sales to each customer, sales in the most pessimistic case, and finally, sales in the most optimistic case.

When the sales manager received all the data of his salespersons, he checked their feasibility by comparing them with last year’s sales to each specific customer. He did this also for the aggregate geographic area. In case of any seemingly unreasonable forecasts, he discussed the specific
cases with the responsible salesperson, after which they came up with a mutual agreed upon forecast.

Finally, the sales manager gave probabilities to each case, multiplied each forecast by this probability figure and aggregated them for each sales person. He now had a sales forecast—that is, a goal for each salesperson. By adding all 10 of these sales forecast, the sales manager obtained the total forecast for the year.

Advantages

• Intimate knowledge of customers, uses of product/service, competitors

• Good for history-less situations, likely to pick up changes in technology, new competition and the like

• Results of forecasts can be by product, territory, customer, and salesmen; “ready to use” for quotas and control points

• If forecasts are to be used for quotas, salespersons are more likely to accept the quotas since they have been involved in making the forecasts

Limitations

• Can be either overly optimistic or pessimistic

• May be biased by most influential persons in sales force

• Salespersons may be unaware of general economic trends or of company plans

• Increases paperwork for salespersons

(Its should be mentioned that most companies adjust salespersons’ estimates before using them.)

Survey of Buyer’s Intentions (Industrial)

This method uses representative samples (in cases where the market is small, a census can be taken) of users’ expectations of their future purchases. To facilitate this survey, “syndicated” services and more general published survey results (such as Business Week’s capital expenditure, Conference Board reports, and many others) are available. For example, in order to determine the demand for its product, a firm (ABC) surveyed a representative sample of present and potential users of their particular product. This market segment was asked to indicate expected quantity needed for the
upcoming year and also whether they would buy it from ABC. In order to get a range of expectations, each respondent was asked to give answers on both questions using a probability factor. For example:

<table>
<thead>
<tr>
<th>Customer A</th>
<th>Probabilities</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>25%</td>
</tr>
<tr>
<td>Expected quantity needed (in units) to be purchased from ABC%</td>
<td>10,000</td>
</tr>
</tbody>
</table>

By multiplying the quantity forecasts for each probability category, the firm was able to estimate the expected sales in units per customer. In customer A’s case, this would be:

\[
\frac{[.25 \times 10,000 + .5 \times 20,000 + .75 \times 15,000]}{1.5} = 15,800 \text{ units}
\]

all to be purchased from ABC (as indicated by the % in the 100% column). By aggregating the responses of all participating clients, ABC could figure out its sales for the next year.

Advantages
- Direct contact with the purchaser
- Early recognition of customers’ changes in purchasing intentions and preferences
- Good for short run demand
- Cost of reaching buyers may be minimal if number are few

Limitations
- Buyers may be reluctant to state their purchasing forecasts
- Purchasing forecasts are based on predictions (of general economy, for instance) which may be in error
- Buyers may not plan their purchases
- Buyers may not have firm purchasing intentions
Survey of Buyer’s Intentions (Consumers)

Survey of consumers may be used to determine their anticipated purchases. Basically the same approach as for the industrial survey of buyer’s intention. The only, and substantial, difference lies in the size of the sample pool, and consequently the sampling techniques used. In the case of consumers buyer’s intention, a representative sample has to be taken, a census can not be used. As long as the sample is representative, the forecast will be accurate, assuming that what people say, is what people do.

Basically, the same strengths and weaknesses apply to survey of consumers’ intentions as to survey of buyers’. However, two points need to be emphasized.

1. Concerning convenience goods such as soap, mouthwash and toothpaste, buyers seldom think of their annual use of if they use more than one brand, how they split their purchases.

2. Consumers are better at predicting their purchases of durable products. However, they usually base these factors on future economic conditions—and consumers (like experts!) have not shown much expertise in such forecasts.

REFERENCES


3

The Language of the FMEA

To further clarify the methodology of a FMEA it seems appropriate to direct attention toward its language and the terms commonly found in conducting the FMEA.

**VOCABULARY OF THE FMEA**

Every discipline has its own special language. This section addresses the specific words used in FMEA and their special meaning that the methodology of the FMEA employs to communicate. For a more detailed vocabulary list of FMEA and Reliability see the glossary.

**Function.** The task that the system, design, process, component, subsystem, service must perform. This function is very important in understanding the entire FMEA process. It has to be communicated in a way that is concise, exact, and easy to understand. It cannot be jargon.

To facilitate this, it is recommended that an active verb be found to describe the function. The active verb defines performance, and performance is what a function is (Stamatis 1989, 1991, 1992). Examples of this may be found in the following words:

Lubricate  Position  Retain  Support

On the CD, Appendix C provides an extensive (not exhaustive) list of verbs and nouns used in the function identification.

**Failure.** The problem, concern, error, challenge. The inability of the system, design, process, service, or subsystem to perform based on the design intent. The designed intent usually comes from an analysis and an evaluation of the
needs, wants, or expectations of the customer. The tool for such an analysis is quality function deployment (QFD).

This inability can be defined as both known and potential. As far as the FMEA is concerned, it is especially interesting when potential failures are identified in terms of functional defectives. At this point, the FMEA is fulfilling its intent and mission of prevention.

Stamatis (1993) defines functional defectives as failures that do not meet the customer’s requirements. The customer, however, receives the product and/or service with some failures (errors) anyway because

- The customer will never detect the failure.
- The customer will find out, but has to use it anyway because:
  - There are no other alternatives (short run).
  - It can be used as is.
  - The manufacturer is the single or the sole supplier.
- Based on the application, the product can be used as is with no significant consequences.

Examples of failures are:

<table>
<thead>
<tr>
<th>Broken</th>
<th>Worn</th>
<th>Noise</th>
<th>Rust</th>
</tr>
</thead>
</table>

**Failure Mode.** This is the physical description of the manner in which a failure occurs. Examples of failure modes include the following:

<table>
<thead>
<tr>
<th>Open circuit</th>
<th>Cracked</th>
<th>Warped</th>
<th>Hole missing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leak</td>
<td>Brittle</td>
<td>Blistered</td>
<td>Rough</td>
</tr>
<tr>
<td>Hot surface</td>
<td>Broken</td>
<td>Corroded</td>
<td>Short/long</td>
</tr>
<tr>
<td>Wrong invoice</td>
<td>Dirty</td>
<td>Grounded</td>
<td>Misaligned</td>
</tr>
<tr>
<td>Bent</td>
<td>Eccentric</td>
<td>Discolored</td>
<td>Omitted</td>
</tr>
<tr>
<td>Over/undersize</td>
<td>Melted</td>
<td>Burred</td>
<td>Binding</td>
</tr>
</tbody>
</table>

A failure mode may have more than one level depending on the complexity of the defined function. This level of relationships is shown in Figure 3.1.

**Causes of Failure.** What is the root cause of the listed failure. Next to the function, cause of failure is perhaps the most important section of the FMEA. This is where one points the way toward preventive and/or corrective action. The more focused one is on the root cause, the more successful one will be in eliminating failures. When addressing the issue of cause of a failure, be careful not to be too eager for a solution. A quick solution may result in becoming a victim of symptoms and short-term remedies, rather than complete elimination of the real problem(s).
Examples of causes of failure include the following:

- **System**
  - Item does not work
  - Shorted lead to ground

- **Design**
  - Vibration
  - Shockloads

- **Process**
  - Voltage surge
  - Worn bearings

- **Service**
  - Human error
  - Poor skills

General examples of failures are:

- Handling damage
- Inaccurate ______
- Improper ______
- Inadequate ______
- Incorrect ______
- Human error

Of special interest in identifying the failure or error is the situation of human error. A system, design, process, and service may have a failure due to human error. Human error may be due to carelessness (in other words, not following instructions and/or procedures). In some cases, however, human error may occur when the operator follows strict instructions and procedures in the belief that a safe product or service exists (Bass 1986).
The general rule about human error is that organizations must be cognizant of it and must build the system, design, process, or service fail proof (Bass 1986; Blanchard 1986; Deming 1986; Kececioglu 1991). In conjunction, with this general rule one also must remember that the majority (92 percent) of all variation is system error as opposed to only 8 percent that is due to operators.

The issue of human error in the FMEA is of profound interest because (1) it offers an expedient answer; (2) it blames someone—and that may or may not be the right person; (3) it focuses on symptoms rather than the root cause; and (4) it is used often.

Before an error can be attributed to human error, management must have placed the workers in a state of self-control by ensuring that:

1. They know what is expected of them.
   - Have the operators been given proper training?
   - Are there up to date, easy-to-understand written instructions, procedures, and so on. Are they available at the work station? Are they appropriate for the expected level of understanding?
   - Do the operators receive prompt notice and instructions when there is an official change in the requirements?
   - Do the operators have (now) or will they receive the appropriate training for the task?
   - Do the operators have ownership of the task?
   - Is the empowerment real?
   - Is the supervisor available to help, coach, direct, and counsel the operators when there are question and review requirements from time to time?

2. They know whether or not they are accomplishing what is expected of them.
   - Are the operators provided with a method to measure their performance level?
   - Do the operators know the criteria for good versus unacceptable work? When to correct the process? Do the operators have the right to adjust the process?
   - Does the supervisor provide the operators with feedback on the quality of their work, good or bad?
3. They have a means of regulating their process.

- Has the process been studied to determine if it is stable and capable, or do chance causes of variation still exist?
- Do the operators know what action to take to correct the process? Who to notify?
- Has everything reasonable been done to foolproof the operators?

If management has met all of these criteria, then the means for doing good work with minimum failures clearly is in the hands of the workers. Yet, in cases where these criteria are fully met, errors may occur anyway. Lack of motivation is not the cause. It is a symptom. Specific errors and failures can be identified as a particular root cause and then eliminated.

From an FMEA perspective, human errors do occur and they are appropriate and legitimate. More often than not, however, they are only a cover-up to the real cause and as such they should be used sparingly (Stamatis 1991). Here it must be noted that some industries (automotive, for instance) do not recognize that human error is a cause in the FMEA, just as they do not recognize inspection and training as legitimate and long term ditaction measures and or solutions for corrective actions. More about this in Chapter 14 about the automotive industry.

Yet another important concern in performing a FMEA is not to fall victim of analysis paralysis. It is very easy to do that and the FMEA team must recognize that there are many traps that will detract a “real” problem from a trivial one (see Chapter 2, Figure 2.19). Contrary to what some specialists may think, the FMEA is not always looking for the subatomic and/or molecular root cause, but rather a functional root cause. The distinction is quite great and we all must be cognizant that all “root causes” are definitional root causes rather than true root causes.

**Effects of Failure.** The outcome of the failure on the system, design, process, or service. In essence the effects of the failure have to do with the questions of: What happens when a failure occurs? What is (are) the consequence(s) of that failure? One must understand, however, that the effects of the failure must be addressed from two points of view. The first viewpoint is local, in which the failure is isolated and does not affect anything else. The second viewpoint is global, in which the failure can and does affect other functions and/or components. It has a domino effect. Generally speaking, the failure with a global effect is more serious than one of a local nature.

The effect of the failure also will define the severity of a particular failure. In fact, the effect of the failure has a direct relationship with severity. So, if the effect is serious, the severity will be high.
Examples of effects of failure follow.

Local: Courtesy lightbulb failure

Global: Power steering failure

General examples include the following:

- Noise
- Excessive effort required
- Loss of life
- Unstable
- Intermittent operation
- Unpleasant odor
- Operation impaired
- Poor appearance
- Unstable
- Erratic operation
- Does not work
- Draft

In the case of the courtesy light failure, one may experience a nuisance, in other words, one cannot read the map. Conversely, the power steering failure may prove catastrophic and life threatening, when loss of control occurs.

Process Validation. Controls that exist now, to prevent the cause(s) of the failure from occurring and to validate repeatability for certain processes, especially with FDA. Examples include:

- Validate the process for certain $C_{pk}$
- Validate the process for certain production

Design Verification. Controls that exist to prevent cause(s) of the failure from occurring in the design phase (Chrysler 1986; Ford 1992, 2000; General Motors 1988; AIAG 2001). Examples include:

- Design guidelines
- Design reviews

Current Controls. Controls that exist to prevent the cause(s) of the failure from occurring in the design, process, or service. Some examples are:

- Capability studies
- Design guidelines
- Design review
- Design of experiments
- Foolproof designs
- Function tests
- SQA approval
- Any SPC tool
- Gauge repeatability and reproducibility (R&R) study
- Operator(s) training
- Durability test
- Simulation testing
- Finite element analysis (FEA)
- Tolerance build-up study

**Data.** System installation and checkout procedures, operating and maintenance instructions, inspections, calibration procedures, modifications, drawings, specifications and all performance items related to the system of operation. *

**Facilities.** All special facilities needed for system, and process operation and the performance of maintenance functions at each level. *

**Computer Resources.** All computer equipment and accessories, software and its accessories, and so on, necessary in the performance of carrying out the objective of FMEA. *

**Supply Support.** Includes all team members and consumable items used in conducting the FMEA. *

**Test and Support Equipment.** Includes all tools, monitor, and diagnostic equipment (metrology, calibration, servicing and handling equipment) to support the function of FMEA. *

There are four types of testing associated with an FMEA:

- **Type 1**—Testing done with the intent of verifying performance and physical design characteristics.
- **Type 2**—Prototype testing for the qualification of the system.
- **Type 3**—Formal tests and demonstrations, conducted after initial qualification and prior to completion of production. Usually these tests are performed at a test site by user personnel.
- **Type 4**—Formal tests conducted during the operational phase to gain further insight into a specific area. These tests are performed in a realistic environment.

*Definitions marked with an asterisk are a composite of ASQ; Chrysler; Ford; General Motors; and Omdahl. See references.
In all testing an outcome is expected. That outcome will drive the decision. The decision will be based on a probability. There are two types of decisions.

1. **Producer’s risk (a)**—The probability of rejecting an item when it really should be accepted. This is known as Type I error.

2. **User’s or consumer’s error (β)**—The probability of accepting an item when it really should be rejected. This is known as Type II error.

The relationship of these risks and testing follows.

**Personnel Training.** Personnel required for the installation, checkout, operation, handling, and proper conduct of the FMEA.*

**Maintenance Planning.** Includes all planning and analysis associated with the establishment of requirements for follow-up in the FMEA process.*

**Probability.** Usually stated as a quantitative expression representing a fraction or a percent signifying the number of times that an event occurs (successes), divided by the total number of trials.*

**Reliability.** A simple definition is the probability that a system or product will perform in a satisfactory manner for a given period of time when used under specified operating conditions.*

<table>
<thead>
<tr>
<th>True state</th>
<th>Accept H₀</th>
<th>Reject H₀</th>
</tr>
</thead>
<tbody>
<tr>
<td>H₀ is true</td>
<td>High P</td>
<td>Low P</td>
</tr>
<tr>
<td></td>
<td>1 – α</td>
<td>1 – α</td>
</tr>
<tr>
<td>H₀ is false</td>
<td>Low P Error, β</td>
<td>High P</td>
</tr>
<tr>
<td>Hₐ is true</td>
<td></td>
<td>1 – β</td>
</tr>
</tbody>
</table>

**Maintainability.** The ability of an item to be maintained.*

**Maintenance.** A series of actions to be taken to restore or retain an item in an effective operational state.*

**Supportability.** Relates to the degree to which the system can be supported, both in terms of the inherent characteristics of prime equipment design and the effectiveness of the overall support capability.*

**Availability.** A function of operating time (reliability) and downtime (maintainability).*

**Dependability.** A function of operating time (reliability) and downtime (maintainability).*
Failure Rate. The rate at which failures occur in a specified time interval.*

Corrective Maintenance. The unscheduled actions accomplished, as a result of failure, to restore a system to a specified level of performance.*

Preventive Maintenance. The scheduled actions accomplished to retain a system at a specified level of performance by providing systematic inspection, detection, servicing, condition monitoring, and/or replacement to prevent impending failures.*

Mean Time Between Maintenance. The mean time between all maintenance actions (corrective and preventive).*

Achieved Availability. The probability that a system or equipment, when used under stated conditions in an ideal support environment (in other words, readily available tools, spares, personnel, and so on), will operate satisfactorily at any point in time.*

Operational Availability. The probability that a system or equipment, when used under stated conditions in an actual operational environment, will operate satisfactorily when called upon.*

Functional Analysis. A logical and systematic approach to system design and development. It constitutes the process of translating system operational and support requirements into specific qualitative and quantitative design requirements. This is an iterative process and is accomplished through the development of functional flow block diagrams.*

Sensitivity Analysis. Used when the analyst is not confident about the analysis (due to inadequate data, pushing the state of the art, and so on). At this point a typical question may be: How sensitive are the results of analysis variations to these uncertain parameters? Variation is accomplished by applying different multiple factors to the input parameters being used.*

Contingency Analysis. Involves the investigation of decisions in terms of relevant changes in the initial criteria.*

REFERENCES


To do a complete job with the best results, an FMEA must be written by a team. This is because the FMEA should be a catalyst to stimulate the interchange of ideas between the functions affected (Stamatis 1991). A single engineer or any other single person cannot do it.

The team should be made of five to nine people (preferably five). All team members must have some knowledge of group behavior, the task at hand, the problem to be discussed, and direct or indirect ownership of the problem. Above all, they must be willing to contribute. Team members must be cross-functional and multidisciplined. Furthermore, whenever possible and/or needed, the customer and/or the supplier should participate—not as a regular team member, but as an ad hoc member.

This chapter covers the basic aspects of teams and how the outcome of the team affects the FMEA. The information in this chapter does not represent the exhaustive knowledge of teams, but does include the issues that concern the FMEA.

**WHAT IS A TEAM?**

A team is a group of individuals who are committed to achieving common organizational objectives; who meet regularly to identify and solve problems, and improve process; who work and interact openly and effectively together; and who produce desired economic and motivational results for the organization. Figure 4.1 shows this relationship.
The factors that influence the performance and productivity of the team are:

- The organization as a whole (culture)
  - Philosophy
  - Rewards
  - Expectations
  - Norms

- The team itself
  - Meeting management
  - Roles and responsibility
  - Conflict management
  - Operating procedures
  - Mission statement

- Individual team members
  - Self-awareness
  - Appreciation of individual differences
  - Empathy
  - Caring

**Figure 4.1** Teams and great expectations.
WHY USE A TEAM?

The theory that encourages the team formation as opposed to the individual is **synergy**. Synergy is defined as the sum of the total is greater than the sum of the individuals. Another way of saying the same thing is two heads working together, are better than two heads working individually. From an FMEA perspective the team is the foundation of improvement. The team defines the issue(s) and problem(s) in the specific assigned task environment, identifies and proposes ideas, provides/recommends the appropriate analysis and/or technique, and provides a decision based on consensus. Generally speaking the team is formed to address concerns about:

- **Work**
  - Task complexity
  - Productivity and quality advantages
  - Work system stability
- **People**
  - Rising expectations
  - Affiliation needs
  - Increased cognitive ability
  - Specific concerns (time related)
  - Direction of the future
  - Survival in a global market

All teams regardless of application must be familiar with the problem-solving process, which includes:

- Statement of the problem
- Root cause analysis
• Solution based on fact(s)
• Implementation
• Evaluation

and must have a clear charter issued by management to:

• Define the task
• Have accountability and responsibility
• Define the boundaries
• Define and communicate the barriers
• Have the authority to request support

To paraphrase Allmendinger (1990): For the team to harness the collective intelligence (synergy) for the benefit of the team and the organization, the following must take place:

• **Relevancy**—The information gathered by the team should be of value.
• **Reliability**—The process by which the information is collected should be consistent, isolated as much as possible from changes in organization, personnel, and so on.
• **Accuracy**—The data should be expressed in a manner that most accurately reflects its information content; in other words accuracy should not be confused with precision.
• **Efficiency**—The design and implementation of the tasks should minimize the burden imposed by the data collection process.

### ABOUT CONSENSUS

Consensus is a collective decision reached through active participation by all members, to which every member is committed (in other words has personal ownership). It requires all members to express a viewpoint, to actively listen, and to differ constructively. Consensus does not mean 100 percent agreement (although it may be), but a decision about which all members of the team can honestly say, “I am not totally sold on it, but... ; I am not 100 percent sure, but... ; I do not agree with it completely, but... ; I can support it, I can live with it.”
In a team environment, discussion continues until the team reaches a decision that every member accepts and will implement even though some may have reservations. Ideally, the team capitalizes on diversity among members to reach a better decision than they could produce independently. Consensus decision making takes time, and like any other skill, requires practice for one to become proficient.

A classic example of true consensus can be seen in the movie *12 Angry Men*. In this movie, one juror (Henry Fonda) holds one opinion which is opposite to the opinions of the other 11. (It is interesting to note that Fonda thought that a guilty verdict was appropriate. His desire to discuss the case from a different perspective, however, made the case quite interesting and appropriate in the discussion of team consensus.) By the end of the movie, all 12 jurors have changed their minds based on probable doubt. There are still unanswered questions about the case, but they all agreed (in the end) that the overwhelming evidence left a doubt—therefore an innocent verdict. For the team to reach consensus, the following four things must take place:

1. Process must be defined as 100 percent participation.
2. Members must actively participate, listen, and voice their disagreement in a constructive manner.
3. The requirement is not 100 percent agreement, but 100 percent commitment.
4. Majority does not rule. Minority sometimes has the correct, right decision. Sometimes a single individual may be on the right track, with everyone else being wrong.

To reach consensus, the team members must be willing to:

- Be open to influence, ideas
- Contribute, not defend
- Actively listen to other points of view
- Find out the reasons for others’ positions
- Avoid averaging the differences
- Confront the differences—politely
- Stand up for one’s thoughts and opinions
To recognize consensus, the team and its members must answer yes to the following four questions:

1. Have I honestly listened?
2. Have I been heard and understood?
3. Will I support the decision?
4. Will I say “We decided,” as opposed to “My idea went through,” or “I decided,” or “I told them and they followed my recommendation”?

TEAM PROCESS CHECK

For the team to be effective and productive, an occasional process check may be appropriate (Stamatis 1991). This is very important, especially for the most complex problems that the team may face. Some of the items that a process check may review are:

- Purpose of meeting not clear
- Meeting was held just to “rubber stamp”
- Repeat of old information
- Too boring; trivial matters discussed
- The leader lectures the team
- Team members not prepared
- Vague assignments
- No summary
- No time or willingness to deal with the unexpected

When the team continues to meet without a process check, errors occur. Some of the most common errors are:

- Errors caused by misunderstandings
- Discovery of the need to capture additional information
- Incomplete data because form is too difficult to complete
- Incomplete or biased data caused by fear
- Failure to use existing data

All of these errors may be prevented through testing, training, and auditing.
HANDLING OF DIFFICULT INDIVIDUALS

The idea of forming a team is to help everyone learn from everyone’s experience and knowledge. To do this, all members should participate. In certain areas, however, that does not happen because some individuals either participate at the expense of others or they do not participate at all. These individuals are called problem individuals, and they fall into three general classifications (Jones 1980; Stamatis 1987, 1992).

**The Individual Who Talks Too Much.** If the discussion turns into a dialogue between the leader and an overtalkative individual, the others will lose interest. Whether or not that individual has something of value to say, the team leader will not want to let the situation be monopolized by the talkative one. Tactful approaches must be used to divert the discussion to others. If the leader knows that someone on the team likes to dominate, the leader should pose questions to the group without looking at that specific individual, or ignore the response that the talkative person gives.

A facilitator and/or the leader of the FMEA team should want to allow everyone to participate. In this participation, however, the leader may find that somebody dominates the discussion because he or she had more experiences to draw from or an educational background that is more extensive. On those occasions, the individual should be used as a resource and a coach for the other team members. On the CD, Appendix I identifies some basic approaches for the leader to use to bring out active participation.

Another situation where a talkative person may interfere is the person who wants to make an impression. This is the individual who is looking to satisfy his or her own ego. The only way to handle such an individual is to let him or her know in advance that the group disapproves of such behavior and/or through team pressure at the time of the incident.

Yet another situation where a talkative person may interfere is the person who takes a long time to express his or her ideas. This is perhaps one of the most sensitive areas of interference because the person participates as expected but simultaneously annoys the rest of the team. The leader must handle this situation in a delicate manner because if he or she says or does the wrong thing, the participant will lose self-confidence and ultimately will withdraw. Usually it is better to tolerate a certain amount of this difficult behavior, rather than discourage the individual too much.

Finally, a situation where a talkative person may interfere is when that person starts a private conversation with the neighbor(s). One can eliminate this problem by asking a direct question to those who are involved or make the team large enough to allow generation of a variety of ideas and small enough to sustain small cliques. Such a team usually consists of five to nine persons with five being the most common.
Members Who Talk Too Little. Members may not want to be there, feel out of place, or not understand the problem at hand. For this type of person, it is the responsibility of the leader and/or the team facilitator to actively draw this individual into the discussion. This can be done through direct questions about the subject at hand and/or motivational statements outside the team environment such as: “We need your input,” and “We value your contribution,” or “You were hand picked because of your experience and knowledge,” and so forth.

Members Who Say the Wrong Things. This problem is common in a team environment (especially in the early stages of team development) where individuals have their own agenda. They talk about all things except what is on the agenda. In this situation, it is the responsibility of the leader to point out the official agenda and/or outline. On rare occasions the leader may want to bring in the whole team by asking, “Do we agree that this point should be taken up right now?”

PROBLEM SOLVING

This text will not discuss the methods and tools available in the problem-solving phase of the team. The focus is to help to understand the mechanics and rationale for pursuing problem-solving methods to eliminate and/or reduce problems, concerns, and so on. Some examples of specific tools and their application are found in Chapter 18. Detailed descriptions of tools may be found in basic SPC books, statistical literature, and organizational development sources. For a good review of the process the reader may want to see Stamatis (2002, 2003).

For most people, the mere presence or prediction of a problem indicates a need for a change in behavior. When an individual or group is actually or potentially in trouble, a unique set of strategies is required. Such strategies usually involve at least a temporary change in behavior—a new course of action. In the absence of a deliberate strategy for deciding on a new course of action, one’s revised behaviors may make the situation worse.

Usually problems are not clear to the individuals who have them. It is difficult to isolate the problem and its related components. Even if this is possible, the selection and implementation of a solution involves degrees of physical or psychological risk. Familiar patterns of behavior are safe. In a problem situation, a person is torn between the need to change and the desire to maintain the old patterns. This conflict results in strong emotions and anxieties, which impose on the cognitive processes that are required to make workable decisions. If the problem is sufficiently severe, cognitive paralysis may result (Pfeiffer 1991).
People and groups who are in trouble need useful tools for understanding the nature of their problem situations, for making decisions about their courses of action, and for managing the new directions once they are chosen. The contents of a generic model of problem identification and problem solving are:

Stage 1. Identify
- Identify the problem

Stage 2. Scope
- Gather the facts
- Organize the data

Stage 3. Define
- Define the problem

Stage 4. Analyze
- Analyze the problem
- List the alternative solutions
- Select a feasible solution

Stage 5. Implement
- Implement the solution

Stage 6. Evaluate
- Evaluate the solution

Stage 7. Follow-up
- Monitor the solution

Stage 8. Improve
- Continually improve

These steps in problem solving represent a category of techniques presented over the years under different names by many people. Some of the specific tools for each stage may be found in Chapter 18. Many of the tools ignore the drives, emotions, needs, preferences, values, and conflicts that are attendant to most human problems. Furthermore, they are of little use in attacking the type of problem that people frequently refer to as intangible. The techniques may be useful for evaluating alternative business plans or buying a new washing machine, but they offer little help in interpersonal problems. Therefore, this book has presented items in this section that incorporate some human issues into the problem-solving process.
PLANNING THE MEETING

Before the team activates itself for the project, some preliminary steps must take place. The first order of business is to plan the meeting. Bradford (1976), Nicoll (1981), Schindler-Rainman, Lippit, and Cole (1988), and Stamatis (1991) have identified the following items of concern:

1. *People*—All meetings involve people. Meeting participants may differ in values, attitude, experience, sex, age, and education. All these differences, however, must be accounted for in the planning of the meeting.

2. *Purpose*—All meetings have reasons for existing. The purpose, objective, and the goal of the meeting must be understood by all, both management and participants.

3. *Atmosphere or climate*—The atmosphere contributes to the effectiveness of the meeting. It is imperative that whoever plans the meeting takes into consideration the climate and atmosphere.

4. *Place and space*—All meetings are held in a space and a place. Therefore, planners must consider the following:
   - Access to the space, available parking
   - Size of the space
   - Acoustics, lighting, temperature control
   - Cost
   - Equipment needed

5. *Costs*—Cost of FMEA is of paramount importance since it has been established that the preparation time of the FMEA is lengthy. In addition, consideration should be given to the fact that often the system, design, process, or service personnel assigned to do the FMEA may be in different places, miles apart.

6. *Time dimensions*—How long will this take? Is an alternate schedule available? Can the participants be spared for this task? Without evaluating time constraints and recognizing that the meeting may be prolonged for unexpected reason, the agenda items and objectives may suffer.

7. *Prework and after the official meeting work*—All the work that the meeting produces is directly related to the amount of planning that goes into the meeting. For the lengthy and complex tasks, it occasionally is required that major portions of the work be done
outside of the meeting and only reviewed by the participants in the meeting.

8. Plans, program, and agenda—All meetings have an agenda. Without an agenda there cannot be a meeting. A detailed, planned program or agenda, which can be shared (no surprises) by all participants, is a valuable addition to a meeting. When planning the agenda, make sure all the objectives of the meeting are covered.

9. Beginning, middle, and end—All meetings, regardless of duration and significance, have a beginning, middle, and an end. Proper planning is essential. Without it, failure to focus on the agenda will cause an unproductive gathering and failure to meet the objectives.

10. Follow-up—After the meeting has ended, there is a need for some follow-up in the areas of:
   - Implementing action items
   - Communicating information to all appropriate personnel
   - Publishing minutes
   - Writing report

IN-PROCESS MEETING MANAGEMENT

In addition to more detailed meeting planning, managers are finding it necessary to pay more attention to the management of meeting participants. Every organization has a hierarchy; part is overt (job titles, designation of managers and subordinates, and so on), and part is unspoken. Within each group of people there tends to be a pecking order, even if the people technically are colleagues on the same rung of the hierarchical ladder. Some members act domineering: they are talkative, they tend to interrupt others, and so on. Less-aggressive members may not feel comfortable challenging the dominant member(s) and may remain silent for the duration of the meeting. This results in uneven participation, which often produces side effects such as boredom and stilted lines of communication.

Mosvick and Nelson (1987) identify 11 steps for ensuring effective decision making in meetings. These items also are good tips for effective meeting management:

1. Spend enough time stating and restating the initial question until everyone agrees on the problem or issue to be discussed.
2. Solicit participants’ honest opinions at the outset of the meeting.

3. Think of opinions as hypotheses; test them instead of arguing over them.

4. Plan a method of testing opinions against reality, considering the issue and the goal.

5. Establish a rule that additional information given during the meeting must be relevant to the agreed-upon topic.

6. Encourage disagreement and differences of opinions.

7. Do not judge others’ opinions hastily. Learn to appreciate the diversity of others’ point of view.

8. Encourage meeting members’ commitment to resolving the issue whenever possible.

9. Compromise as needed.

10. Ask whether a decision is necessary. Remember that choosing to do nothing is a legitimate choice.

11. Construct a process for feedback to determine whether the decision was successful.

**AVOIDING COMMON MEETING PITFALLS**

The following are some dysfunctional patterns and behaviors that commonly are found in meetings (Bradford 1976):

- Vying for power, often by challenging the leader or by wooing a group of supporters, thus dividing the group
- Joking and clowning excessively, which not only is a distraction but also may disguise hostility
- Failing to agree on the issue or problem
- Arguing about others’ opinions or suggestions, which stifles the brainstorming process and can cause embarrassment or discomfort
- Wandering off the topic at hand
- Forcing meeting members to answer to the chairperson (usually someone who is higher on the organizational ladder than they are)
Awareness of these traps can help the meeting facilitator avoid them. Constructive, rather than punitive, confrontation is an effective technique for dealing with many disruptive and dysfunctional meeting behaviors. A meeting leader who chooses to confront must be sure to discuss the behaviors, not the person. More desirable behaviors should be suggested in a direct but caring way.

Jones (1980) suggests two approaches to dealing with disruptive meeting participants. The first approach requires the meeting leader to communicate directly with the disruptive person. Some examples follow:

- Turn a dominating person’s question into statements, thus forcing the person to take responsibility for his or her opinion.
- Refuse to engage in a debate. Point out that debates have winners and losers; therefore, the desired win-win outcome is impossible.
- Suggest that the meeting leader and the disruptive person swap roles. This gives the person a sense of what he or she is doing to the group.
- Use active-listening techniques to mirror the person’s feelings. For example, “You seem particularly upset today, especially when I disagree with you.”
- Agree with the person’s need to be heard and supported.

The second approach that Jones suggests to deal with disruptive meeting members uses the other meeting participants as allies against the disruptive person. Some examples follow:

- Ask the participants to establish norms that will discourage “You’re wrong, I’m right” thinking.
- Post all participants’ input anonymously on flip charts. This makes information available to all and lessens repetition.
- Break the participants into small groups. This immediately limits a dominating person’s sphere of influence. Give the groups a task that requires them to reach consensus.

**UTILIZING THE MEETING-MANAGEMENT GUIDELINES**

Meeting leaders may find that the use of small groups can help prevent the participants from falling into the common meeting traps. When people break into small groups to discuss an issue, less-assertive persons often become more
willing to participate. A small group is not as likely to wander off the subject as a large group. Because fewer people are competing for attention in a small group, members feel a stronger sense of commitment. Finally, small groups can diffuse aggressive members’ tendency to dominate the conversation.

Meeting leaders will find that their meetings will become more interesting, lively, and balanced as they follow the guidelines that have been presented in this section. The core points to remember are that all meeting participants must be treated equally; honesty must be the norm; and all opinions must be respected (Stamatis 1992).

REFERENCES


This chapter discusses, in detail, the concept and method of constructing an FMEA for the system.

A system FMEA (sometimes called a concept FMEA) usually is accomplished through a series of steps to include conceptual design, detail design and development, and test and evaluation. A typical flow of this development was shown in Chapter 2, Figure 2.3. The design in this phase is an evolutionary process involving the application of various technologies and methods to produce an effective system output. This result will be used as an input for the design FMEA which in turn becomes an input for the process/assembly, part, and/or the service FMEA. This is illustrated in Figures 5.1, 5.2, and 5.3.

The selection of appropriate technologies may include the utilization of existing system(s), standardized approaches currently known or proposed, results of directed research, or a combination of all of these.

Effective system FMEA is basically realized through the system engineering process, product development, research and development (R&D), or a combination of all these entities (Blanchard 1986). The focus, in this stage, is to:

1. Transform an operational need into a description of system performance parameters and as perfect as possible system configuration through the use of an interactive process of functional analysis, synthesis, optimization, definition, design, test, and evaluation.

2. Integrate related technical parameters and assure compatibility of all physical, functional, and program interfaces in a manner that optimizes the total system definition and design.
3. Integrate reliability, maintainability, engineering support, human factors, safety, security, structural integrity, producibility, and other related specialties into the total engineering effort.

The goal of the system FMEA is to define and demonstrate a proper balance among operational (in other words, effectiveness and performance) and economic factors. To accomplish the objective, the system FMEA must base its requirements on solid needs, wants, and expectations of the customer. As a general rule that information may be the result of a quality function deployment (QFD) (preferred) or an internal need for improvement. In either case, one of the first steps in conducting the FMEA should be to include a feasibility study directed toward defining a set of

Note: The failure modes of the system FMEA generate all the essential information for the design and process FMEA. Although the effect stays the same, the causes in the system FMEA become the failure modes in the design, which in turn generate their own causes, which ultimately become the failure modes in the process FMEA. It is imperative that the failure modes in the manufacturing (process) should not be listed in the design FMEA.

Figure 5.1 Relationship of system, design, and process FMEA.
useful solutions to the problem being addressed. The objective of this early (not a definitive) stage is to identify, establish, and evaluate alternative technical approaches and a functional baseline.

The outcome of the system FMEA is a preliminary design (often called advance development stage) with a baseline configuration and functional specifications toward translating the established requirements into detailed qualitative and quantitative design and process characteristics. Some of the generic concerns in a system FMEA may be the following.

**General Concerns**

- System operational requirements defined
- Effectiveness factors established
- System maintenance concept defined

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### System FMEA

<table>
<thead>
<tr>
<th>Failure mode</th>
<th>Effect</th>
<th>Cause</th>
</tr>
</thead>
<tbody>
<tr>
<td>The problem</td>
<td>The ramifications of the problem</td>
<td>The cause(s) of the problem</td>
</tr>
</tbody>
</table>

### Assembly FMEA

<table>
<thead>
<tr>
<th>Failure mode</th>
<th>Effect</th>
<th>Cause</th>
</tr>
</thead>
<tbody>
<tr>
<td>The causes of the problem from the system FMEA</td>
<td>The effect from the system FMEA with perhaps a better definition</td>
<td>New root causes for the assembly failure modes</td>
</tr>
</tbody>
</table>

### Part FMEA

<table>
<thead>
<tr>
<th>Failure mode</th>
<th>Effect</th>
<th>Cause</th>
</tr>
</thead>
<tbody>
<tr>
<td>The causes of the problem from the assembly FMEA</td>
<td>The same effect as the assembly FMEA</td>
<td>Specific root causes for the assembly failure modes</td>
</tr>
</tbody>
</table>

**Note:** The failure modes of the system FMEA generate all the essential information for the assembly and part FMEA. Although the effect stays the same, the causes in the system FMEA become the failure modes in the assembly, which in turn generate their own causes, which ultimately become the failure modes in the part FMEA.

**Figure 5.2** Relationship of system, assembly, and part FMEA.
Support Elements

In this area one must do a thorough investigation as to whether or not the requirements are known and/or can be optimized for:

- Test and support equipment
- Personnel and training
- Repair and spare parts
Design Features

- Standardization
- Accessibility
- Technical data
- Transportability
- Reliability
- Test provisions
- Controls
- Procedures
- Producibility
- Software
- Interchangeability
- Functional analysis
- Connectors
- Safety

STEP-BY-STEP SYSTEM FMEA ANALYSIS

There are two requirements to complete a system FMEA. The first requirement is identification of the appropriate form; the second is identification of the rating guidelines.

The form for the system FMEA is not universal. It is not standardized. Each company has its own form that reflects the needs of the organization and concerns of the customer. In the automotive industry, however, efforts have been successful and as of July 1, 1993 there is a standardized form and approach published by the Automotive Industry Action Group (AIAG). (See CD, Appendix E, Figure E.10.)

This section addresses a form to show the generally accepted items that should be addressed as part of a system FMEA. Appendix E includes additional system FMEAs which show the diversity that exists between industries. Remember, there is no such thing as the system FMEA form.

Rating guidelines also are not universal or standardized. Each company has its own guidelines that reflect the needs of the organization, the product, and the concerns of the customer.

Generally, there are two ways that the rating guidelines can be formulated—qualitative and quantitative. In either case, the numerical values can be from 1 to 5 or 1 to 10, with the 1 to 10 range being the most common. Again, there is no such thing as the rating guideline for the system FMEA.

Figure 5.4 shows the most common system FMEA form. The form is divided into three parts. The first part, items 1 through 9, reflect the introduction of the form. None of the items are mandatory; however, they do add
information to the system FMEA and provide essential information that may be needed in the course of writing the FMEA.

The second part of the form consists of items 10 through 23. They reflect the mandatory items for any system FMEA. The order of the columns may be changed, more columns may be added, but none of the columns presented may be removed. Items 10 through 23 may be viewed as the body of the system FMEA.

The third part of the form includes items 24 and 25. Although they are not mandatory, they do reflect the authority and responsibility of the team to undertake the project of writing the system FMEA. The signatures may be viewed as the closure of the FMEA. All numbers in parentheses are coded numbers for the discussion of the form.

**System Identification (1).** Identify the system name or the identification title of the FMEA.

**System Responsibility (2).** Name the responsible organization, division, or department that has responsibility for the system design.

**Person Responsibility (2A).** Sometimes it is necessary to name the person who is responsible for the system design.

**Involvement of Other Areas (3).** Name other people or activities (within the organization) that affect the design of the system.

**Involvement of Suppliers or Others (4).** Name other people, suppliers, and/or plants (outside the organization) that affect the design of the system, and are involved either in the design, manufacturing or assembly, or service of the system.

**Model or Product (5).** Name the model and/or the product using the system.

**Engineering Release Date (6).** Identify the date (Mo-Day-Yr) that the system design specification is scheduled to be released.

**Prepared by (7).** Generally, the name of the system design engineer responsible for the FMEA is identified. Sometimes, additional information also is recorded, such as:

- Telephone number of the system design engineer
- Address of the system design engineer
- Organizational activity (in other words, division, department, and so on)
- Team members (name, telephone, address, and so on)
**Figure 5.4**  A form for system FMEA.
FMEA Date—Original (8). Record the date (Mo-Day-Yr) of the initiation of the system FMEA.

FMEA Date—Revision (9). Record the date (Mo-Day-Yr) of the latest revision.

System Function (10). The engineer writes the design intent, purpose, goal, or objective of the system. The system function must be derived from customer needs, wants, and expectations. Typically, these include safety requirements, government regulations, and other constraints identified as either internal or external to the organization.

Generally, these needs, wants, and expectations are defined through a QFD and include several other considerations. Some of these considerations are the result of courts through product liability issues, warranty concerns, industrial standards, and/or very specific customer requisitions.

For the system function to be effective, it must be identified in detail with a statement that is (1) concise, (2) exact, and (3) easy to understand (no jargon). It may also be identified through a functional block diagram, which will show the system elements (components) as functional blocks into which the system may be decomposed. (Figure 2.13 is such an example; see Chapter 2.) It is important to note that the objective of the functional block diagram is to show the major elements of the system and to understand how the interaction of those elements affects the system itself or the other system(s) outside itself.

If a statement is used to describe the function, that function should be described in very specific terms. To facilitate this, the writer of the FMEA should try to think of active verbs and appropriate nouns. The active verbs define performance, and performance defines function. The combination of the active verb with the noun defines the relationship; consequently, the identification process becomes much easier. Examples include:

- Incorrect logic code
- Corrupted data
- Inappropriate algorithm
- Control speed

Potential Failure Mode (11). The problem. The concern. The opportunity to improve. The failure. When one thinks of the potential failure mode one must think of the loss of a system function—a specific failure. The more specific the team is, the better opportunity it will have to identify the effects and causes of the failure.
For each system function identified in column 10 of the form, one must list the corresponding failure of the function. There can be more than one failure from one function. To help in the identification of the potential failure mode one may think of the negative or loss of the function. Examples include:

- Fails to open
- Coil fails to produce EMF
- Fails to provide adequate power
- Fails to operate
- Fails to close
- Cannot control speed

**Potential Effect(s) of Failure (12).** A potential effect of the failure is the consequence of a system failure mode. The question usually asked is: “What happens or what is (are) the ramification(s) of this problem or failure?” The consequences may be to the system itself, the product, the customer, and/or government regulations. Often the failure effect is evaluated from a customer’s perspective or experiences.

To identify the potential effects, some of the documents one may review are:

- Warranty documents
- Customer complaints
- Field service data
- Reliability data
- Feasibility studies

No matter how the potential effect(s) is (are) identified the ramifications of the loss to the system function must be determined. Consideration must be given to the system itself, other systems, the product, and the customer. If safety considerations may be an issue, this is the column where the appropriate notation should be made. Examples of potential effect of failure may be:

- Next higher system: fails to operate circuit relay
- Next lower system: none
- Other system(s): none
- Product: motor overheats
• Customer: complete dissatisfaction; system fails to operate
• Government: may not comply with STD-XXX

Critical Characteristics (13). Critical characteristics usually are not associated with system FMEAs because that hardware has not yet been defined in this early stage. Until hardware is defined, critical and/or significant characteristics cannot be identified (Slone 1986). The place where the identification of critical characteristics is made is in the design FMEA where the characteristics are used only to designate special controls for the process, assembly, and/or service FMEA. From here they are transferred to the control plan.

Severity of Effect (14). Severity is a rating indicating the seriousness of the effect of the potential system failure mode. The severity always applies to the effect of a failure mode. In fact, there is a direct correlation between effect and severity. For example, if the effect is critical, the severity is high. On the other hand, if the effect is not critical, the severity is very low.

The severity is reviewed from the perspective of the system itself, other systems, the product, the customer, and/or the government regulations. For evaluation purposes there usually is a rating table that reflects the issues of the organization in conjunction with the customer and/or the government regulations. An example of such rating may be seen in Table 5.1.

In the system FMEA the severity rating should be based on the worst effect of the failure mode. After this is done, rank the failure modes on the basis of the severity of their effects. At this point the FMFA is identical to the FMCA.

Potential Cause(s) of Failure (15). The cause of a system failure mode is the system design deficiency that results in the failure mode. There are two ways failures may be examined:

1. As they relate to specific failures
2. As they relate to the reliability bathtub curve, in terms of early, chance, and wear-out failure causes

Examples of these two conditions are:
• Early failure causes: Insufficient burning in; insufficient debugging; substandard parts; human error; improper installation; and so on.
• Chance failures: Misapplication; abuse; act of God; insufficient design; and so on.
• Wear-out failures: Corrosion; aging; wear; fatigue; short life design; creep; and so on.

Illustrations of these failure modes are in Figures 5.5, 5.6, and 5.7.
### Table 5.1  Severity guideline for system FMEA* (1–10 qualitative scale).

<table>
<thead>
<tr>
<th>Effect</th>
<th>Rank</th>
<th>Criteria</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>1</td>
<td>No effect.</td>
<td>If the numerical value falls between two numbers, always select the higher number.</td>
</tr>
<tr>
<td>Very slight</td>
<td>2</td>
<td>Customer not annoyed. Very slight effect on product or system performance.</td>
<td>If the team has a disagreement in the ranking value, the following may help.</td>
</tr>
<tr>
<td>Slight</td>
<td>3</td>
<td>Customer slightly annoyed. Slight effect on product or system performance.</td>
<td>1. If the disagreement is an adjacent category, average out the difference. For example, if one member says 5 and someone else says 6, the ranking in this case should be 6 (5 and 6 are adjacent categories. Therefore $5 + 6 = 11, 11/2 = 5.5$).</td>
</tr>
<tr>
<td>Minor</td>
<td>4</td>
<td>Customer experiences minor nuisance. Minor effect on product or system performance.</td>
<td>2. If the disagreement jumps one category, then consensus must be reached. Even with one person holding out total consensus must be reached. No average, no majority. Everyone in that team must have ownership of the ranking. They may not agree 100 percent, but they can live with it.</td>
</tr>
<tr>
<td>Moderate</td>
<td>5</td>
<td>Customer experiences some dissatisfaction. Moderate effect on product or system performance.</td>
<td></td>
</tr>
<tr>
<td>Serious</td>
<td>9</td>
<td>Potential hazardous effect. Able to stop product without mishap—time dependent failure. Compliance with government regulation is in jeopardy.</td>
<td></td>
</tr>
</tbody>
</table>

*All of the above guidelines and rankings may be changed to reflect specific situations.*
It must be emphasized repeatedly that when one focuses on the cause(s) one must look at the root cause, not the symptom of the failure. Obviously, some logic and knowledge about the system will guide the prioritization and where to draw the line between real causes and trivial causes.

To do a good job of proper potential cause(s) of failure identification, one must understand the system and ask the appropriate questions. Some of the techniques that may be used are brainstorming, cause-and-effect analysis, analysis of the block diagram, and affinity charts.

The basic question to ask is “In what way can this system fail to perform its intended function?” Another method is to ask five whys in a row. The rationale for this is that it becomes a progressively more difficult and thought-provoking assignment to identify the whys. The first questions are superficial, but the later ones are more substantive.

A failure mode can be caused by one or more individual components or by:

- Interaction with other components
- Interaction with components of other systems

![Figure 5.5](image-url)  
*Figure 5.5* Reliability bathtub curve.
Interaction with the government

Interaction with the customer

At this point, it must be emphasized that a major benefit of the system FMEA is identification of potential system failure modes caused by system and/or component interactions. These interactions also may involve human factors and as such they must be reviewed thoroughly.

Figure 5.6  Cases of no-failure performance.
Reprinted by permission of Prentice Hall, Englewood Cliffs, N.J.
The relationship between the failure mode and the cause(s) is not linear or one-to-one. Do not be surprised if there are several if not many causes for one failure mode. (Sometimes a one-to-one relationship exists.) List as many causes as possible—all of them. These causes will be transferred to the design FMEA as potential failure modes (see Figure 5.1). The more causes identified in the system FMEA, the easier the design FMEA becomes.

Examples of causes of failures are:

- Intermittent operation
- Software errors
- Failure to stop
- Degradation of output
- Failure to start

In the system FMEA the failure causes sometimes are not that obvious. In fact, there are at least three conditions that one should examine:

1. The specific cause is unknown, but it does exist. In this case, there are two outcomes:
   a. The failure mode is detected, in which case the detection mechanism is adequate. What is necessary, however, is that a design action is required to remove the cause, or further analysis is needed to precisely identify the cause.
b. The failure mode is not detected, in which case the detection mechanism is not working. As part of the system FMEA, recommendations should be to increase sample quantity or develop a new test/technique for detection.

2. A specific cause exists, but cannot be detected. In this case there are two outcomes:
   a. The verification/detection technique is capable, in which case the sample may be too low and it should be increased.
   b. The verification/detection technique is not capable, in which case development of a new or a modification of the verification/detection test or technique is needed. The new or modified test/technique should be more sensitive than the existing technique for detecting the specific cause.

3. A specific cause exists and can be detected. In this case there are two outcomes:
   a. Cause is detected, in which case further analysis and/or testing is required to determine the appropriate action to remove the root cause failure.
   b. Cause is not detected, in which case a design problem may exist or insufficient tests are performed. In this case, DOE and/or a review of existing testing is highly recommended.

**Occurrence (16).** Occurrence is the rating value corresponding to the estimated number (sometimes cumulative number) of failures that could occur for a given cause over the design life of the system. To identify the frequency for each of the causes, one may use reliability mathematics that are beyond the scope of this book, use expected frequencies, or more simply use a cumulative number of component failures (CNF) per 100 or 1000 components (CNF/100 or CNF/1000, respectively) over the design life of the component under study. Design life in the system FMEA is the durability target of the component (Bass 1991). The specific attribute of the target will be component dependent.

Another way to define the design life for the system FMEA is the target (goal) period or useful life after which the component is discarded because (1) it ceases to function as designed (normal wear), and (2) it is too expensive to repair.

If the expected frequency and/or cumulative number of failures cannot be estimated, it is acceptable for the system FMEA to look at similar or surrogate systems and/or components for similar information.

Generally, the system FMEA operates under the assumption of a single-point failure (in other words, if the component fails, the system fails). A sin-
gle-point failure is defined as a component failure that would cause the system failure and which is not compensated by either redundancy or an alternative method. For example, single pieces of hardware and heavily loaded cable runs, place a high degree of dependence on single components, which usually can be avoided through the use of redundancy. In this case, the installation of duplicate cables into a heavily loaded area, with terminals intermingled on one of the two cables, can minimize service disruption in the event of a cable cut.

It is imperative when the occurrence/frequency is calculated, it must be for every single cause of the failure. It also must be a consensus agreement of the entire team. A typical occurrence guideline is shown in Table 5.2.

Detection Method (17). A method (procedure), test, design review, or an engineering analysis. These are some of the first-level methods to detect a failure in the system. They can be very simple (in other words, brainstorming) or very technical and advanced (in other words, finite element analysis, computer simulation, and laboratory tests).

The objective is to detect a design deficiency as early as possible. That deficiency may be viewed as a weakness in the system to reveal, detect, or eliminate the problem from the system (Chien 1985). The idea of early detection in the system FMEA is to provide efficient design controls.

Because the system FMEA is performed very early, it sometimes is difficult to assess the detection rating. In these cases one may use historical information, or similar types of information from similar components and/or systems. In some cases, it is possible to have no method, test, or technique to identify the failure. In that case, the entry in this column should state something like “None identified at this time.”

Another way of focusing on the detection is to use the brainstorming technique to identify new methods and tests as they apply to the task at hand. Two of the leading questions in the brainstorming process should be:

- How can this failure be discovered?
- In what way can this failure be recognized?

To answer such questions a checklist may be of help. An extensive checklist is provided on the CD, Appendix B. A typical system design review checklist should cover the following (partial list):

- General
  - System operational requirements defined
  - Effectiveness factors established
  - System maintenance defined

- Support elements
If the numerical value falls between two numbers, always select the higher number.

If the team has a disagreement in the ranking value, the following may help.

1. If the disagreement is an adjacent category, average out the difference. For example, if one member says 5 and someone else says 6, the ranking in this case should be 6 (5 and 6 are adjacent categories. Therefore $5 + 6 = 11$, $11/2 = 5.5$).

2. If the disagreement jumps one category, then consensus must be reached. Even with one person holding out, total consensus must be reached. No average, no majority. Everyone in that team must have ownership of the ranking. They may not agree 100 percent, but they can live with it.

*All of the above guidelines and rankings may be changed to reflect specific situations.*
- Test and support equipment
- Personnel training

- Spare and repair parts
- Design features
  - Standardization
  - Interchangeability
  - Safety
  - Producibility
  - Test provisions
  - Handling
  - Storage
  - Reliability

**Detection (18).** Detection is a rating corresponding to the likelihood that the proposed system controls will detect a specific root cause of a failure mode (first-level causes) before the part is released for design. To identify a detection rating one must estimate the ability for each of the controls identified in item 17 to detect the failure before it reaches the customer. In other words, are the controls identified in item 17 effective for the system design?

If the ability of the controls to detect the failure is unknown or the detection cannot be estimated, then the detection rating should be 10. A typical detection guideline is shown in Table 5.3.

**Risk Priority Number (RPN) (19).** This number is the product of severity, occurrence, and detection. The RPN defines the priority of the failure. By themselves the RPNs have no value or meaning. They are used only to rank (define) the potential system deficiencies.

**Recommended Action (20).** No FMEA should be done without a recommended action. The recommended action may be specific action(s) or it may be further studying. The idea of the recommended action in the system FMEA is to reduce the severity, occurrence, detection, or all of them. In essence, the system FMEA is done to eliminate system deficiencies and therefore to eliminate failures.

To facilitate this goal the FMEA team must prioritize those failure modes with:

- The highest RPN
- The highest severity
- The highest occurrence
(However, in some cases the priority is based on severity, criticality, and finally RPN.)

Typical recommendations may be:

- No action at this time
- Add built-in detection devices
- Provide alternatives to the system
- Add a redundant subsystem

**Responsible Area or Person and Completion Date (21).** This section looks for the responsible person/area and the target completion date for the recommended action.

**Action Taken (22).** This is the follow-up. Just because something was recommended, that does not mean that something was done. It is imperative that someone (usually the system design engineer) will follow up on the recommendations to determine if they have been addressed adequately, properly, and/or if they are in need of updating.

Note that all FMEAs are living documents and as such someone must be responsible to update them. Often the person who is responsible for updating is the system design engineer. She or he has the responsibility to make sure that the system FMEA is indeed a living document and that it reflects the latest relevant information and actions.

After the action has been taken, the effective date or completion date with a brief description of the action should be entered.

**Revised RPN (23).** After the actions are incorporated in the system, the FMEA team should reevaluate the consequences of severity, occurrence, and detection. The results should be reviewed by the FMEA team and a new RPN is calculated and the failures are ranked. This process is repeated as needed until the FMEA team decides that all relevant information has been covered. If no actions are taken, then these columns will remain blank.

**Approval Signatures (24).** These signatures define the authority to carry out the FMEA. The names and titles will depend on the organization. Typical names may be those of the system design manager, R&D director, and engineering manager.

**Concurrence Signatures (25).** These define the responsibility of carrying out the completion and implementation of the FMEA. The names and titles will depend on the organization. Typical names may be those of the engineering manager, manufacturing manager, and quality assurance manager.
### Table 5.3 Detection guideline for system FMEA* (1–10 qualitative scale).

<table>
<thead>
<tr>
<th>Detection</th>
<th>Rank</th>
<th>Criteria</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Almost certain</td>
<td>1</td>
<td>Proven detection methods available in concept stage.</td>
<td>If the numerical value falls between two numbers, <em>always</em> select the higher number.</td>
</tr>
<tr>
<td>Very high</td>
<td>2</td>
<td>Proven computer analysis available in early design stage.</td>
<td>If the team has a disagreement in the ranking value, the following may help.</td>
</tr>
<tr>
<td>High</td>
<td>3</td>
<td>Simulation and/or modeling in early stage.</td>
<td>1. If the disagreement is an adjacent category, average out the difference. For example, if one member says 5 and someone else says 6, the ranking in this case should be 6 (5 and 6 are adjacent categories. Therefore $5 + 6 = 11, 11/2 = 5.5$).</td>
</tr>
<tr>
<td>Moderately high</td>
<td>4</td>
<td>Tests on early prototype system elements.</td>
<td>2. If the disagreement jumps one category, then consensus must be reached. Even with one person holding out total consensus must be reached. No average, no majority. Everyone in that team must have ownership of the ranking. They may not agree 100 percent, but they can live with it.</td>
</tr>
<tr>
<td>Medium</td>
<td>5</td>
<td>Tests on preproduction system components.</td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>6</td>
<td>Tests on similar system components.</td>
<td></td>
</tr>
<tr>
<td>Slight</td>
<td>7</td>
<td>Tests on product with prototypes with system components installed.</td>
<td></td>
</tr>
<tr>
<td>Very slight</td>
<td>8</td>
<td>Proving durability tests on products with system components installed.</td>
<td></td>
</tr>
<tr>
<td>Remote</td>
<td>9</td>
<td>Only unproven or unreliable technique(s) available.</td>
<td></td>
</tr>
<tr>
<td>Almost impossible</td>
<td>10</td>
<td>No known techniques available.</td>
<td></td>
</tr>
</tbody>
</table>

*All of the above guidelines and rankings may be changed to reflect specific situations.*
RECOMMENDED TEAM

A team is necessary to conduct a system FMEA. The team makeup should be five to nine individuals with a multidisciplined and multifunctional background. In addition, all members should have ownership of the problem (Stamatis 1992). A typical team may include the following:

- System engineer (mandatory)
- Reliability engineer
- Test engineer
- Marketing representative
- Design engineer (mandatory)

Other recommended participants may include:

- Quality engineer
- Material engineer
- R&D representative
- Process engineer
- Field service engineer
- Product engineer

Note that there is no such thing as the team. The team composition should reflect the needs and requirements of the problem and the culture of the organization.

(A final comment about the system [concept] FMEA. The reader should be cognizant of the fact that the system design in the real world is hardly ever completed. Generally it is conducted in the very early stages of development to identify major constraints of the design. It is not unusual that by the time the team gets to the point where “causes” are to be identified, the system may be either aborted or passed on to the design function, at which time the design FMEA takes over.)

REFERENCES


A design FMEA is a disciplined analysis/method of identifying potential or known failure modes and providing follow-up and corrective actions before the first production run occurs. A first production run is viewed as the run that generates a product or service for a specific customer with the intent of getting paid. This definition of the first run is very important because it excludes initial sample runs (ISR), trial runs, occasional prototype run(s), and so on. The threshold of the first production run is important, because up to that point modifying and/or changing the design is not a major problem. After that point, however, the customer gets involved through the letter of deviation, waiver of change, or some other kind of formal notification.

A design or product FMEA usually is accomplished through a series of steps to include component, subsystems/subassemblies, and/or systems/assemblies. The design FMEA is an evolutionary process (dynamic as opposed to static) involving the application of various technologies and methods to produce an effective design output. This result will be used as an input for the process or assembly, and/or the service FMEA (see Chapter 5, Figures 5.1, 5.2, and 5.3).

Selection of appropriate technologies may include the utilization of existing system(s), standardized approaches currently known or proposed, results of directed research, results of the system FMEA, or a combination of all these factors.

Effective design FMEA is basically realized through the system engineering process, product development, research and development (R&D), marketing, manufacturing, or a combination of all these entities (Blanchard 1986). The focus in this stage is to minimize failure effects on the system, regardless of what level FMEA is being performed.
This can be realized through a definition of design specifications which may include the following:

I. Scope of design

II. Applicable documents
   A. Standards
   B. Safety and warranty documents
   C. Documents on prior or similar products

III. General information
   A. Product functions
   B. Understanding who the customer is
   C. Customer’s needs, wants, and expectations
   D. Understanding of customer’s uses and misuses

IV. Requirements
   A. Design requirements
      1. Electrical
      2. Mechanical
      3. Reliability
      4. Service life
      5. Safety
      6. Material
      7. Environmental
      8. Controls
      9. Parts standardization
   B. Maintenance considerations
   C. Cost objective
   D. Design alternatives
   E. Critical systems
V. Product assurance

A. Documentation requirements

B. Testing and inspection requirements

C. Packaging and handling requirements

The goal, purpose, and/or objective of the design FMEA is to define and demonstrate engineering solutions in response to functional requirements as defined by the system FMEA and the customer.

To accomplish this objective the design FMEA must base its requirements on solid needs, wants, and expectations of the customer. As a general rule that information may be the result of a quality function deployment QFD (preferred), or an internal need for improvement, or the results of a system FMEA. In either case, one of the first steps in conducting the FMEA should be to include a feasibility study and/or a risk-benefit analysis directed toward defining a set of useful solutions to the problem(s) being addressed. The objective of this early (not definitive) stage is to maximize the system quality, reliability, cost, and maintainability, regardless of what level FMEA is being performed. This can be accomplished by at least the following considerations.

- Transform an operational need into a description of system performance parameters and as perfect as possible system configuration through the use of an interactive process of functional analysis, synthesis, optimization, definition, design, design reviews, test, and evaluation.

- Integrate related technical parameters and assure compatibility of all physical, functional, and program interfaces in a manner that optimizes the total system definition and design.

- Integrate reliability, maintainability, engineering support, human factors, safety, security, structural integrity, producibility, and other related specialties into the total engineering effort.

The outcome of the design FMEA is a preliminary design (it may change with new or modified information) with a baseline configuration and functional specifications toward translating the established requirements into detailed qualitative and quantitative process and assembly or service characteristics. Some of the generic concerns in a design FMEA may be the following.
General Concerns

- Design operational requirements defined
- Effectiveness factors established
- Design maintenance concept defined

Support Elements

In this area one must do a thorough investigation as to whether or not the requirements are known and/or can be optimized for:

- Test and support equipment
- Personnel and training
- Repair and spare parts

Design Features

- Standardization
- Accessibility
- Connectors
- Safety
- Test provisions
- Controls
- Transportability
- Reliability
- Interchangeability
- Technical data
- Producibility
- Software

Specific questions in the course of performing a design FMEA may be:

1. What does the product do and what are its intended uses?
2. How does the product perform its function?
3. What raw materials and components are used to build the product?
4. How, and under what conditions, does the product interface with other products?
5. What by-products are created by the product or by the use of the product?
6. How is the product used, maintained, repaired, and disposed of at the end of its useful life?

7. What are the manufacturing steps in the production of the product?

8. What energy sources are involved and how?

9. Who will use or be in the vicinity of the product, and what are the capabilities and limitations of these individuals?

Finally, when conducting a design FMEA, it is assumed that the system is the best it can be. If this assumption is not made, the FMEA team will end up doing the system and design FMEAs at the same time and will move in a circular pattern not accomplishing its task. The only way to address the system FMEA in the process of conducting the design FMEA is when the root causes of the failure modes in the design are caused by the system specifications.

**STEP-BY-STEP DESIGN FMEA ANALYSIS**

Traditionally, there have been two methods of designing products: design-to-cost and design-to-customer requirements. In the design-to-cost approach, the designer’s aim is to develop the design within certain cost limits (Stamatis 1993). This approach is called value engineering analysis and is beyond the scope of this book. In the design-to-customer requirements approach, the designer gives the customer what the customer wants with added requirements to satisfy regulatory obligations, safety concerns, and any other criteria that seem to be appropriate for the design. This second method will be pursued in this section.

To perform a design FMEA there are two requirements. The first requirement is the identification of the appropriate form. The second requirement is identification of the rating guidelines.

The form for the design FMEA is not universal. It is not standardized. Each company has its own form that reflects the needs of the organization and the concerns of the customer. In the automotive industry, however, efforts have been successful and on July 1, 1993 a standardized form and procedure was published by AIAG. (See CD, Appendix E, Figure E.10.)

This section addresses a form displaying generally accepted items that should be addressed as part of a system FMEA. On the CD, Appendix E, there are additional design FMEAs that show the diversity that exists between industries. Remember, there is no such thing as *the* design FMEA form.
The rating guidelines are not universal. They are not standardized. Each company has its own guidelines to reflect the needs of the organization, the product, and the concerns of the customer.

Generally, there are two ways that the rating guidelines can be formulated. The first method is qualitative; the second method quantitative. In either case the numerical values can be from 1 to 5 or 1 to 10, with the 1 to 10 range being the most common. Examples of both guidelines will be shown.

Figure 6.1 shows the most common design FMEA form. The form is divided into three parts. The first part, items 1 through 10 reflect the introduction of the form. None of the items are mandatory; however, they do add information to the design FMEA and provide essential information that may be needed in the course of writing the FMEA.

The second part of the form includes items 11 through 24. They reflect the mandatory items for any design FMEA. The order of the columns may be changed; more columns may be added but none of the columns presented may be removed. Items 11 through 24 may be viewed as the body of the system FMEA.

The third part of the form consists items 25 and 26. Although they are not mandatory, they do reflect the authority and responsibility of the team to undertake the project of writing the system FMEA. The signatures may be viewed as the closure of the FMEA. All numbers in parentheses are coded numbers for the discussion of the form.

**Subsystem Identification (1).** Identifies the subsystem name of the identification title of the FMEA.

**Design Responsibility (2).** Name the responsible organization, division, or department that has responsibility for the system design.

**Person Responsibility (2A).** Sometimes it is necessary to name the person who is responsible for the system design.

**Involvement of Other Areas (3).** Name other people or activities (within the organization) that affect the design of the system.

**Involvement of Suppliers or Others (4).** Identify other people, suppliers, and/or plants (outside the organization) that affect the design and are involved in the design, manufacturing or assembly, or service of the system.

**Model or Product (5).** Name the model and/or the product using the system.

**Engineering Release Date (6).** Identify the date (Mo-Day-Yr) that the product is scheduled to be released.
Design FMEA

<table>
<thead>
<tr>
<th>Design function</th>
<th>Potential failure mode</th>
<th>Potential effect(s) of failure</th>
<th>S E V</th>
<th>Potential cause(s) of failure</th>
<th>O C C</th>
<th>Detection method</th>
<th>D E T</th>
<th>R P N</th>
<th>Recommended action</th>
<th>Individual/area responsible and completion date</th>
<th>Action results</th>
</tr>
</thead>
</table>

*Figure 6.1* A form for design FMEA.
Prepared by (7). Generally, the name of the design engineer responsible for the FMEA is identified. Sometimes, additional information also is recorded, such as:

- Telephone number of the system design engineer
- Address of the system design engineer
- Organizational activity (in other words, division, department)
- Team members (name, telephone, address, and so on)

FMEA Date—Original (8). Record the date (Mo-Day-Yr) of the initiation of the design FMEA.

FMEA Date—Revision (9). Record the date (Mo-Day-Yr) of the latest revision.

Part Name (10). Identify the part name or number. Often the latest engineering drawing number is identified.

Design Function (11). The engineer writes the design intent, purpose, goal, or objective of the design. The design function must be derived from customer needs, wants, and expectations. Typically they include safety requirements, government regulations, and other internal or external constraints to the organization.

Generally, these needs, wants, and expectations are defined through a QFD and include several other considerations. Some of these considerations are a result of courts through product liability issues, warranty concerns, industrial standards, and/or specific customer requisitions.

For the design function to be effective, it must be identified in detail through a statement that is concise, exact, and easy to understand (no jargon). It also can be identified through a functional block diagram, which will show the system elements as functional blocks into which the system may be decomposed. It is important to note that the objective of the functional block diagram is to show the major elements of the system and to understand how the interaction of those elements affects the system itself or the other external system(s).

If a statement is used to describe the function, that function should be described in specific terms. To facilitate this, the writer of the FMEA should try to think of active verbs and appropriate nouns. The active verbs define performance and performance defines function. The combination of the active verb with the noun defines the relationship; consequently, the identification process becomes much easier. This can be facilitated through a part function worksheet (see Figure 6.2).
Examples of functions include:
- Provide bonded unit
- Provide cured subassembly
- Facilitate manufacturing
- Provide vibration damping

**Potential Failure Mode (12).** The problem. The concern. The opportunity to improve. The failure. The defect. When considering the potential failure mode one must think of the loss of a design function—a specific failure. The more specific one is the better opportunity there will be to identify the effects and causes of the failure. Design failures occur when a product does not adequately protect against risks of injury, fails to perform intended functions safely, or fails to minimize avoidable consequences in the event of an accident.

For each design function identified in item 11 the corresponding failure of the function must be listed. There can be more than one failure from

<table>
<thead>
<tr>
<th>No.</th>
<th>Verb</th>
<th>Noun</th>
<th>Basic</th>
<th>Second</th>
<th>Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
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</tbody>
</table>

**Figure 6.2** Function evaluation worksheet.
one function. To help identify of the potential failure mode one may think of the negative or loss of the function.

Examples of corresponding failure include:

- Fails to open
- Component shorts
- Broken
- Coil fails to produce EMF
- Subassembly leaks
- Corroded
- Cannot control speed

Another way to identify the failure mode anticipated is to ask the question “How could this system, design, component, subsystem, or process fail?” or “Can it break, wear, bind, and so on?” The emphasis is on the engineer who must try to anticipate how the design being considered could possibly fail, not whether or not it will fail.

Still another way of identifying failure mode is through a fault tree analysis (FTA). In the FTA structure the top level is the loss of the part function and then progressively on the lower levels the failure modes are identified. An example of an FTA may be viewed on the CD, Appendix D, Example 11.

Potential Effect(s) of Failure (13). A potential effect of the failure is the consequence of its failure on the next higher design, system, product, customer, and/or government regulations. The questions usually asked are: “What does the customer experience as a result of the failure mode described?” or “What happens or what is (are) the ramification(s) of this problem or failure?” The consequences may be to the design itself, the product, the customer, and/or government regulations. Often, the failure effect is evaluated from a customer’s perspective or experiences.

To identify the potential effects, some of the documents one may review are:

- Historical data
- Warranty documents
- Field service data
- Feasibility studies
- Customer complaints
• Similar current or past FMEAs
• Reliability data

No matter how the potential effect(s) is (are) identified, the ramifications of the loss to the design function must be determined. Consideration must be given to the design itself, other systems, the product, and the customer. If safety considerations may be an issue, this is the column where the appropriate notation should be made. Examples of potential effect of failure may be:

• Next higher system: fails to operate
• Next lower system: none
• Other system(s): none
• Product: performance degradation
• Customer: complete dissatisfaction; system fails to operate
• Government: may not comply with STD-XXX

**Critical Characteristics** (14). Critical characteristics usually are associated with design FMEAs because the hardware begins to be formalized in the design stage. Until and when hardware is defined, critical and/or significant characteristics cannot be identified (Slone 1986). This is the place where the identification of critical characteristics is made. The identification of the criticality or significance in the design FMEA is only to designate special controls for the process, assembly, and/or service FMEA. From here they are transferred to the control plan.

Examples of possible critical items may be dimensions, specifications, tests, processes, tooling, and usage. Critical characteristics are identified when:

• Process requirements can affect safety.
• Process requirements can affect compliance with government regulations.
• Process requirements are necessary for special actions/controls.

The entry to this column is a “Y” for yes, “N” for no (this designates the potentiality of the criticality which will be defined ultimately in the process FMEA). Its purpose is to flag a potential critical characteristic that may or may not exist. A good indication of criticality is when severity is rated 9 or 10 with occurrence and detection higher than 3. In the automotive industry, there is a slight variation of this rule. More about this in Chapter 14.
Severity of Effect (15). Severity is a rating indicating the seriousness of the effect of the potential design failure mode. The severity always applies to the effect of a failure mode. In fact, there is a direct correlation between effect and severity. For example, if the effect is critical, the severity is high. Conversely, if the effect is a nuisance, the severity is very low.

Severity is reviewed from the perspective of the system, design itself, other systems, the product, the customer, and/or the government regulations. For evaluation purposes there usually is a rating table that reflects the issues of the organization in conjunction with the customer and/or the government regulations. An example of such rating may be seen in Table 6.1.

In the design FMEA the severity rating should be based on the worst effect of the failure mode. When complete, rank the failure modes on the basis of the severity of their effects. At this point the FMEA is identical to the FMCA.

Potential Cause(s) of Failure (16). The cause of a design failure mode is the design deficiency that results in the failure mode. It must be emphasized repeatedly that when one focuses on the cause(s) one must look at the root cause, not the symptom of the failure.

To do a good job of proper potential cause(s) of failure identification, one must understand both the system and design, and ask appropriate questions. Specificity is of paramount importance. The more one zooms in on the root cause, the better one understands the failure. For example, “Would poor wire insulation cause the short?” Some of the techniques that may be used are brainstorming, cause-and-effect analysis, analysis of the block diagram, and affinity charts.

The basic question to ask is “In what way can this system fail to perform its intended function?” Another way is to ask five whys in a row. The rationale for this is that it progressively becomes a more difficult and thought-provoking assignment to identify the whys. The early ones are superficial, where the later ones are more substantive. Other questions that may be asked are: “What circumstances could cause the failure?” and “How or why can the part fail to meet its engineering specifications?”

A failure mode can be caused by one or more of the individual components or by (partial list):

- Hardware failure due to inadequate product design
- Improper selection of component parts
- Improper use of processes
- Inadequate control procedures
- Failure to enforce process and quality controls
<table>
<thead>
<tr>
<th>Effect</th>
<th>Rank</th>
<th>Criteria</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>1</td>
<td>No effect.</td>
<td>If the numerical value falls between two numbers, always select the higher number.</td>
</tr>
<tr>
<td>Very slight</td>
<td>2</td>
<td>Customer not annoyed. Very slight effect on product performance. Nonvital fault noticed sometimes.</td>
<td>If the team has a disagreement in the ranking value, the following may help.</td>
</tr>
<tr>
<td>Slight</td>
<td>3</td>
<td>Customer slightly annoyed. Slight effect on product performance. Nonvital fault noticed most of the time.</td>
<td>1. If the disagreement is an adjacent category, average out the difference. For example, if one member says 5 and someone else says 6, the ranking in this case should be 6 (5 and 6 are adjacent categories. Therefore $5 + 6 = 11, \frac{11}{2} = 5.5$).</td>
</tr>
<tr>
<td>Minor</td>
<td>4</td>
<td>Customer experiences minor nuisance. Minor effect on product performance. Fault does not require repair. Nonvital fault always noticed.</td>
<td>2. If the disagreement jumps one category, then consensus must be reached. Even with one person holding out total consensus must be reached. No average, no majority. Everyone in that team must have ownership of the ranking. They may not agree 100 percent, but they can live with it.</td>
</tr>
<tr>
<td>Moderate</td>
<td>5</td>
<td>Customer experiences some dissatisfaction. Moderate effect on product performance. Fault on nonvital part requires repair.</td>
<td></td>
</tr>
<tr>
<td>Serious</td>
<td>9</td>
<td>Potential hazardous effect. Able to stop product without mishap—time-dependent failure. Compliance with government regulation is in jeopardy.</td>
<td></td>
</tr>
</tbody>
</table>

*All of the above guidelines and rankings may be changed to reflect specific situations.*
Improper installation, maintenance
Lack of safety devices, environmental factors
Misuse, abuse
Alteration of the product
Improper operating instructions
Human error
Improper choice of materials
Stress concentrations
Fatigue, uniform attack
Corrosion, galvanic corrosion, crevice corrosion
Hydrogen damage, pitting, blistering
Decarbonization, abrasion and wear, shock and vibration
Interaction with other components
Interaction with components of other systems
Interaction with the government
Interaction with the customer

This area in the FMEA is important because 76 percent of all engineering changes are due to corrections of bad design and only 24 percent of engineering changes are due to improvements (Curley and Ryder 1992). It is imperative that the focus in performing the FMEA should be to identify all potential failures.

At this point, it must be emphasized that a major benefit of the design FMEA is identification and removal of potential failure modes caused by system and/or component interactions. These interactions also may involve human factors and must be reviewed thoroughly.

The relationship between the failure mode and the cause(s) is not linear or one-to-one. Do not be surprised if there are several if not many causes for one failure mode. (Sometimes a one-to-one relationship exists.) List as many causes as possible—all of them. These causes will be transferred to the process FMEA as potential failure modes. Therefore, the more causes identified in the design FMEA, the easier the process FMEA becomes.

Examples of failure causes include:

Torque too high or low
Wrong usage of fastener
- Hardness
- Viscosity too high or low
- Porosity

Note: If the effect of the failure is rated 8 through 10, special effort should be made to identify as many root causes as possible.

**Occurrence (17).** Occurrence (frequency) is the rating value corresponding to the estimated number of frequencies and/or cumulative number of failures that could occur for a given cause over the life of the design. To identify the frequency for each of the causes one may use reliability mathematics (which is beyond the scope of this book), expected frequencies, or a cumulative number of component failures (CNF) per 100 or 1000 components (CNF/100 or CNF/1000, respectively) over the design life of the component under study. Design life in the design FMEA is the component’s durability target. The specific attribute of the target will be component dependent.

Another way to define the design life is the target (goal) period or useful life after which the component is discarded because it ceases to function as designed (normal wear). Thus, it is too expensive to repair.

If expected frequencies and/or cumulative number of failures cannot be estimated, it is acceptable for the design FMEA to examine similar or surrogate systems and/or components for similar information.

Generally, the design FMEA operates under the assumption of a single-point failure (in other words, if the component fails, the system fails). A single-point failure is defined as a component failure, which would cause the system failure and is not compensated by redundancy or an alternative method. For example, single pieces of hardware and heavily loaded cable runs that place a high degree of dependence on single components, usually can be avoided through the use of redundancy. In this case, the installation of duplicate cables into a heavily loaded area with terminals intermingled on one of the two cables could minimize service disruption in the event of a cable cut.

When occurrence/frequency is calculated it must be for every single cause of the failure. If it cannot be estimated, then the occurrence should be entered as 10. It must also be a consensus agreement of the entire team. A typical occurrence guideline is shown in Table 6.2.

**Detection Method; Design Verification; Existing Control (18).** A method (procedure), test, design review, or an engineering analysis. These are some of the first-level methods to detect a failure in the design or part (Blanchard
Chapter Six

Resolution

If the numerical value falls between two numbers, always select the higher number.

If the team has a disagreement in the ranking value, the following may help.

1. If the disagreement is an adjacent category, average out the difference. For example, if one member says 5 and someone else says 6, the ranking in this case should be 6 (5 and 6 are adjacent categories. Therefore \( 5 + 6 = 11, \frac{11}{2} = 5.5 \approx 6 \)).

2. If the disagreement jumps one category, then consensus must be reached. Even with one person holding out, total consensus must be reached. No average, no majority. Everyone in that team must have ownership of the ranking. They may not agree 100 percent, but they can live with it.

---

**Table 6.2 Occurrence guideline for design FMEA* (1–10 qualitative scale).**

<table>
<thead>
<tr>
<th>Occurrence</th>
<th>Rank</th>
<th>Criteria</th>
<th>CNF/1000</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Almost impossible</td>
<td>1</td>
<td>Failure unlikely. History shows no failures.</td>
<td>&lt;.00058</td>
<td>If the numerical value falls between two numbers, always select the higher number.</td>
</tr>
<tr>
<td>Remote</td>
<td>2</td>
<td>Rare number of failures likely.</td>
<td>.0068</td>
<td>If the team has a disagreement in the ranking value, the following may help.</td>
</tr>
<tr>
<td>Very slight</td>
<td>3</td>
<td>Very few failures likely.</td>
<td>.0063</td>
<td>1. If the disagreement is an adjacent category, average out the difference. For example, if one member says 5 and someone else says 6, the ranking in this case should be 6 (5 and 6 are adjacent categories. Therefore ( 5 + 6 = 11, \frac{11}{2} = 5.5 \approx 6 )).</td>
</tr>
<tr>
<td>Slight</td>
<td>4</td>
<td>Few failures likely.</td>
<td>.46</td>
<td>2. If the disagreement jumps one category, then consensus must be reached. Even with one person holding out, total consensus must be reached. No average, no majority. Everyone in that team must have ownership of the ranking. They may not agree 100 percent, but they can live with it.</td>
</tr>
<tr>
<td>Low</td>
<td>5</td>
<td>Occasional number of failures likely.</td>
<td>2.7</td>
<td></td>
</tr>
<tr>
<td>Medium</td>
<td>6</td>
<td>Medium number of failures likely.</td>
<td>12.4</td>
<td></td>
</tr>
<tr>
<td>Moderately high</td>
<td>7</td>
<td>Moderately high number of failures likely.</td>
<td>46</td>
<td></td>
</tr>
<tr>
<td>High</td>
<td>8</td>
<td>High number of failures likely.</td>
<td>134</td>
<td></td>
</tr>
<tr>
<td>Very high</td>
<td>9</td>
<td>Very high number of failures likely.</td>
<td>316</td>
<td></td>
</tr>
<tr>
<td>Almost certain</td>
<td>10</td>
<td>Failure almost certain. History of failures exists from previous or similar designs.</td>
<td>&gt;316</td>
<td></td>
</tr>
</tbody>
</table>

*All of the above guidelines and rankings may be changed to reflect specific situations.*
and Lowery 1969). They can be very simple (in other words, brainstorming) or very technical and advanced (in other words, finite element analysis, design reviews, computer simulation, and laboratory tests). In either case, the focus is on the effectiveness of the control method/technique to catch the problem before it reaches the customer.

The objective is to detect a design deficiency as early as possible. That deficiency may be viewed as a weakness in the design to reveal, detect, or eliminate the problem from the design (Chien 1985). The idea of early detection in the design FMEA is to provide efficient design controls.

Because the design FMEA is done very early, it sometimes is difficult to assess the detection rating. In these cases one may use historical information, or similar types of information from similar components and/or systems. In some cases, it is possible to have no method, test, or technique to identify the failure. In that case, the entry in this column should state something like “None identified at this time.”

Another way to focus on the detection is to use the brainstorming technique to identify new methods and tests as they apply to the task at hand. Two of the leading questions in the brainstorming process should be:

- How can this failure be discovered?
- In what way can this failure be recognized?

To answer such questions, a checklist may be helpful; however, some of the most effective ways to detect a failure in the design stage are:

- Proven simulation techniques
- Mathematical modeling
- Prototype testing
- Design of experiments
- Design verification testing
- Specific product testing
- Tolerance stack-up studies
- Design review
- Material review

The majority of the items in detecting failures are quantifiable. The design review, however, is also an important tool that is used to review the appropriateness of the system and/or design. It can be quantifiable, but it can also be a qualitative and systematic methodology of questioning the design. A typical design review may include:
• **Preliminary design review**—The purpose for the preliminary design review is to define and select a design approach to meet the functional requirements of the product. The result is a description of product features, production cost estimates, estimates of life use, and the description of the foreseeable environment of use. In this stage, probabilistic, reliability, and statistical modeling and testing may be required.

• **Intermediate design review**—The purpose of the intermediate design review is to determine whether the product will achieve its functional requirements at an acceptable level of safety, producibility, and profitability. In this stage, design trade-offs can be assessed, test results reviewed, safety margins examined, material selections evaluated, and tooling and manufacturing processes reviewed.

• **Final design review**—The purpose of the final design review is to review and approve the detailed design information necessary to manufacture the product.

In this stage, the completeness of the documentation is assessed. It provides a last check of the functions, features, producibility, compliance to the appropriate standards, operator misuse, profitability, and safety of the design before manufacturing the product.

*Design review checklist*—A typical checklist may consider the following (Bass 1991; Blanchard 1986; Ford 1989; Stamatis 1992, 2002):

Define product in its use environment

• What are the product’s uses?

• What are the foreseeable environments of use?

• Describe the skill and capability of foreseeable users?

Identify safety and assess risk

• What are the hazards?

• Estimate the probability of occurrence and seriousness of resulting harm for each hazard

Evaluate alternatives

• What alternative design features or production techniques are available, including warnings and instructions, that can be expected to reduce or eliminate safety issues?
Evaluate alternative designs by considering:
- Characteristics and comparisons of different products
- Other safety issues introduced by the alternative design
- Their effect on the usefulness of the product
- Their effect on the ultimate cost of the product

The CD, in Appendix B, includes an extensive checklist. It should be modified to reflect one’s organization and requirements before it is used.

In the case of human errors a detection method may be developed with the following criteria based on MIL-STD-1472c and Woodson’s (1981) (partial) list:

- Control and display integration
  - Controls and displays should be together.
  - Controls and displays with similar functions should be grouped.
  - Displays should reflect the proper direction for control movement.

- Visual displays
  - Visual displays should provide only the information necessary for the operation of a system.
  - Critical displays should be located in the operator’s optimum viewing area.
  - Indicator lights must follow certain standard color codes.
  - Figure size must be based on operator viewing distance.

- Audio displays
  - Audio signals must be of a frequency and amplitude that can be heard in the operating environment.
  - The frequency response and range must be appropriate for the working environment.

- Controls
  - Control movement must relate to standard norms and to the direction of movement of the equipment which they control.
  - Controls should be arranged in the sequence in which they are used.
  - Control color coding standards should be followed.
  - Controls should be coded by shape, color, size, and location.

- Labels/warnings
  - Labels/warnings should be readable and understandable under foreseeable operating conditions by expected users.
  - Labels and warning must (where appropriate)
    - Identify the fact that there is a safety problem.
    - Indicate the level of safety problem.
    - Indicate the likelihood of the safety issue resulting in harm.
- Explain how to avoid the safety issue.
- Describe the consequences of the safety issue if the warning is not heeded.

- Anthropometry
  - Equipment should be designed to accommodate the full range of potential users.

- Operating area criteria
  - Controls must be placed within the reach of the operator.
  - Design criteria must exist for standing/seating operator.
  - Design criteria must exist for operator’s seat and control console.

- Environmental design criteria
  - Heating, ventilating, air conditioning, and humidity standards for safe and efficient job performance
  - Proper illumination
  - Proper noise levels
  - Proper vibration and acceleration limits

- Maintainability design criteria
  - Accessibility criteria
  - Weight limitations

- Checklists
  - Specific checklists for specific functions

Detection (19). Detection is a rating corresponding to the likelihood that the proposed design controls will detect a specific root cause of a failure mode before the part is released for production. To identify a detection rating one must estimate the ability for each of the controls identified in item 18 to detect the failure before it reaches the customer. In other words, are the controls identified in item 18 effective for the design?

If the ability of the controls to detect the failure is unknown or the detection cannot be estimated, then the detection rating should be 10. A typical detection guideline is shown in Table 6.3.

Risk Priority Number (RPN) (20). This number is the product of severity, occurrence, and detection. The RPN defines the priority of the failure. By themselves the RPNs have no value or meaning. They are used only to rank (define) the potential design deficiencies.

In the design FMEA, one must always remember that the goal is to reduce the RPN, but in a specific way. The specific way is through a reduction in severity, occurrence, and detection.
Table 6.3  Detection guideline for system FMEA* (1–10 qualitative scale).

<table>
<thead>
<tr>
<th>Detection</th>
<th>Rank</th>
<th>Criteria</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Almost certain</td>
<td>1</td>
<td>Has the highest effectiveness in each applicable category</td>
<td>If the numerical value falls between two numbers, <em>always</em> select the higher number.</td>
</tr>
<tr>
<td>Very high</td>
<td>2</td>
<td>Has very high effectiveness</td>
<td>If the team has a disagreement in the ranking value, the following may help.</td>
</tr>
<tr>
<td>High</td>
<td>3</td>
<td>Has high effectiveness</td>
<td></td>
</tr>
<tr>
<td>Moderately high</td>
<td>4</td>
<td>Has moderately high effectiveness</td>
<td>1. If the disagreement is an adjacent category, average out the difference. For example, if one member says 5 and someone else says 6, the ranking in this case should be 6 (5 and 6 are adjacent categories. Therefore 5 + 6 = 11, 11/2 = 5.5 ≈ 6).</td>
</tr>
<tr>
<td>Medium</td>
<td>5</td>
<td>Has medium effectiveness</td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>6</td>
<td>Has low effectiveness</td>
<td></td>
</tr>
<tr>
<td>Slight</td>
<td>7</td>
<td>Has very low effectiveness</td>
<td>2. If the disagreement jumps one category, then consensus must be reached. Even with one person holding out total consensus must be reached. No average, no majority. Everyone in that team must have ownership of the ranking. They may not agree 100 percent, but they can live with it.</td>
</tr>
<tr>
<td>Very slight</td>
<td>8</td>
<td>Has lowest effectiveness in each applicable category</td>
<td></td>
</tr>
<tr>
<td>Remote</td>
<td>9</td>
<td>Is unproven, or unreliable, or effectiveness is unknown</td>
<td></td>
</tr>
<tr>
<td>Almost impossible</td>
<td>10</td>
<td>No design technique available or known, and/or none is planned</td>
<td></td>
</tr>
</tbody>
</table>

*All of the above guidelines and rankings may be changed to reflect specific situations.
The severity can be reduced only through a change in design. If that is attainable, then the failure is eliminated.

The occurrence can be reduced by improving engineering specifications and/or requirements with the intent of preventing causes or reducing their frequency.

The detection can be reduced by adding or improving the design evaluation technique or increasing sample size, and/or adding detection equipment. The result will be improvement in the ability to detect the failure before it reaches the customer.

**Recommended Action (21).** No FMEA should be done without a recommended action. The recommended action may be specific action(s) or it may be further studying. The idea of the recommended action in the design FMEA is to reduce the severity, occurrence, detection, or all of these elements. In essence the design FMEA is done to eliminate design deficiencies and therefore eliminate failures.

To facilitate this goal, the FMEA team must prioritize those failure modes with the highest RPN, the highest severity, the highest occurrence. Typical recommendations may be:

- No action at this time
- Add build-in detection devices
- Provide alternatives to the design
- Add redundant subsystem

**Responsible Area or Person and Completion Date (22).** Identify the responsible person/area and the target completion date for the recommended action.

**Action Taken (23).** This is the follow-up. Just because something was recommended, does not mean that something was done. It is imperative that someone (usually the design engineer) will follow up on the recommendations to determine if indeed they have been addressed adequately, properly, and/or if they are in need of updating.

Note that all FMEAs are a living document and as such someone must be responsible to update them. Often the person who is responsible is the design engineer. She or he has the responsibility to make sure that the design FMEA is a living document and that it reflects the latest relevant information and actions.

After the action has been taken, the effective date or completion date with a brief description of the action should be entered.
Revised RPN (24). After the actions are incorporated in the design, the FMEA team should reevaluate the consequences of severity, occurrence, and detection. The results should be reviewed by the FMEA team, a new RPN must be calculated and the failures ranked. This process is repeated as needed until such time the FMEA team decides that all relevant information has been covered. If no actions are taken, these columns will remain blank.

Approval Signatures (25). Define the authority to carry out the FMEA. The names and titles will depend on the organization. Typical names may be those of the design manager, reliability manager, and engineering manager.

Concurrence Signatures (26). Define the responsibility of carrying out the completion and implementation of the FMEA. The names and titles will depend on the organization. Typical names may be those of the engineering, manufacturing, or quality assurance manager.

Sometimes a design FMEA is associated with a product FMEA. The method for the development and the rationale for the product FMEA is the same as that for the design. A pictorial overview of the product development and flow from the system to design to product is shown in Figures 6.3 and 6.4, respectively.

**RECOMMENDED TEAM**

A team is necessary to perform a design FMEA. The team makeup should be five to nine individuals with a multidisciplined and multifunctional background. In addition, all members should have ownership of the problem (Stamatis 1992). A typical team may include the following:

- System engineer (mandatory)
- Reliability engineer
- Test engineer
- Material engineer
- Process engineer (mandatory)
- Marketing representative
- Design engineer (mandatory)

Other recommended participants may include:

- Quality engineer
- Process engineer
- Material engineer
• Field service engineer
• R&D representative
• Tooling engineer
• Product engineer

Note that there is no such thing as *the* team. A team is made to reflect the needs and requirements that the problem and culture of the organization requires.

Figure 6.3  Part deployment.
REFERENCES

A process FMEA is a disciplined analysis/method of identifying potential or known failure modes and providing follow-up and corrective actions before the first production run occurs. A first production run is viewed as the run that produces a product or service for a specific customer with the intent of getting paid. This definition of the first run is very important because it excludes initial sample runs (ISR), trial runs, an occasional prototype run(s), and so on. The threshold of the first production run is important because up to that point modifying and/or changing the design is usually not a major event. At the point of the true first production, process, product, and procedure validation is defined. The customer has the important role of defining the process, product, procedure, and so forth. After that point, however, the customer becomes involved through the letter of deviation, waiver of change, or some other formal notification.

A process FMEA usually is accomplished through a series of steps to include labor, machine, method, material, measurement, and environment considerations. Of course, each of these components has its own components, which may react individually, in tandem, or as an interaction to create a failure. Because of this convolution, completing a process FMEA is more complicated and time-consuming than the system and/or design FMEAs.

The process FMEA is an evolutionary process (dynamic as opposed to static). It involves the application of various technologies and methods to produce an effective process output. The result is a defect-free product; or information that may be used as input for the product, assembly, and/or the service FMEA.

The selection of appropriate technologies may include the customer’s request, the utilization of existing system(s), standardized approaches and/or
procedures currently known or proposed, results of directed research, results of the design FMEA, or a combination of all the above.

Effective process FMEA is realized basically through the design engineering process, product development, R&D, quality assurance, marketing, manufacturing, or a combination of all these entities (Blanchard 1986). Thus, the focus of the process FMEA is to minimize production process failure effects on the process (system), regardless of what level FMEA is being performed.

This can be realized through a specific definition of design specifications and a good understanding of what the process can do. For the understanding of design specifications see Chapter 6. To understand the process, however, the following may be helpful.

Production (manufacturing) involves utilization of six components: labor, machine, method, material, measurement, and environment. The goal of these components is the production of an end item that meets or exceeds the safety and quality characteristics of the design documentation. An integral element of the process documentation should be the design FMEA. It is extremely difficult (if not impossible) to do a thorough process FMEA without completion of (or at least some information from) a design FMEA (Stamatis 1992, 1993).

It is true, however, that it is difficult to evaluate the entire production process in the early stages—the initiation of production. In most cases, the reality is that the process evaluation develops over time. As such, the process FMEA becomes a living document (dynamic as opposed to static) to reflect the process’ changes.

Generally, there are two basic types of process evaluation techniques that are utilized in the early stages:

1. **Process capability studies.** Such studies are used to determine the inherent capability of specific elements of the production processing. Examples include machine acceptance capability, process potential study (short-term capability), and long-term capability.

2. **Mandatory process evaluation.** As mentioned, it is difficult to evaluate all process parameters. Thus, each company establishes mandatory evaluation points for specific variables that are critical to the operation and/or the customer. They may be helped in this identification by:
   - Customer requirements
   - Government regulations
• Internal engineering guidelines
• Design FMEA
• Industrial standards/guidelines
• Generally accepted practices
• Courts through product liability

Some of the evaluation points may be:

• Certification of operators. Certification may be necessary for critical skills (in other words, boiler operators, welders).

• Tool proofing. Tools, jigs, and fixtures may be required to be validated.

• Critical process. Most critical processes as defined by safety, customers, or government regulations require evaluation and prior approval (in other words, practically all drug and medical device processes, heat treating).

• Test operation. Most complex testing operations require review and approval to ensure accuracy.

The goal, purpose, and/or objective of the process FMEA is to define, demonstrate, and maximize engineering solutions in response to quality, reliability, maintainability, cost, and productivity as defined by the design FMEA and the customer. The key in this definition is that one cannot emphasize one of the elements (quality, reliability, maintainability, cost, productivity) at the expense of the others. All of them must be satisfied at optimum so the process can be at maximum. The optimum for each of the elements is an operational definition and may be defined in any way that the organization views itself in the market. This optimum really defines niches in the market for differentiation of product and/or service.

To accomplish this objective, the process FMEA must base its requirements on solid needs, wants, and expectations of the customer. As a general rule that information may be the result of a QFD (preferred), or an internal need for improvement, or the results of a design FMEA. In either case, one of the first steps in conducting the FMEA should be to include a feasibility study and/or a risk-benefit analysis directed toward defining a set of useful solutions to the problem(s) being addressed. The objective of this early (not definitive) stage is to maximize the system quality, reliability, cost, productivity, and maintainability, regardless of
what level the FMEA is being performed. This can be accomplished through the following considerations:

1. Transform an operational need into a description of process performance parameters and as perfect as possible process configuration through the use of an interactive process of functional analysis, synthesis, optimization, definition, design, design reviews, test, and evaluation.

2. Integrate related technical parameters and ensure compatibility of all physical, functional, and program interfaces in a manner that optimizes the total process definition and manufacturing.

3. Integrate reliability—maintainability, engineering support, human factors, safety, security, structural integrity, producibility, and other related specialties into the total engineering effort.

The outcome of the process FMEA is a process (it may change with new or modified information) with a baseline configuration and functional specifications toward translating the established requirements into detailed qualitative and quantitative product and assembly or service characteristics. This change may cause a process FMEA to iterate the causes of failures. The flow of this iteration is shown in Figure 7.1. Some of the generic concerns in a process FMEA follow:

**General Concerns**

- Process operational requirements defined
- Effectiveness factors established
- Process maintenance concept defined

**Support Elements**

One must do a thorough investigation of support elements as to whether or not the requirements are known and or can be optimized for:

- Test and support equipment
- Personnel and training
- Repair and spare parts
Process Features

- Standardization
- Interchangeability
- Controls
- Transportability
- Safety
- Software
- Test provisions
- Accessibility
- Technical data, procedures
- Producibility
- Reliability

Note: It is not unusual to have an iteration of the causes in a process FMEA. The flow of the iteration is demonstrated. The iteration stops when the RPN is sufficiently low—less than 50 in a 1 to 10 guideline scale.

Figure 7.1 Relationship of a process FMEA in an iteration mode of failure identification.
Specific questions in the course of performing a process FMEA may be:

1. What is the true performance and effectiveness of the process?
2. What does the product do and what are its intended uses?
3. What is the true effectiveness of the support capability?
4. Are the initially specified requirements appropriate for the process? Are they being met?
5. How does the process perform its function?
6. What raw materials and components are used in the process?
7. How, and under what conditions, does the process interface with other processes?
8. What by-products are created by the process or by the use of this process?
9. How is the process used, maintained, repaired, and disposed of at the end of its useful life?
10. What are the manufacturing steps in the production of the product?
11. What energy sources are involved and how?
12. Who will use or be in the vicinity of the process, and what are the capabilities and limitations of these individuals?
13. Is the process cost-effective?

Finally, when conducting a process FMEA, it is assumed that the design is the best it can be. If this assumption is not made, the FMEA team will perform the design and process FMEAs simultaneously and will move in a circular pattern not accomplishing its task. The only way to address the design FMEA in the process of conducting the process FMEA is when the root causes of the failure modes in the process are caused by the design specifications.

**STEP-BY-STEP PROCESS FMEA ANALYSIS**

There are two requirements to perform a process FMEA. The first requirement is identification of the appropriate form. The second requirement is identification of the rating guidelines.
The form for the process FMEA is not universal. It is not standardized. Each company has its own form to reflect the needs of the organization and the concerns of the customer. In the automotive industry, however, efforts have been successful and as of July 1, 1993 there is a standardized form and procedure published by AIAG. (See CD: Appendix E, Figure E.6.)

This section introduces a form to illustrate the generally accepted items that should be addressed as part of a process FMEA. On the CD, Appendix E includes additional process FMEAs that show the diversity that exists between industries. Remember, there is no such thing as the process FMEA form.

The rating guidelines also are not universal. They are not standardized. Each company’s rating system reflects the needs of the organization, the product, and the concerns of the customer.

Generally, there are two ways that the rating guidelines can be formulated: qualitative and quantitative. In either case the numerical values can be from 1 to 5 or 1 to 10, with the 1 to 10 range being the most common. Remember, there is no such thing as the rating guideline for the process FMEA. Both kinds of guidelines will be shown.

Figure 7.2 shows the most common process FMEA form. The form is divided into three parts. The first part, items 1 through 9, reflect the introduction of the form. None of the items are mandatory; however, they do add information to the process FMEA and provide essential information that may be needed in the course of writing the FMEA.

The second part of the form contains items 10 through 23. These items are the mandatory items for any process FMEA. The order of the columns may be changed, and more columns may be added, but none of the columns presented may be removed. Items 10 through 23 may be viewed as the body of the process FMEA.

The third part of the form, items 24 and 25, are the signatures. Although they are not mandatory, they do reflect the authority and responsibility of the team to undertake the project of writing the system FMEA. The signatures may be viewed as the closure of the FMEA. All numbers in parentheses are coded numbers for the discussion of the form.

**Process Identification (1).** Identify the process or assembly name, or reference numbers, or process codes as appropriate.

**Part Name (1A).** On special occasions the part name or number is identified. Often the latest engineering drawing number is identified.

**Manufacturing and/or Design Responsibility (2).** Name the primary responsibility for the process (machine, material, and so on). Enter the name of the activity responsible for the design of the system, assembly, and
### Figure 7.2  A form for process FMEA.

<table>
<thead>
<tr>
<th>Process function</th>
<th>Potential failure mode</th>
<th>Potential effect(s) of failure</th>
<th>S E V</th>
<th>Potential cause(s) of failure</th>
<th>O C C</th>
<th>Detection method</th>
<th>D E T</th>
<th>Recommended action</th>
<th>Individual/area responsible and completion date</th>
<th>Action taken</th>
<th>Action results</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>

**Team effort**

(24) Approval signatures

(25) Concurring signatures
even the component, if appropriate. This is used strictly for a cross-reference point to the design and/or assembly.

**Person responsibility (2A).** Sometimes it is necessary to name the person who is responsible for the process FMEA.

**Involvement of Other Areas (3).** Name other persons or activities (within the organization) that are affected or are involved in the manufacturing or assembly of the part.

**Involvement of Suppliers or Others (4).** Identify other people, suppliers, and/or plants (outside the organization) that affect the design and are involved in the part’s design, manufacturing, or assembly.

**Model or Product (5).** Name the model and/or the product using the process (manufacturing and/or assembly).

**Engineering Release Date (6).** Identify the date (Mo-Day-Yr) that the product is scheduled to be released.

**Key Production Date (6A).** Identify milestone dates (Mo-Day-Yr), such as those for specific reviews, date for initial sample report (ISR), and so on.

**Prepared by (7).** Generally, the name of the process engineer responsible for the FMEA is recorded. Sometimes, additional information, with an attachment, also is recorded such as:

- Telephone number of the system design engineer
- Address of the system design engineer
- Organizational activity (in other words, division, department, and so on)
- Team members (name, telephone, address, and so forth)

**FMEA Date—Original (8).** Record the date (Mo-Day-Yr) of the initiation of the process FMEA.

**FMEA Date—Revision (9).** Record the date (Mo-Day-Yr) of the latest revision.

**Process Function (10).** The engineer writes the process intent, purpose, goal, or objective of the process. The process function must be derived from the design specifications and the what is the process now. Not what should the process be.

Generally, the process function is identified with a process flow diagram followed by a task analysis. The process flow diagram will identify sequentially the flow of operations among personnel and the interaction among personnel and major equipment components.

Conversely, the task analysis will serve as the basis of workload analysis by defining the specific sequence of tasks that each person in the process
must perform. This step is important because inefficient distribution of workload can result in increased human error and subsequent safety or critical problems (Bass 1991).

Task analysis and task identification are not the same, nor can they be used interchangeably. A task analysis defines:

- What initiates the task
- Equipment used to perform the task
- Human response
- Task feedback
- Characteristics of the task output, including performance requirements

Task identification defines the work through one or more of the following techniques:

- System analysis
  - Functional flow block diagrams
  - Decision/action diagrams
  - Functional allocation
- Time lines
- Time and motion analysis
- Human reliability analysis
- Operational sequence diagram

For the process function to be effective it must be identified in detail through a statement that is concise, exact, and easy to understand (no jargon). In the statement that is used to describe the function, that function should be described in specific terms. To facilitate this, the FMEA writer should try to think of active verbs and appropriate nouns. The active verbs define performance and performance defines function. The combination of the active verb with the noun defines the relationship; consequently, the identification process becomes easier. Examples of functions include:

- Provide bonded unit
- Provide cured subassembly
- Facilitate manufacturing
- Provide vibration damping
Another way to facilitate the formation of the function is to ask questions such as “What is the purpose, objective, function, goal of the process?” or “What is the process supposed to do?” If there is more than one purpose or function it is imperative that they should all be identified separately because they probably will have different potential failure modes.

**Potential Failure Mode (11).** The problem. The concern. The opportunity to improve. The failure. The reject. The defect. When one thinks of the potential failure mode one must think of the loss of a process function—a specific failure. The more specific one is, the better opportunity there will be to identify the effects and causes of the failure. Process failures occur when a product does not adequately protect against risks of injury, fails to perform intended functions safely (as defined by engineering specifications), or fails to minimize avoidable consequences in the event of an accident.

Generally, there are four categories of process failure modes:

- Testing and/or inspection
  - Accept or reject bad or good parts, respectively
- Assembly
  - Relational concerns, misoriented parts, and/or missing parts
- Receiving inspection
  - Why is the received part rejected?
- Manufacturing
  - Visual characteristics
  - Dimensional characteristics
  - Design characteristics

For each process function identified in item 10 one must list the corresponding failure of the function. There can be more than one failure from one function. To help identify the potential failure mode one may think of the negative or loss of the function.

Examples include:

- Fails to open
- Part leaking
- Broken
- No pressure
- Cannot control speed
• Hole is not round (eccentric)
• Part undersized, oversized, porous, damaged

Another way to identify the failure mode anticipated is by asking the following questions (partial list):

• How could this process fail to complete its intended function?
• Why could this part be rejected at this operation?
• What does the customer find unacceptable?
• How would the part not conform to specifications at this operation?

The emphasis is on the engineer, who must try to anticipate how the part being considered could possibly fail, not whether or not it will fail. Another way of identifying failure modes is through a review of warranty records, historical documentation, customer complaints, design FMEA, and any other applicable documentation.

**Potential Effect(s) of Failure (12).** A potential effect of the failure is the consequence of its failure on the next process, operation, product, customer, and/or government regulations. The questions usually asked are: “What does the customer experience as a result of the failure mode described?” or “What happens or what is (are) the ramification(s) of this problem or failure?” The consequences may be to the design itself, the product, the customer, and/or government regulations. Quite often, the failure effect is evaluated from a customer’s perspective or experiences.

To identify the potential effects, some of the documents one may review are:

• Historical data
• Warranty documents
• Customer complaints
• Field service data
• Reliability data
• Feasibility studies
• Similar current or past FMEAs (both process and design)

No matter how the potential effect(s) is (are) identified, the ramifications of the loss to the process function must be determined. Consideration
must be given to the process itself, other processes, the product, safety, government regulations, machines and equipment, and the customer (both the next and the ultimate). If safety considerations may be an issue, this is the column where the appropriate notation should be made. Examples of potential effect of failure may be:

- Next process: fails to open
- Subsequent operation: cannot position part correctly
- Other operation(s): none
- Part: part function incomplete
- Product: poor performance
- Customer: complete dissatisfaction; product incomplete
- Government: may not comply with STD-XXX

Note: A special consideration for the effects of the failure is that the process engineer must interface with the design engineer to correctly describe the effect(s) of a potential process failure on the component, process, or assembly (Bass 1991; Blanchard 1986).

**Critical Characteristics (13).** Critical characteristics usually are associated with design FMEAs because the hardware begins to be formalized in the design stage. However, even in the design FMEA they remain as “potential critical characteristics.” On the other hand, it is in the process FMEA that critical and or significant characteristics become formally defined as such. In other words, in the process FMEA, the critical characteristics become of paramount importance because they define the process requirements, sequences, tooling, and anything that can affect the customer or government regulations (Chrysler 1986; Ford 1988, 1989, 1992, 2000; General Motors 1988; AIAG 2001).

The critical characteristic column applies only when compliance with the government regulations, safety, and engineering specifications for the product and/or process is of concern.

The identification of the criticality or significance in the process FMEA is only to designate special controls for the process, assembly, and/or service FMEA. From here they are transferred to the control plan.

Examples of possible critical items may be:

- Dimensions
- Tests
- Tooling
- Specifications
- Processes
- Usage
Critical characteristics are identified when:

- Process requirements can affect safety.
- Process requirements can affect compliance with government regulations.
- Process requirements are necessary for special actions/controls.

The entry to this column is a “Y” for yes, or “N” for no, or a notation symbol (in other words, inverted delta). Its purpose is to flag a potential critical characteristic which may or may not exist. A good indication of criticality is when severity is rated 9 or 10 with occurrence and detection higher than 3.

**Severity of Effect (14).** Severity is a rating indicating the seriousness of the effect of the potential process failure mode. The severity always applies to the effect of a failure mode. In fact, there is a direct correlation between effect and severity. For example, if the effect is critical, the severity is high. On the other hand, if the effect is not critical, the severity is very low.

The severity is reviewed from the perspective of the system, design itself, other systems, the product, the customer, and/or the government regulations. For evaluation purposes there usually is a rating table that reflects the issues of the organization in conjunction with the customer and/or the government regulations. An example of such rating may be seen in Table 7.1.

In the process FMEA the severity rating should be based on the worst effect of the failure mode. When complete, rank the failure modes on the basis of the severity of their effects. At this point the FMEA is identical to the FMCA.

**Potential Cause(s) of Failure (15).** The cause of a process failure mode is the process deficiency that results in the failure mode. It must be emphasized repeatedly that when one focuses on the cause(s) one must look at the root cause, not the symptom of the failure.

To do a good job of proper potential cause(s) of failure identification, one must understand both the design and process and ask the appropriate questions. Specificity is essential. The more one focuses on the root cause, the better one understands the failure. For example, questions such as “Would inadequate venting and gauging cause misruns, porosity, and leaks?” or “Would inefficient die cooling cause die hot spots?” must be asked. Some of the techniques that may be used are brainstorming, FTA, cause-and-effect analysis, analysis of the block diagram, and affinity charts.

The basic question is “In what way can this system fail to perform its intended function?” Another method is to ask five whys in a row. The rationale for this is that it progressively becomes a more difficult and thought-provoking assignment to identify the whys. The early questions are
**Table 7.1** Severity process and/or service guidelines.*

<table>
<thead>
<tr>
<th>Rank</th>
<th>Description</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Minor: Unreasonable to expect that the minor nature of this failure would cause any real effect on the product and/or service. Customer will probably not even notice the failure.</td>
<td>If the numerical value falls between two numbers, <em>always</em> select the higher number. If the team has a disagreement in the ranking value, the following may help.</td>
</tr>
<tr>
<td>2–3</td>
<td>Low: Low severity ranking due to nature of failure causing only a slight customer annoyance. Customer probably will notice a slight deterioration of the product and/or service, a slight inconvenience in the next process, or minor rework action.</td>
<td>1. If the disagreement is an adjacent category, average out the difference. For example, if one member says 2 and someone else says 6, the ranking in this case should be 4 (2 and 6 are adjacent categories. Therefore $2 + 6 = 8, \frac{8}{2} = 4$).</td>
</tr>
<tr>
<td>4–6</td>
<td>Moderate: Moderate ranking because failure causes some dissatisfaction. Customer is made uncomfortable or is annoyed by the failure. May cause the use of unscheduled repairs and/or damage to equipment.</td>
<td>2. If the disagreement jumps one category, then consensus must be reached. Even with one person holding out, total consensus must be reached. No average, no majority. Everyone in that team must have ownership of the ranking. They may not agree 100 percent, but they can live with it.</td>
</tr>
</tbody>
</table>

*All of the above guidelines and rankings may be changed to reflect specific situations.*

(Continued)
<table>
<thead>
<tr>
<th>Rank</th>
<th>Description</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>7–8</td>
<td>High: High degree of customer dissatisfaction due to the nature of the failure such as an inoperable product or inoperative convenience. Does not involve safety issues or government regulations. May cause disruptions to subsequent processes and/or services.</td>
<td>If the numerical value falls between two numbers, always select the higher number.</td>
</tr>
<tr>
<td>9–10</td>
<td>Very high: Very high severity is when the failure affects safety and involves noncompliance with government regulations.</td>
<td>1. If the disagreement is an adjacent category, average out the difference. For example, if one member says 2 and someone else says 6, the ranking in this case should be 4 (2 and 6 are adjacent categories. Therefore $2 + 6 = 8, \frac{8}{2} = 4$).</td>
</tr>
<tr>
<td></td>
<td>Very high severity ranking when safety issues are involved or compliance to government regulations is ignored.</td>
<td>2. If the disagreement jumps one category, then consensus must be reached. Even with one person holding out total consensus must be reached. No average, no majority. Everyone in that team must have ownership of the ranking. They may not agree 100 percent, but they can live with it.</td>
</tr>
</tbody>
</table>

*All of the above guidelines and rankings may be changed to reflect specific situations.*
superficial, but the later ones are more substantive. Two other questions that may be asked are “What circumstances could cause the failure?” and “How or why can the part fail to meet its engineering specifications?”

A failure mode can be caused by one or more individual components or by (partial list):

- Hardware failure due to inadequate product design
- Improper selection of component parts
- Improper use of processes
- Inadequate control procedures
- Failure to enforce process and quality controls
- Improper installation, maintenance
- Lack of safety devices, environmental factors
- Misuse, abuse
- Alteration of the product
- Improper operating instructions
- Human error
- Improper choice of materials
- Stress concentrations
- Fatigue
- Corrosion, galvanic corrosion, uniform attack, crevice corrosion
- Hydrogen damage, pitting, blistering
- Decarbonization, abrasion and wear, shock and vibration
- Interaction with other components
- Interaction with components of other systems
- Interaction with the government
- Interaction with the customer

At this point, it must be emphasized that a major benefit of the process FMEA is the identification of potential failure modes caused by process and/or component interactions. These interactions also may involve human factors and as such they must be reviewed thoroughly.
The relationship between the failure mode and the cause(s) is not linear or one-to-one. Do not be surprised if there are several if not many causes for one failure mode. (Sometimes a one-to-one relationship exists.) List as many causes as possible—all of them. These causes may be transferred to the product or assembly FMEA as potential failure modes. Therefore, the more causes identified in the process FMEA, the easier the product and/or assembly FMEA becomes.

Examples of failure causes include:

- Torque too high or low
- Air pressure too high or low
- Cure time too short or long
- Tool worn
- Speed not constant
- Human error

Note: If the effect of the failure is rated 8 through 10, special effort should be made to identify as many root causes as possible.

**Occurrence (16)**. Occurrence is the rating value corresponding to the estimated number of frequencies and/or cumulative number of failures that could occur for a given cause over a given quantity of parts produced with the existing controls. (Usually, this is given to the process from the life of the design.) To identify the frequency for each of the causes one may use reliability mathematics (beyond the scope of this book), use the expected frequencies, or use a cumulative number of component failures (CNF) per 100 or 1000 components (CNF/100 or CNF/1000, respectively) over the design life of the component under study. Design life was explained in Chapter 6.

Another way to help identify occurrences is the target (goal) period or useful life after which the component is discarded because it (1) ceases to function as designed (normal wear) and/or (2) is too expensive to repair.

If expected occurrences and/or cumulative number of failures cannot be estimated, it is acceptable for the process FMEA to study similar or surrogate processes and/or components for similar information.

Generally, the process FMEA operates under the assumption of single-point failure (in other words, if the component fails the system fails). A single-point failure is defined as a component failure that would cause the system failure and which is not compensated by either redundancy or an alternative method. For example, single pieces of hardware and heavily loaded cable runs that place a high degree of dependence on single components
usually can be avoided through the use of redundancy. In this case, the installation of duplicate cables into a heavily loaded area (with terminals intermingled on one of the two cables), can minimize service disruption in the event of a cable cut.

When the occurrence/frequency is calculated, it is imperative that it must be for every single cause of the failure. If it cannot be estimated, then the occurrence should be entered as 10. It also must be a consensus agreement of the entire team. There are a variety of ways to generate occurrence guidelines. A typical occurrence guideline is shown in Table 7.2.

Occurrence ratings also could be selected based on:

- FITS scale—1 FIT equals approximately 1 occurrence per 109 hrs
- $C_{pk}$—If variable data are available and the process is in statistical control
- Cumulative failure data—If attribute data are available
- Subjective criteria—If no data are available (the evaluation becomes very subjective)

For failures that typically exist in the semiconductor industry, it is not unusual to encounter instances where only one data point of a test is known. Such is the case in “so many device-hours of testing resulting in a certain number of failures at one temperature.”

Eachus (1992) explains the procedure to follow in this case, by assuming (1) the Arrhenius equation and (2) an activation energy in lieu of any known value. Then use the Chi-square distribution to ascertain with a certain probability $F$ that the failure rate is less than a certain value given device-hours of testing and number of failures.

Another option in the semiconductor industry (because failure rates are inherently low) is to use a scale expressed as percent per thousand hours or failures per billion device hours (FITS). FITS scale—1 FIT approximately equals 1 occurrence per 109 hrs.

**Detection Method; Process Verification/Validation; Existing Control (17).** A method (procedure), test, or an engineering analysis. These are some of the first-level methods to detect or prevent a failure in the process, part, or in subsequent operations, and/or the customer. They can be very simple (brainstorming, audits, sampling based on statistical techniques) or very technical and advanced (finite element analysis, military standards, computer simulation, and laboratory tests). In either case, the focus is on the effectiveness of the control method/technique to catch the problem before it reaches the customer.
### Table 7.2 Occurrence process and/or service guidelines.*

<table>
<thead>
<tr>
<th>Rank</th>
<th>Description</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Remote probability of occurrence. Capability shows at least X-bar $\pm 3\sigma$ within specifications (1/10,000).</td>
<td>If the numerical value falls between two numbers, always select the higher number.</td>
</tr>
<tr>
<td>2–5</td>
<td>Low probability of occurrence. Process in statistical control. Capability shows at least X-bar $\pm 3\sigma$ within specifications (1/5000–1/500).</td>
<td>If the team has a disagreement in the ranking value, the following may help.</td>
</tr>
<tr>
<td>6–7</td>
<td>Moderate probability of occurrence. Process in statistical control with occasional failures, but not in major proportions. Capability shows more than X-bar $\pm 2.5\sigma$ within specifications (1/20–1/200).</td>
<td>1. If the disagreement is an adjacent category, average out the difference. For example, if one member says 2 and someone else says 6, the ranking in this case should be 4 (2 and 6 are adjacent categories. Therefore $2 + 6 = 8, \frac{8}{2} = 4$). 2. If the disagreement jumps one category, then consensus must be reached. Even with one person holding out total consensus must be reached. No average, no majority. Everyone in that team must have ownership of the ranking. They may not agree 100 percent, but they can live with it.</td>
</tr>
<tr>
<td>8–9</td>
<td>High probability of occurrence. Process in statistical control with failures often occurring. Capability shows X-bar $\pm 1.5\sigma$ (1/100–1/20).</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Very high probability of occurrence. Failure is almost certain. (1/10+).</td>
<td></td>
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</tbody>
</table>

Note: To use a criteria scale such as this, one must have a substantial amount of data to support statistical control and $C_{pk}$ values. This is a very powerful scale if one has the data; if not, do not try to generate the data to support the scale. Use a theoretical scale which is more qualitative but through the synergy of the team becomes just as powerful.

*All of the above guidelines and rankings may be changed to reflect specific situations.
The only controls for the process FMEA that should be considered are those that will contribute to the estimation of the detection rating. Controls intended to prevent or reduce the occurrence of the cause of the failure should be considered when estimating the occurrence rating.

The objective is to detect a process deficiency as early as possible. That deficiency may be viewed as a weakness in the process to reveal, detect, or eliminate the problem from the process (Chien 1985). The idea of early detection in the process FMEA is to provide efficient manufacturing and/or product controls.

Because the process FMEA is done very early, it is sometimes very difficult to assess the detection rating. In these cases one may use historical information or similar types of information from similar processes and/or components. In some cases, it is possible to have no method, test, or technique to identify the failure. In that case, the entry in this column should state something like “None identified at this time.”

Another way of focusing on the detection is to use the brainstorming technique to identify new methods and tests as they apply to the task at hand. Two of the leading questions in the brainstorming process should be:

- How can this failure be discovered?
- In what way can this failure be recognized?

Some of the most effective ways to detect a failure are:

- Proven simulation techniques
- Mathematical modeling
- Prototype testing
- Design of experiments
- Process verification testing
- Specific product testing
- Tolerance stack-up studies

Typical controls may include:

- Probabilistic, reliability, and statistical modeling and testing as required.
- Reviewing test results, examining safety margins, evaluating material selections, and auditing tooling and manufacturing processes.
• Checklists for completeness of the documentation. A checklist may provide a last check of the functions, features, producibility compliance to the appropriate standards, operator misuse, profitability, and safety of the manufacturing process.

A typical checklist may include the following:

• Define product in its use environment.
  – What are the product’s uses?
  – What are the foreseeable environments of use?
  – Describe the skill and capability of foreseeable users.

• Identify safety and assess risk.
  – What are the hazards?
  – Estimate the probability of occurrence and seriousness of resulting harm for each hazard.

• Evaluate alternatives.
  – What alternative process features or production techniques are available, including warnings and instructions, that can be expected to reduce or eliminate safety issues?
  – Evaluate alternative process/product by considering the following:
    a. Characteristics and comparisons of different products
    b. Other safety issues that may be introduced by the alternative process
    c. Their effect on the usefulness of the product
    d. Their effect on the ultimate cost of the product

In the case of human errors, a detection method may be developed based on MIL-STD-1472c and Woodson’s (1981) list with the following criteria (partial list):

• Control and display integration
  – Controls and displays should be together.
  – Controls and displays with similar functions should be grouped.
  – Displays should reflect the proper direction for control movement.

• Visual displays
  – Visual displays should provide only the information necessary for the operation of a system.
  – Critical displays should be located in the operator’s optimum viewing area.
– Indicator lights must follow certain standard color codes.
– Figure size must be based on operator viewing distance.

• Audio displays
  – Audio signals must be of a frequency and amplitude that can be heard in the operating environment.
  – The frequency response and range must be appropriate for the working environment.

• Controls
  – Control movements must relate to standard norms and to the direction of movement of the equipment that they control.
  – Controls should be arranged in the sequence in which they are used.
  – Control color coding standards should be followed.
  – Controls should be coded by shape, color, size, and location.

• Labels/warnings
  – Labels/warnings should be readable and understandable under foreseeable operating conditions by the expected users.
  – Labels and warning must, where appropriate:
    1. Identify the fact that there is a safety problem
    2. Indicate the level of safety problem
    3. Indicate the likelihood of the safety issue resulting in harm
    4. Explain how to avoid the safety issue
    5. Describe the consequences of the safety issue if the warning is not heeded

• Anthropometry
  – Equipment should be designed to accommodate the full range of potential users.

• Operating area criteria
  – Controls must be placed within the reach of the operator.
  – Design criteria must exist for standing/seating operator.
  – Design criteria must exist for operator’s seat and control console.

• Environmental process criteria
  – Heating, ventilating, air conditioning, and humidity standards for safe and efficient job performance
- Proper illumination
- Proper noise levels
- Proper vibration and acceleration limits

- Maintainability process criteria
  - Accessibility criteria
  - Weight limitations

- Checklists
  - Specific checklists for specific functions

Detection (18). Detection is a rating corresponding to the likelihood that the current process controls will detect a specific root cause of a failure mode before the part leaves the manufacturing area. To identify a detection rating one must estimate the ability for each of the controls identified in item 17 to detect the failure before it reaches the customer. The assumption here is that the failure has occurred.

In addressing detection issues in the process FMEA, three items are very important:

1. Do not make the assumption that the detection should be low, just because the occurrence is low. The two ratings may or may not be correlated with each other for this particular item.

2. If 100 percent automatic gauging is listed as a control (for example, x-ray gauging in the steel industry) or 100 percent voltage output in motor testing (for example, in automotive and computer industry) the FMEA team must consider the effectiveness based on:
   - Condition of the gauge
   - Condition of the testing equipment
   - Calibration of the gauge and testing equipment
   - Variation of gauge and testing equipment (based on repeatability and reproducibility study—R&R)
   - Likelihood that the system will fail or be bypassed

3. If 100 percent visual, as opposed to automatic (for example, process controller, brush recorders, artificial vision, and so on), inspection is listed, the FMEA team must consider the effectiveness based on:
   - One hundred percent visual inspection is only 79 percent to 100 percent effective depending on inspector and conditions of inspection.
• Who may perform the inspections? How is the consistency of evaluation going to be monitored?
• The nature of the failure. Is the failure obscure, where a very high level of inspection ability is required—either through training and/or experience, or is the failure so obvious that anyone can identify it?

If the ability of the controls to detect the failure is unknown or the detection cannot be estimated, then the detection rating should be 10. A typical detection guideline is shown in Table 7.3.

**Risk Priority Number (RPN) (19).** This number is the product of severity, occurrence, and detection. The RPN defines the priority of the failure. By themselves the RPNs have no value or meaning. They are used only to rank (define) the potential process deficiencies.

In the process FMEA, one must always remember that the goal is to reduce the RPN, but in a specific way. The specific way is through a reduction in:

• Severity (if design actions have been taken)
• Occurrence
• Detection

The severity can be reduced only through a change in design. If that is attainable, then the failure is eliminated.

The occurrence can be reduced by improving engineering specifications and/or requirements in the process with the intent of preventing causes or reducing their frequency. The detection can be reduced by adding or improving evaluation techniques or increasing sample size, and/or adding detection equipment. The result will be improvement in the ability to detect the failure before it reaches the customer.

**Recommended Action (20).** No FMEA should be done without a recommended action. The recommended action may be specific action(s) or it may be further studying. The idea of the recommended action in the design FMEA is to reduce the severity, occurrence, detection, or all of these actions. In essence, the design FMEA is performed to eliminate design deficiencies and therefore eliminate failures.

To facilitate this goal, the FMEA team must prioritize those failure modes with the highest RPN, the highest severity, the highest occurrence. Typical recommendations may be:

• No action at this time.
• Add built-in detection devices.
Table 7.3  Detection process and/or service guidelines.*

<table>
<thead>
<tr>
<th>Rank</th>
<th>Description</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Very high: Controls almost certainly will detect the existence of a defect.</td>
<td>Remote likelihood that the product or service will be delivered (1/10,000). The defect is functionally obvious and readily detected. Detection reliability at least 99.99 percent.</td>
</tr>
<tr>
<td>2–5</td>
<td>High: Controls have a good chance of detecting the existence of a failure.</td>
<td>Low likelihood that the product would be delivered with the defect. The defect is obvious (1/5000–1/500). Detection reliability at least 99.80 percent.</td>
</tr>
<tr>
<td>6–8</td>
<td>Moderate: Controls may detect the existence of a defect.</td>
<td>Moderate likelihood that the product will be delivered with the defect. The defect is easily identified (1/200–1/50). Detection reliability at least 98.00 percent.</td>
</tr>
<tr>
<td>9</td>
<td>Low: Controls more likely will not detect the existence of a defect.</td>
<td>High likelihood that the product would be delivered with the defect. The defect is subtle (1/20). Detection reliability greater than 90 percent.</td>
</tr>
<tr>
<td>10</td>
<td>Very low: Controls very likely will not detect the existence of a defect.</td>
<td>Very high likelihood that the product and/or service will be delivered with the defect. Item is usually not checked or not checkable. Quite often the defect is latent and would not appear during the process or service (1/10+). Detection reliability 90 percent or less.</td>
</tr>
</tbody>
</table>

*All of the above guidelines and rankings may be changed to reflect specific situations.

Resolution

If the numerical value falls between two numbers, always select the higher number.

If the team has a disagreement in the ranking value, the following may help.

1. If the disagreement is an adjacent category, average out the difference. For example, if one member says 2 and someone else says 6, the ranking in this case should be 4 (2 and 6 are adjacent categories. Therefore $2 + 6 = 8$, $8/2 = 4$).

2. If the disagreement jumps one category, then consensus must be reached. Even with one person holding out total consensus must be reached. No average, no majority. Everyone in that team must have ownership of the ranking. They may not agree 100 percent, but they can live with it.
• Provide alternatives to the design.
• Add redundant subsystem.

**Responsible Area or Person and Completion Date (21).** Identify the responsible person/area and the target completion date for the recommended action.

**Action Taken (22).** This is the follow-up. Just because something was recommended, does not mean that something was done. It is imperative that someone (usually the process engineer) follow up on the recommendations to see if they have been addressed adequately, properly, and/or if they are in need of updating.

Note that all FMEAs are living documents and as such someone must be responsible to update them. Often the person who is responsible is the process engineer. That person has the responsibility to make sure that the process FMEA is a living document and reflects the latest relevant information and actions.

After the action has been taken, the effective date or completion date with a brief description of the action should be entered.

**Revised RPN (23).** After the actions are incorporated in the process, the FMEA team should reevaluate the consequences of severity, occurrence, and detection. The results should be reviewed by the FMEA team and a new RPN calculated and the failures ranked. This process is repeated as needed until such time as the FMEA team decides that all relevant information has been covered. If no actions are taken, these columns will remain blank.

Generally, the anticipated changes with the process FMEA are in the area of occurrence and detection. The severity remains the same. For the severity to change, the following must take place.

• As part of the root cause analysis, it was identified that the failure was caused by a design issue.
• The recommended action was to change the design based on the findings of the cause analysis.
• The design changes were implemented as recommended or modified.

At this point, the result is that the ratings (occurrence, severity, and detection) may all change, or some will change, or none will change.

**Approval Signatures (24).** Define the authority to carry out the FMEA. The names and titles will depend on the organization. Typical names may be those of the design and engineering manager.
Concurrence Signatures (25). Define the responsibility of carrying out the completion and implementation of the FMEA. The names and titles depend on the organization. Typical names may be those of the plant manager, manufacturing manager, and quality assurance manager.

**RECOMMENDED TEAM**

To perform a process FMEA, a team is necessary. The team makeup should be five to nine individuals with multidisciplined and multifunctional backgrounds. In addition, all members should have ownership of the problem (Stamatis 1992). A typical team may include the following:

- Quality engineer
- Reliability engineer
- Tooling engineer
- Process engineer (mandatory)
- Design engineer (mandatory)
- Responsible operators from all shifts (mandatory)

Other recommended participants may be:

- Marketing representatives
- Material engineer
- Field service engineer
- Product engineer

Note that there is no such thing as the team. A team is made to reflect the needs and requirements that the problem and culture of the organization requires.

**REFERENCES**


Service FMEA

A service FMEA is a disciplined analysis/method of identifying potential or known failure modes and providing follow-up and corrective actions before the actual (first) service. A first service run is viewed as the act (service) that is performed for a specific customer as part of the everyday operation. This definition of the first service is important because it excludes trial and training runs. The threshold of the first service run is important, because up to that point, to modify and/or change the service generally is not a major event. At the point of the true first service, process and procedure validation is defined and the customer has a very important role in defining the service, process, product, procedure, and so on. After that point, however, the customer gets involved through the complaint letter, adjustment of services, or some other kind of formal notification, or perhaps discontinuance of the service due to dissatisfaction.

A service FMEA usually is accomplished through a series of interactions that include labor, machine, method, material, measurement and environment considerations. Of course, each one of these components has its own parts, which may react individually, in tandem, or as an interaction to create a failure. Because of this convolution, to perform a service FMEA is complicated and time-consuming. Often an iteration of the service is required to identify the root cause of the failure. This is shown in Figure 8.1.

The list of applications of a service FMEA is too long to list. A service FMEA, however, may be done in any situation for any industry that provides a service. Some examples include:

- **Maintenance contractors**—May perform FMEAs to identify preventive maintenance cycles of repair, as well as possible trouble spots in the machinery under contract (Regalyi 1990; Bass 1991).
Financial institutions—May perform FMEAs to identify the degree of effectiveness of their services, as well as to focus on issues that present uniqueness for the customer (in other words, loan approvals, verification of funds transfer advice, bad loans, mispostings, transfer errors, encoder problems, wrong placement of magnetic ink character recognition (MICR) codes) (Latzko 1986).

Law firms—May perform FMEAs to identify or track the logic of witness preparation or answers from the witness of the other side.

Organizations that deal with safety and hazardous issues—FMEAs may be performed to identify not only the problems, the consequences, and the effects, but also to anticipate and plan accordingly for the failure. When used in conjunction with an FTA and/or hazard analysis, the service FMEA (in this case) becomes a powerful technique to resolve the safety and hazard issues (Bass 1986).

Note: It is not unusual to have an iteration of the causes in a service FMEA. The flow of the iteration is demonstrated. The iteration stops when the RPN is sufficiently low—less than 50 in a 1 to 10 guideline scale.

Figure 8.1 The relationship of a service FMEA in an iteration mode of failure identification.

- Financial institutions—May perform FMEAs to identify the degree of effectiveness of their services, as well as to focus on issues that present uniqueness for the customer (in other words, loan approvals, verification of funds transfer advice, bad loans, mispostings, transfer errors, encoder problems, wrong placement of magnetic ink character recognition (MICR) codes) (Latzko 1986).

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• All engineering contractors—May perform FMEAs to identify the problems and concerns that their service may provide to the customer (Blanchard and Lowery 1969; Blanchard 1986).

• Hospitality industry (hotels/motels/resorts and restaurants)—May perform FMEAs to identify specific problems and consequences in their service (in other words, employees not friendly, poor overall service, morning wake-up call not made, slow check-in/check-out, high employee turnover, poor housekeeping, cold food when served (should be hot)) (Hall 1990).

• Government and educational institutions—May perform FMEAs to focus on poor service to their customer (in other words, traffic control signs, playground and play areas, information signs, sidewalks, budgetary issues, poor resource utilization, retention of students, scheduling human resources, classes too crowded, tuition too high, low/high enrollment) (Lefevre 1992; Spanbauer 1992).

• Health care—May perform FMEAs to define the consequences of known and/or potential problems before they happen (in other words, unplanned return to the operating room on same admission, medicine errors, death, patient/family dissatisfaction issues, postoperative complications) (Sloan and Chmel 1991; Pozgar 1993).

The service FMEA is an evolutionary process (dynamic as opposed to static) involving the application of various technologies and methods to produce an effective process output. This result is a defect-free service.

The selection of appropriate technologies may include the customer’s request, the utilization of existing system(s), standardized approaches, and/or procedures currently known or proposed, results of directed research, and/or a combination of all the above.

Effective service FMEA is basically realized through the active participation of customer service, service (product) development, research, quality assurance, marketing, operations, or a combination of all these entities. Thus, the focus of the service FMEA is to minimize process failure effects on the service (system), regardless of what level of FMEA is being performed.

This can be realized through a specific definition of the service specifications and a good understanding of what the service will provide. For the understanding of design specifications, Griffiths (1990) and Stamatis (1992, 1992a) suggest a look at (partial list):

Benchmarking—A way to identify what the competition is doing and how to incorporate the best into the organization. The way to being a world-class organization.
Quality function deployment—The way to identify the needs, wants, and expectations of the customer. The voice of the customer.

Market research—The way to identify the market’s need through mathematical modeling and surveying.

Focus groups—The way to identify how the customer will react to a service/product offered by an organization.

Total unduplicated research and frequency (TURF) analysis—A way to plan optimization of service/product lines or to provide guidance for possible line extensions in service and/or product. Generally, it offers reliable, cost-effective guidance to research and marketing decisions. TURF analysis may be conducted as a stand-alone service/product or integrated into more comprehensive service/product line (Cohen 1993).

Conjoint analysis—A way to decompose the total evaluation score into components relating to each attribute or to combinations of the attributes and to measure these components. This method is suitable for design of services, as well as to determine the optimum mix or portfolio of services/products (Sheth 1977).

Quality measuring systems (QMS)—A way to define what to measure. It can be useful in giving the people involved a better sense of their operations as well as an insight into a problem area that was not clearly understood (Pfeifer 1991).

By definition, a service dictates some kind of friendly action and/or conduct in the process of a given activity (in other words, friendly conduct in the process of providing any professional service). In understanding the service, however, the following may be helpful.

Service involves the utilization of six components: labor, machine, method, material, measurement, and environment. The goal of this is the production of an end item that meets or exceeds the safety and quality characteristics of the defined service (Welch and Geissler 1992). An integral element of the service documentation should be the design specifications. It is difficult to do a thorough service FMEA without the completion or at least some information of a design specification as defined or expected from the customer.

It is very difficult to evaluate the entire service, especially in the early stages or initiation of the service. In most cases, the reality is that the service evaluation develops over time and as such the service FMEA becomes a living document (dynamic as opposed to static) to reflect the changes of the service.
Generally, there are two basic types of service evaluation techniques that are utilized in the early stages:

1. **Process capability studies**—Such studies are used to determine the inherent capability of specific elements of the service. Examples include machine acceptance capability, process potential study (short-term capability), and long-term capability. The questions usually are “Can this service be provided?” and “How can the organization provide this service?”

2. **Mandatory service evaluation**—As previously pointed out, it is difficult to evaluate all service parameters. Thus, each company establishes mandatory evaluation points for specific variables that are critical to the service and/or the customer. They may be helped in this identification by:
   - Customer requirements
   - Government regulations
   - Internal guidelines
   - Design specifications
   - Industry standard/guidelines
   - Generally accepted practices

Some of the evaluation points may be:

- **Certification of personnel**—Certification may be necessary for critical skills (in other words, cashiers, loan officers, nurses).

- **Tool verification**—Tools, jigs, and fixtures may be required to be validated (in other words, cashing machines, CAT scan machines, x-ray machines, check-decoding machines).

- **Critical process**—Most critical processes as defined by safety, customers, general practices, or government regulations require evaluation and prior approval (for example, practically all drug and medical device processes; authorization for deposit or withdrawal of funds).

- **Test operation**—Most complex testing operations require review and approval to ensure accuracy.

The goal, purpose, and/or objective of the service FMEA is to define, demonstrate, and maximize solutions in response to quality, reliability, maintainability, cost, and productivity as defined by the design specifications and the customer.

To accomplish this objective the service FMEA must base its requirements on solid needs, wants, and expectations of the customer. As a general
rule that information may be the result of a QFD (preferred), an internal need for improvement, the results of benchmarking (Trace 1993), or some other input.

In any case, one of the first steps in conducting the FMEA should be to include a feasibility study and/or a risk-benefit analysis directed toward defining a set of useful solutions to the problem(s) being addressed. The objective of this early (not definitive) stage is to maximize the service quality, reliability, cost, productivity, and maintainability, regardless of what level the FMEA is being performed. This can be accomplished by the following considerations:

1. Transform an operational need as defined by the design specification into a description of service performance parameters and as perfect as possible service configuration through the use of an interactive service of functional analysis, synthesis, optimization, definition, test, and evaluation.

2. Integrate related technical parameters and ensure compatibility of all physical, functional, and program interfaces in a manner that optimizes the total service definition and delivery of that service.

3. Integrate reliability, maintainability, human factors, safety, security, structural integrity, producibility, and other related specialties into the total service effort.

The outcome of the service FMEA is a service (it may change with new or modified information) with a baseline configuration and functional specifications toward translating the established requirements into detailed qualitative and quantitative service characteristics. Some of the generic concerns in a service FMEA include:

**General Concerns**

- Service operational requirements defined
- Effectiveness factors established
- Service maintenance concept defined
Support Elements

In this area one must do a thorough investigation as to whether or not the requirements are known and/or can be optimized for:

- Test and support equipment
- Personnel and training
- Repair and spare parts

Service Features

- Standardization
- Interchangeability
- Controls
- Transportability
- Safety
- Software
- Test provisions
- Accessibility
- Technical data, procedures
- Producibility
- Reliability
- Traceability

Specific questions in the course of performing a service FMEA may be:

1. What is the true performance and effectiveness of the service?
2. What does the service do and what are its intended uses?
3. What is the true effectiveness of the support capability?
4. Are the initially specified requirements appropriate for the service? Are they being met?
5. How does the service perform its function?
6. What materials, and/or other services are used in the delivery of the service?
7. How, and under what conditions, does the service interface with other services (current or projected)?
8. What by-products are created by the service or by the delivery of this service?
9. How is the service used, maintained, modified, and discontinued at the end of its useful life?
10. What are the operational steps in the delivery of the service?
11. What energy sources are involved and how?
12. Who will use or be in the vicinity of the service?
13. What are the capabilities and limitations of these individuals?
14. Is the service cost-effective?

Finally, when conducting a service FMEA, it is assumed that the design specifications are the best they can be. If this assumption is not made, the FMEA team will end up doing the design specifications and service FMEAs simultaneously and will move in a circular pattern not accomplishing its task. The only way to address the design specifications in the service FMEA is when the root causes of the failure modes in the service are caused by the design specifications.

**STEP-BY-STEP SERVICE FMEA ANALYSIS**

There are two requirements to perform a service FMEA. The first requirement is identification of the appropriate form. The second requirement is identification of the rating guidelines.

The form for the service FMEA is not universal or standardized. Each company has its own form that reflects the needs of the organization and the concerns of the customer.

This section addresses a form to illustrate the generally accepted items that should be addressed as part of a service FMEA. On the CD, Appendix E includes various FMEA forms that apply to service applications. Remember, there is no such thing as the service FMEA form.

The rating guidelines also are not universal or standardized. Each company has its own guidelines to reflect the needs of the organization, the product, and the concerns of the customer.

Generally, there are two ways that the rating guidelines can be formulated—qualitative and quantitative. In either case the numerical values can be from 1 to 5 or 1 to 10, with the 1 through 10 range being the most common. Again, there is no common rating guideline for the system FMEA. This section addresses the two different guidelines.

Figure 8.2 shows the most common service FMEA form. The form is divided into three parts. The first part, items 1 through 9 reflect the introduction of the form. None of the items are mandatory, but they contribute additional information to the task of the service FMEA and provide essen-
### Figure 8.2  A form for service FMEA.
tial information that may be needed in the course of writing and/or completing the FMEA.

The second part of the form includes items 10 through 23. These are mandatory items for any service FMEA. The order of the columns may be changed, more columns may be added, but none of the columns presented may be removed. Items 10 through 23 may be viewed as the body of the service FMEA.

The third part of the form, items 24 and 25, includes the signatures. Although they are not mandatory, they do reflect the authority and responsibility of the team to undertake the project of writing the service FMEA. The signatures may be viewed as the closure of the FMEA. All numbers in parentheses are coded numbers for the discussion of the form.

**Service Identification (1).** Identify the service name or reference numbers or service codes as appropriate.

**Service Responsibility (2).** Name the primary responsibility for the service (machine, material, and so on). Enter the name of the activity responsible for the service, if appropriate. This is used strictly for a cross-reference point to other services.

**Person Responsibility (2a).** Sometimes it is necessary to name the person who is responsible for the service FMEA.

**Involvement of Other Areas (3).** Identify other persons or activities (within the organization) that are affected or are involved in the service.

**Involvement of Suppliers or Others (4).** Name other persons, suppliers, and/or plants (outside the organization) that affect the service and are involved in the definition and/or the delivery of the service.

**Release Date (5).** Identify the date (Mo-Day-Yr) that the service is scheduled to be released.

**Key Service Date (6).** Identify milestone dates (Mo-Day-Yr) (in other words, dates for specific reviews, date for initial trial, and so on).

**Prepared by (7).** Generally, the name of the responsible person for the service FMEA is identified. Sometimes, additional information, with an attachment, also is recorded such as:

- Telephone number of the system design engineer
- Address of the system design engineer
- Organizational activity (in other words, division, department, and so on)
- Team members (name, telephone, address, and so on)
FMEA Date—Original (8). Record the date (Mo-Day-Yr) of the initiation of the service FMEA. The starting date.

FMEA Date—Revision (9). Record the date (Mo-Day-Yr) of the latest revision.

Service Function (10). The facilitator writes the intent, purpose, goal, or objective of the service. The service function must be derived from the design specifications and describe what the service is now, not what it should be.

Generally, the service function is identified with a process flow diagram followed by a task analysis. The process flow diagram identifies sequentially the flow of operations among personnel and the interaction among personnel and major equipment components.

The task analysis serves as the basis of workload analysis by defining the specific sequence of tasks that each person in the service must perform. This step is important because inefficient distribution of workload can result in increased human error and subsequent safety or critical problems (Bass 1991).

Task analysis and task identification are not the same, nor can they can be used interchangeably. A task analysis defines:

- What initiates the task
- The equipment used to perform the task
- The human response
- The task feedback
- The characteristics of the task output, including performance requirements

Task identification defines the task through one or more of the following techniques:

- System analysis
  - Functional flow block diagrams
  - Decision/action diagrams
  - Functional allocation
  - Time lines
  - Time and motion analysis
  - Human reliability analysis
  - Operational sequence diagram

For the service function to be effective it must be identified in detail through a statement that is concise, exact, and easy to understand (no jar-
gon). The statement that is used to describe the function should be described in specific terms. To facilitate this, the writer of the FMEA should try to think of active verbs and appropriate nouns. The active verbs define performance and performance defines function. The combination of the active verb with the noun defines the relationship, consequently, the definition of the service becomes much easier.

Examples include:

- Provide 24-hour service.
- Service all TV models.
- Repair roofs.
- Provide tutoring in the home.

Another way to facilitate the formation of the function is to ask questions such as “What is the purpose, objective, function, goal of the service?” or “What is the service supposed to do?” If there is more than one purpose or function it is imperative that each should be identified separately because it probably will have different potential failure modes.

**Potential Failure Mode (11).** The problem. The concern. The opportunity to improve. The error/mistake. The failure. The reject. The defect. As mentioned earlier, a service defect (nonconformity) exists when the service does not meet the defined criteria of the design and/or the customer. Peters (1992) identified some of those criteria:

- **Usability**—Is the service usable? Does the service contribute utility in the organization? If yes, how? Can it be improved? If not, should it? Why not?
- **Signature, personality, distinction**—Is the service unique? How is it viewed by the customers and/or the competition? Are aesthetic considerations accounted for? If yes, how? If not, why not?
- **Attitude**—What is the attitude about the service from the customer’s, supplier’s, and employee’s perspective?

The contribution of failures based on these criteria for a given service has been identified by Peters (1992) through a regression analysis as:

- Reliability (30 percent). The ability to perform the promised service dependably and accurately
- Responsiveness (25 percent). The willingness to help customers and provide prompt service
• Assurance (20 percent). The knowledge and courtesy of employees and their ability to convey trust and confidence

• Empathy (16 percent). The caring, individualized attention provided to the customer

• Tangibles (7 percent). The appearance of physical facilities, equipment, personnel, and communication materials

Specifically, when one considers the potential failure mode one must think of the loss of a service function—a specific failure. The more specific one is, the better opportunity one will have to identify the effects and causes of the failure. Service failures occur when a service does not adequately protect against risks of injury, fails to perform intended functions safely (as defined by design specifications), or falls to minimize avoidable consequences in the event of an accident, avoidance of the service, and/or fails to deliver the expected service.

Generally, there are two categories of service failure modes. They are:

1. Evaluation (testing and/or inspection)
   – Accept or reject bad or good service respectively

2. Process
   – Relational concerns, misoriented services and/or missing services

For each service function identified in item 10 one must list the corresponding failure of the function. There can be more than one failure from one function. To help identify the potential failure mode think of the negative or loss of the function. Examples include:

• Bad service
• Poor communication
• Poor customer service
• Cashier not knowledgeable about returns

Another way of identifying the anticipated failure mode is by asking questions such as (partial list):

• How could this process fail to complete its intended function?
• Why can this part be rejected at this operation?
• What does the customer find unacceptable?
• How would the part not conform to specifications at this operation?
The emphasis is on the facilitator to try to anticipate how the service being considered could possibly fail, not whether or not it will fail. Another way of identifying failure modes is through a review of historical documentation, customer complaints, and any other applicable documentation.

**Potential Effect(s) of Failure (12).** A potential effect of the failure is the consequence of its failure on the next process, operation, product, customer, and/or government regulations. The questions usually asked are: “What does the customer experience as a result of the failure mode described?” or “What happens or what is (are) the ramification(s) of this problem or failure?” The consequences may be to the design itself, the product, the customer, and/or government regulations. Often, the failure effect is evaluated from a customer’s perspective or experience.

To identify the potential effects, some of the documents one may review include:

- Historical data
- Similar current or past FMEAs
- Customer complaints
- Field service data
- Reliability data
- Feasibility studies

No matter how the potential effect(s) is (are) identified the ramifications of the loss to the process function must be determined. Consideration must be given to the service itself, other processes, the product, safety, government regulations, machines and equipment, and the customer (both the next and the ultimate). If safety considerations may be an issue, this is the column where the appropriate notation should be made. Examples of potential effect of failure may be:

- Subsequent operation: “Nobody knows anything about it”
- Other operation(s): None
- Task: Task function incomplete
- Service: Poor performance
- Customer: Complete dissatisfaction; service incomplete
- Government: May not comply with STD-XXX

Note: A special consideration for the effects of the failure is that the maximum effect of the service FMEA can only be attained through truly open
communication of the team that is conducting the FMEA. This can be facilitated through multidisciplined and multifunctional team members.

**Critical Characteristics (13).** Critical characteristics usually are associated with design FMEAs because in the design stage the hardware begins to be formalized. In the service FMEA, however, the critical characteristics gain paramount importance because they define the service, process requirements, sequences, tooling, and anything that can affect the customer or government regulations.

The critical characteristic column applies only when compliance with the government regulations, safety and design specifications for the service, and/or process are of concern.

The identification of the criticality or significance in the service FMEA is only to designate special controls for the process and/or service FMEA. From this point they are transferred to the control plan.

Examples of possible critical items may be:

- Dimensions
- Specifications
- Tests
- Processes
- Procedures
- Usage

Critical characteristics are identified when (1) service requirements can affect safety, (2) service requirements can affect compliance with government regulations, and (3) service requirements are necessary for special actions/controls.

The entry to this column is a “Y” for yes, or “N” for no, or a notation symbol (in other words, inverted delta). Its purpose is to flag a potential critical characteristic that may or may not exist. A good indication of criticality is when severity is rated 9 or 10 with occurrence and detection higher than 1.

**Severity of Effect (14).** Severity is a rating indicating the seriousness of the effect of the potential service failure mode. The severity always applies to the effect of a failure mode. In fact, there is a direct correlation between effect and severity. For example, if the effect is critical, the severity is high. On the other hand, if the effect is not critical, the severity is very low.

Severity is reviewed from the perspective of the system, the service, other systems/services, the customer, and/or government regulations. For evaluation purposes there usually is a rating table that reflects the issues of
the organization in conjunction with the customer and/or the government regulations. An example of such a rating may be seen in Chapter 7, Table 7.1.

In the service FMEA, the severity rating should be based on the worst effect of the failure mode. When this is complete, rank the failure modes on the basis of the severity of their effects.

Blanchard (1986) suggests the severity for the service FMEA may be viewed from the following perspective:

**Category 1** *Catastrophic*—In this category, failure of the service may contribute to a disastrous result (for example, a last-minute witness on a murder case or an automatic teller machine gives out more money than it is coded for).

**Category 2** *Critical*—In this category, failure of the service may contribute to a major damage (for example, the deposit coupon of the mortgage payment was not read correctly by the computer).

**Category 3** *Marginal*—In this category, failure of the service may contribute to a minor damage (for example, the waitperson was not friendly).

**Category 4** *Negligible*—In this category, failure of the service may contribute to a nuisance rather than anything else (for example, vending machine does not provide change).

**Potential Cause(s) of Failure (15).** The cause of a service failure mode is the service deficiency that results in the failure mode. It must be emphasized repeatedly that when one focuses on the cause(s) one must look at the failure’s *root cause*, not the symptom.

To do a good job of proper potential cause(s) of failure identification, one must understand the service and ask the appropriate questions. Specificity is of paramount importance. The more one focuses on the root cause, the better one understands the failure. For example, questions such as “Would an inadequate promotion campaign cause the low turnover?” or “Would inefficient training cause misrouting of the documents?” must be asked. Some of the techniques that may be used are brainstorming, cause-and-effect analysis, analysis of the functional diagram, and affinity charts.

The basic question to ask is: “In what way can this service fail to perform its intended function?” Another method is to ask five *whys* in a row. This is because it becomes a progressively more difficult and thought-provoking assignment to identify the why's. The early questions are superficial, but the later ones are more substantive. Other questions that may be asked are: “What circumstances could cause the failure?” and “How or why can the service fail to meet its customer specifications?”
A failure mode can be caused by one or more individual components or by (partial list):

- Hardware failure due to inadequate product design
- Improper selection of component parts
- Improper use of processes
- Inadequate control procedures
- Failure to enforce process and quality controls
- Improper installation, maintenance
- Lack of safety devices, environmental factors
- Misuse, abuse
- Alteration of the service/product
- Improper operating instructions
- Human error
- Improper training
- Improper choice of materials
- Stress concentrations
- Interaction with other services/components
- Interaction with systems
- Interaction with the government
- Interaction with the customer

At this point, it must be emphasized that a major benefit of the service FMEA is identification of potential failure modes caused by the service itself and/or process interactions. These interactions may also involve human factors and must be reviewed thoroughly.

The relationship between the failure mode and the cause(s) is not linear or one-to-one. Do not be surprised if there are several causes for one failure mode. (Sometimes a one-to-one relationship exists.) List as many causes as possible. These causes will identify flaws and opportunities for improvement of the service. Therefore, the more causes identified in the service FMEA, the easier the corrective action becomes.
Examples of failure causes:

- Poor instructions
- Not appropriately trained
- Surprise in the process
- Human error

Note: If the effect of the failure is rated 8 through 10, special effort should be made to identify as many root causes as possible.

Occurrence (16). Occurrence (frequency) is the rating value corresponding to the estimated expected frequencies and/or cumulative number of failures that could occur for a given cause over the length of the service with the existing controls. (Usually this is given as part of the specification.) To identify the frequency for each of the causes one may use reliability mathematics (beyond the scope of this book), use the expected frequencies, or use a cumulative number of component failures (CNF) per 100 or 1000 components (CNF/100 or CNF/1000, respectively) over the design life of the component under study. Design life was explained in the design FMEA section.

Another way to help identify occurrences is the target (goal) period or useful life after which the service is discarded because it ceases to function as designed (normal life). Thus, it is too expensive to reinstall.

If expected frequencies and/or cumulative number of failures cannot be estimated, it is acceptable for the service FMEA to look at similar or surrogate services and/or processes for similar information.

Generally, the service FMEA operates under the assumption of the single-point failures (in other words, if a single service failure occurs the system fails). A single-point failure was defined in Chapter 7. The single-point failure can help minimize service disruption after it is identified. Please note, this is not to suggest that every single service failure is catastrophic, rather that each service failure should be addressed because it contributes to the dissatisfaction of the customer.

When the occurrence/frequency is calculated, it is imperative that it must be for every single cause of the failure. If it cannot be estimated, then the occurrence should be entered as 10. It must also be a consensus agreement of the entire team. A typical occurrence guideline is shown in Chapter 7, Table 7.2.

Detection Method; Existing Control (17). A method (procedure), test, or analysis. These are some of the first-level methods to detect or prevent a failure in the service, process, and/or the customer (Blanchard 1969). They can be very simple (in other words, brainstorming, audits, sampling based
on statistical techniques) or very technical and advanced (in other words, military standards and computer simulation). In either case, the focus is on the effectiveness of the control method/technique to catch the problem before it reaches the customer.

The only controls for the service FMEA that should be considered must contribute to the estimation of the detection rating. Controls intended to prevent or reduce the occurrence of the cause of the failure should be considered when estimating the occurrence rating.

The objective of the detection is to identify a service deficiency as early as possible. That deficiency may be viewed as a weakness in the process to reveal, detect, or eliminate the problem from the service (Chien 1985). The purpose of early detection in the service FMEA is to provide efficient service controls.

Because the service FMEA is completed early, it is sometimes difficult to assess the detection rating. In these cases one may use historical information, or similar types of information from similar services and/or processes. Occasionally, it is possible to have no method, test, or technique to identify the failure. In that case, the entry in this column should state something like “None identified at this time.”

Another way of focusing on detection is to use the brainstorming technique to identify new methods and tests as they apply to the task at hand. Two of the leading questions in the brainstorming process should be:

- How can this failure be discovered?
- In what way can this failure be recognized?

Some of the most effective ways to detect a failure are:

- Proven simulation techniques
- Mathematical modeling
- Trial testing
- Design of experiments
- Process verification testing

Typical controls may include:

- Probabilistic, reliability, and statistical modeling and testing as required.
- Reviewing test results, examining safety margins, evaluating material selections, and auditing of the service and processes.
- Checklists for completeness of the documentation. A checklist may provide a last check of the functions, features, producibility,
compliance to the appropriate standards, operator misuse, profitability and safety of the services, and its effect(s) on the process.

A typical checklist may include the following:

- Define service in its use environment.
  - What are the service’s uses?
  - What are the foreseeable environments of use?
  - Describe the skill and capability of foreseeable users.

- Identify safety and assess risk.
  - What are the hazards?
  - Estimate the probability of occurrence and seriousness of resulting harm for each hazard.

- Evaluate alternatives.
  - What alternative service features or techniques are available that can be expected to reduce or eliminate safety issues?
  - Evaluate alternative services/process by considering the following:
    - Characteristics and comparisons of different services
    - Other safety issues that may be introduced by the alternative services
    - Their effect on the usefulness of the service
    - Their effect on the ultimate cost of the service

In the case of human errors, a detection method may be developed based on similar guidelines given in the process FMEA section based on MIL-STD-1472c and Woodson (1981).

**Detection (18).** Detection is a rating corresponding to the likelihood that the current process controls will detect a specific root cause of a failure mode before the service is completed. To identify a detection rating one must estimate the ability for each of the controls identified in item 17 to detect the failure before it reaches the customer. The assumption is that the failure has occurred.

In addressing detection issues in the service FMEA, three items are very important.

1. Do not make the assumption—it happens quite often—that the detection should be low, just because the occurrence is low. The two ratings may or may not be correlated with each other for this particular item.
2. If 100 percent automatic control is listed as a control, the FMEA team must consider the effectiveness based on:
   - Condition of the control
   - Condition of the testing equipment
   - Calibration of the gauge and testing equipment
   - Variation of gauge and testing equipment (based on repeatability and reproducibility study—R&R)
   - Likelihood that the system will fail or be bypassed

3. If 100 percent visual (as opposed to automatic-process controller, brush recorders, artificial vision, and so on) inspection is listed, the FMEA team must consider the effectiveness based on:
   - One hundred percent visual inspection is only 79 percent to 100 percent effective, depending on inspector and conditions of inspection.
   - The number who may perform the inspections—How is the consistency of evaluation going to be monitored?
   - The nature of the failure. Is the failure obscure where a very high level of inspection ability is required (through training and/or experience), or is the failure so obvious that anyone can identify it?

   If the ability of the controls to detect the failure is unknown, or the detection cannot be estimated, then the detection rating should be 10. A typical detection guide is shown in Chapter 7, Table 7.3.

**Risk Priority Number (RPN)** (19). This number is the product of severity, occurrence, and detection. The RPN defines the priority of the failure. By themselves the RPNs have no value or meaning. They are used only to rank (define) the potential service deficiencies.

In the service FMEA one must always remember that the goal is to reduce the RPN, but in a specific way. The specific way is through a reduction in:

- Severity (if design actions have been taken)
- Detection
- Occurrence

The severity can be reduced only through a change in design. If that is attainable, then the failure is eliminated.

The occurrence can be reduced by improving task specifications and/or requirements in the service/process with the intent of preventing causes or reducing their frequency. The detection can be reduced by adding or improving evaluation techniques, increasing sample size, and/or add
detection equipment. The result will be improvement in the ability to detect the failure before it reaches the customer.

**Recommended Action (20).** No FMEA should be done without a recommended action. The recommended action may be specific action(s) or it may be further studying. The purpose of the recommended action in the service FMEA is to reduce the severity, occurrence, detection, or all of these factors. In essence the service FMEA is done to eliminate deficiencies and thus eliminate failures.

To facilitate this goal, the FMEA team must prioritize those failure modes with the highest RPN, the highest severity, the highest occurrence. Typical recommendations may be:

- No action at this time
- Add built-in detection devices
- Provide alternatives to the design/service
- Add redundant subsystem

**Responsible Area or Person and Completion Date (21).** This section includes the responsible person/area and the target completion date for the recommended action.

**Action Taken (22).** This is the follow-up. Just because something was recommended, does not mean that something was done. It is imperative that someone (usually the department head) will follow up on the recommendations to determine if they have been addressed adequately, properly, and/or if they are in need of updating.

Note that all FMEAs are living documents and as such someone must be responsible to update them. Often the person who is responsible is the department head. She or he has the responsibility to make sure that the service FMEA is a living document and it reflects the latest relevant information and actions.

After the action has been taken, the effective date or completion date with a brief description of the action should be entered.

**Revised RPN (23).** After the actions are incorporated in the process, the FMEA team should reevaluate the consequences of severity, occurrence, and detection. The results should be reviewed by the FMEA team and a new RPN is calculated and the failures are ranked. This process is repeated as needed until such time as the FMEA team decides that all relevant information has been covered. If no actions are taken, then these columns will remain blank.
As a general rule, the anticipated changes with the service FMFA are in the area of occurrence and detection. The severity stays the same. For the severity to change, the following must take place:

1. As part of the root cause analysis, it must be identified that the failure was caused because of a design/system issue.
2. The recommended action was to change the design based on the findings of the cause analysis.
3. The design changes were implemented as recommended or modified.

At this point the result is that the ratings (occurrence, severity, and detection) may all change, or some will change, or none will change.

**Approval Signatures (24).** Define the authority to carry out the FMEA. The names and titles will depend on the organization. Typical names may be the those of branch (department) manager, marketing manager, and area supervisor.

**Concurrence Signatures (25).** Define the responsibility of carrying out the completion and implementation of the FMEA. The names and titles will depend on the organization. Typical names may be those of the department head, marketing manager, and quality assurance manager.

**RECOMMENDED TEAM**

A team is necessary to complete a service FMEA. The team makeup should consist of five to nine individuals with a multidisciplined and multifunctional background. In addition, all members should have ownership of the problem (Stamatis 1992).

Selecting a service FMEA team is both important and difficult. Team members should include those:

- Who have the time to devote to the project
- With upward mobility
- With administrative skills
- Who have the respect of their peers
- With knowledge of the service
- With experience in similar services
• Who are willing to participate
• Who are politically astute in the organization

A typical service FMEA team includes the following:
• Department head (mandatory)
• Department supervisor (mandatory)
• Personnel involved with the service (mandatory)

Other recommended participants may be:
• Marketing representatives
• Material manager
• Field service manager

Once again, remember there is no such thing as the team. A team is made to reflect the needs and requirements that the problem and culture of the organization requires.

REFERENCES

This chapter provides an overview of the machine failure mode and effect analysis (MFMEA). The machinery FMEA is a systematic approach that applies the traditional tabular method to aid the thought process used by simultaneous engineering teams to identify the machine’s potential failure modes, potential effects and potential causes of the potential failure mode, and to develop corrective action plans that will remove or reduce the impact of the potential failure mode. Generally, the delivery of a MFMEA is the responsibility of the supplier who generates a functional MFMEA for system and subsystem levels. This is in contrast to a DFMEA where the responsibility is still on the supplier, but now the focus is to generate transfer mechanisms, spindles, switches, and cylinders exclusive of assembly level equipment.

A typical MFMEA follows a hierarchical model in that it divides the machine into subsystems, assemblies, and lowest replaceable units. For example:

Level 1: System level—Generic machine
   Level 2: Subsystem level—Electrical, mechanical, controls
      Level 3: Assembly level—Fixtures/tools, material handling, drives
         Level 4: Component level
   And so on

Therefore, for all intended purpose, the majority of MFMEAs are treated as a variation of a design FMEA. The predominant focus of this variation is on identifying safety and reliability issues.
Identify the Scope of the MFMEA

Use the boundary diagram. Once the diagram has been completed, the MFMEA team can focus on the low mean time between failure (MTBF) and reliability values.

Identify the Function

Define the function in terms of an active verb and a noun. Use functional diagram and/or the P-diagram to find the “ideal” function. Always focus on the intent of the system, subsystem, or component under investigation.

Failure Mode

A failure is an event when the equipment/machinery is not capable of producing parts at specific conditions when scheduled, or is not capable of producing parts or performing scheduled operations to specifications.

Machinery failure modes can occur in three ways:

- Component defect (hard failure)
- Failure observation (potential)
- Abnormality of performance constitutes the equipment as failed

Potential Effects

The consequence of a failure mode on the subsystem is described in terms of safety and the big seven or top seven losses. (The big/top seven losses may be identified through warranty and or historical data.)

- Describe the potential effects in terms of downtime, scrap, and safety issues.
- If functional approach is used, then list the causes first before developing the effects listing.

Associated with the potential effects is the severity, which is a rating corresponding to the seriousness of the effect of a potential machinery failure mode. Typical descriptions are:

Downtime:

- **Breakdowns:** Losses that are a result of a functional loss or function reduction on a piece of machinery requiring maintenance intervention.
• **Setup and adjustment:** Losses that are a result of set procedures. Adjustments include the amount of time production is stopped to adjust process or machine to avoid defect and yield losses, requiring operator or job setter intervention.

• **Startup losses:** Losses that occur during the early stages of production after extended shutdowns (weekends, holidays, or between shifts), resulting in decreased yield or increased scrap and defects.

• **Idling and minor stoppage:** Losses that are a result of minor interruptions in the process flow, such as a process part jammed in a chute or a limit switch sticking, for instance, requiring only operator or job setter intervention. Idling is a result of process flow blockage (downstream of the focus operation) or starvation (upstream of the focus operation). Idling can only be resolved by looking at the entire line/system.

• **Reduced cycle:** Losses that are a result of differences between the ideal cycle time of a piece of machinery and its actual cycle time.

**Scrap:**

• **Defective parts:** Losses that are a result of process part quality defects resulting in rework, repair and/or scrap.

• **Tooling:** Losses that are a result of tooling failures/breakage or deterioration/wear (for example, cutting tools, fixtures, welding tips, punches).

**Safety:**

• **Safety considerations:** Immediate life or limb threatening hazard or minor hazard

**Severity Rating**

Severity is comprised of three components:

1. Safety of the machinery operator (primary concern)
2. Product scrap
3. Machinery downtime

Rating should be established for each effect listed. Rate the most serious effect first. Begin the analysis with the function of the subsystem that will affect safety, government regulations, and downtime of the equipment.
A very important point here is the fact that a reduction in severity rating may be accomplished only through a design change. A typical rating is shown in Table 9.1.

It should be noted that these guidelines may be changed, modified to reflect specific situations. Also, the basis for the criteria may be changed to reflect the specificity of the machine and its “real world” usage.

**Classification**

The classification column is not typically used in the MFMEA process, but should be addressed if related to safety or non-compliance with government regulations.

- Address the failure modes with a severity rating of 9 or 10.
- Failure modes that effect worker safety will require a design change.
- OS (Operator Safety) means that this potential effect of failure is critical and needs to be addressed by the equipment supplier. Enter “OS” in the class column. Other notations (such as HI = High Impact) can be used but should be approved by the equipment user.

**Potential Causes**

The potential causes should be identified as design deficiencies. These could translate as:

- Design variations, design margins, environmental, or defective components
- Variation during the build/install phases of the equipment that can be corrected or controlled

Identify first level causes that will cause the failure mode. Data for the development of the potential causes of failure can be obtained from:

- Surrogate MFMEA
- Failure logs
- Interface matrix (focusing on: physical proximity, energy transfer, material, information transfer)
- Warranty data
- Concern reports (things gone wrong, things gone right)
### Table 91  Machinery guidelines for severity, occurrence, and detection.

<table>
<thead>
<tr>
<th>Effect</th>
<th>Criteria severity</th>
<th>Rank</th>
<th>Probability of failure</th>
<th>Criteria occurrence</th>
<th>Alternate criteria for occurrence</th>
<th>Detection</th>
<th>Criteria for detection</th>
<th>Rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazardous without warning</td>
<td>Very high severity: Affects operator, plant or maintenance personnel, safety and or effects non-compliance with government regulations without warning</td>
<td>10</td>
<td>Failure occurs every hour</td>
<td>R(t)&lt;1 Or some MTBF</td>
<td>10</td>
<td>1 in 1</td>
<td>Very low</td>
<td>10</td>
</tr>
<tr>
<td>Hazardous with warning</td>
<td>High severity: Affects operator, plant or maintenance personnel, safety and or effects non-compliance with government regulations with warning</td>
<td>9</td>
<td>Failure occurs every shift</td>
<td>R(t)=5%</td>
<td>9</td>
<td>1 in 8</td>
<td>Team’s discretion</td>
<td>9</td>
</tr>
<tr>
<td>Very high</td>
<td>Downtime of 8+ hrs or, the production of defective parts for over 2 hrs</td>
<td>8</td>
<td>Failure occurs every day</td>
<td>R(t)=20%</td>
<td>8</td>
<td>1 in 24</td>
<td>Team’s discretion depending on machine and situation</td>
<td>8</td>
</tr>
<tr>
<td>High</td>
<td>Downtime of 2–4 hrs or, the production of defective for up to 2 hrs</td>
<td>7</td>
<td>Failure occurs every week</td>
<td>R(t)=37%</td>
<td>7</td>
<td>1 in 80</td>
<td>Low</td>
<td>7</td>
</tr>
<tr>
<td>Moderate</td>
<td>Downtime of 60–120 min or, the production of defective parts for up to 60 min</td>
<td>6</td>
<td>Failure occurs every month</td>
<td>R(t)=60%</td>
<td>6</td>
<td>1 in 350</td>
<td>Team’s discretion depending on machine and situation</td>
<td>6</td>
</tr>
<tr>
<td>Low</td>
<td>Downtime of 30–60 min with no production of defect parts or, the production of defective parts for up to 30 min</td>
<td>5</td>
<td>Failure occurs every 3 months</td>
<td>R(t)=78%</td>
<td>5</td>
<td>1 in 1,000</td>
<td>Medium</td>
<td>5</td>
</tr>
<tr>
<td>Very low</td>
<td>Downtime of 15–30 min with no production of defect parts</td>
<td>4</td>
<td>Failure occurs every 6 months</td>
<td>R(t)=85%</td>
<td>4</td>
<td>1 in 2,500</td>
<td>Team’s discretion depending on machine and situation</td>
<td>4</td>
</tr>
<tr>
<td>Minor</td>
<td>Downtime up to 15 min with no production of defect parts</td>
<td>3</td>
<td>Failure occurs every year</td>
<td>R(t)=90%</td>
<td>3</td>
<td>1 in 5,000</td>
<td>High</td>
<td>3</td>
</tr>
<tr>
<td>Very minor</td>
<td>Process parameter variability not within specification limits. Adjustments may be done during production. No down time and no defects</td>
<td>2</td>
<td>Failure occurs every 2 years</td>
<td>R(t)=95%</td>
<td>2</td>
<td>1 in 10,000</td>
<td>Team’s discretion depending on machine and situation</td>
<td>2</td>
</tr>
<tr>
<td>None</td>
<td>Process parameter variability within specification limits. Adjustments may be performed during normal maintenance</td>
<td>1</td>
<td>Failure occurs every 5 years</td>
<td>R(t)=98%</td>
<td>1</td>
<td>1 in 25,000</td>
<td>Very high</td>
<td>1</td>
</tr>
</tbody>
</table>
• Test reports
• Field service reports

**Occurrence Ratings**

Occurrence (O) is the rating corresponding to the likelihood of the failure mode occurring within a certain period of time (see Table 9.1). The following should be considered when developing the occurrence ratings:

• Each cause listed requires an occurrence rating.

• Controls can be used that will prevent or *minimize* the likelihood that the failure cause will occur, but should not be used to estimate the occurrence rating.

Data to establish the occurrence ratings should be obtained from:

• Service data
• MTBF data
• Failure logs
• Maintenance records
• Surrogate MFMEAs

**Current Controls**

Current controls are described as being those items that will be able to detect the failure mode or the causes of failure. Controls can be either design controls or process controls.

A design control is based on tests or other mechanisms used during the design stage to detect failures. Process controls are those used to alert the plant personnel that a failure has occurred. Current controls are generally described as devices to:

• Prevent the cause/mechanism failure mode from occurring
• Reduce the rate of occurrence of the failure mode
• Detect the failure mode
• Detect the failure mode and implement corrective design action
Detection Rating

Detection (D) rating is the method used to rate the effectiveness of the control to detect the potential failure mode or cause. The scale for ranking these methods is based on 1–10 scale (see Table 9.1).

Risk Priority Number (RPN)

The RPN is a method used by the MFMEA team to rank the various failure modes of the equipment. This ranking allows the team to attack the highest probability of failure and remove it before the equipment leaves the supplier floor.

The RPN typically:

- Has no value or meaning. Ratings and RPNs in themselves have no value or meaning. They should be used only to prioritize the machine’s potential design weakness (failure mode) for consideration of possible design actions to eliminate the failures or make them maintainable.
- Is used to prioritize potential design weaknesses (root causes) for consideration of possible design actions.
- Is a product of severity, occurrence and detection. (Formula: \( RPN = S \times O \times D \))

(Special note on risk identification: Whereas it is true that most organizations using FMEA guidelines do use the RPN for identifying the risk priority, there are some who do not follow that path. Instead, they use a three step approach based on:

Step 1. Severity
Step 2. Criticality
Step 3. Detection

This means that regardless of the RPN the priority is based on the highest severity first—especially if it is a 9 or a 10—and is followed by the criticality, which is the product of Severity and Occurrence \( [S = 5 \text{ to } 8 \text{ and } O \text{ higher than } 3] \) and then the RPN.)

Recommended Actions

- Each RPN value should have a recommended action listed.
- Designed to reduce severity, occurrence and detection ratings.
• Actions should address in order the following concerns:
  – Failure modes with a severity of 9 or 10
  – Failure mode/cause that has a high severity occurrence rating
  – Failure mode/cause/design control that has a high RPN rating

• When a failure mode/cause has a severity rating of 9 or 10, the design action must be considered before the engineering release to eliminate safety concerns.

**Date, Responsible Party**

• Document the person, department and date for completion of the recommended action.

• Always place the responsible party’s name in this area.

**Actions Taken/Revised RPN**

• After each action has been taken, document the actions.

• Results of an effective MFMEA will reduce or eliminate equipment downtime.

• The supplier is responsible for updating the MFMEA. The MFMEA is a living document. It should reflect the latest design level and latest design actions.

• Any equipment design changes need to be communicated to the MFMEA team.

**Revised RPN**

• Recalculate S, O, and D after the action taken has been completed. Always remember that only a change in design can change the Severity. Occurrence may be changed by a design change and/or a redundant system. Detection may be changed by a design change and/or better testing or better design control.

• If changes in S, O, or D have occurred, the new RPN has to be evaluated to determine if additional design actions are necessary.
SUMMARY STEPS OF CONDUCTING THE FMEA

1. Select a project and scope.
2. If DFMEA, construct a block diagram.
3. If PFMEA, construct a process flow diagram.
4. Select an entry point based on the block or process flow diagram.
5. Collect the data.
6. Analyze the data.
7. Calculate results. (Results must be data driven!)
8. Evaluate/confirm/measure the results
   - Better off
   - Worse off
   - Same as before
9. Do it all over again.

An example of a machinery FMEA is shown in Figure 9.1.
<table>
<thead>
<tr>
<th>Description</th>
<th>Failure mode analysis</th>
<th>Action plan</th>
<th>Action results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subsystem name: function and performance requirements</td>
<td>Potential failure mode</td>
<td>Effects of failure</td>
<td>SC</td>
</tr>
<tr>
<td>Modular oven to provide heat for a period of 10 minutes at a temperature of 350°F</td>
<td>Does not heat</td>
<td>Downtime 5 hours</td>
<td>6</td>
</tr>
<tr>
<td>The oven shall circulate air to cure the rocker panels of the vehicle</td>
<td>Does not heat</td>
<td>Downtime 3 hours</td>
<td>3</td>
</tr>
<tr>
<td>MTBF—1500 hrs; MTTR—30 min.</td>
<td>Does not heat</td>
<td>Downtime 20 min.</td>
<td>2</td>
</tr>
<tr>
<td>Availability—99.9%</td>
<td>Does not heat</td>
<td>Downtime 30 min.</td>
<td>2</td>
</tr>
<tr>
<td>CFM—38000 with 5% contamination</td>
<td>Does not heat</td>
<td>Downtime 30 min.</td>
<td>2</td>
</tr>
<tr>
<td>Environmental: 90°F 90-99% relative humidity</td>
<td>Over temperature</td>
<td>Overbake Downtime 30 min.</td>
<td>9 OS</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Figure 9.1 An example of a machinery FMEA. (Continued)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Machine FMEA

<table>
<thead>
<tr>
<th>Issue</th>
<th>Severity</th>
<th>Occurrence</th>
<th>Detection</th>
<th>Cause</th>
<th>Frequency</th>
<th>Remediation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paint solvents</td>
<td></td>
<td></td>
<td></td>
<td>Low air flow</td>
<td></td>
<td></td>
</tr>
<tr>
<td>conveyor</td>
<td></td>
<td></td>
<td></td>
<td>Underbake 45 min.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vibration</td>
<td></td>
<td></td>
<td></td>
<td>80dBa.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flame amplifier</td>
<td>3</td>
<td>10</td>
<td>270</td>
<td>None</td>
<td>SAA</td>
<td>Eng. R. Munro 6/4/03 SAA Install automatic shut off temp control</td>
</tr>
<tr>
<td>Defective gas train</td>
<td>3</td>
<td>10</td>
<td>270</td>
<td>None</td>
<td>SAA</td>
<td>Eng. E. Rice 6/4/03 SAA Install automatic shut off temp control</td>
</tr>
<tr>
<td>Dirty filter</td>
<td>2</td>
<td>2</td>
<td>16</td>
<td>Air flow switch</td>
<td>No action</td>
<td>SAA No action</td>
</tr>
<tr>
<td>Closed damper</td>
<td>4</td>
<td>6</td>
<td>96</td>
<td>Temperature alarm</td>
<td>Review PM schedule and design of damper</td>
<td>SAA 6/4/03 Install automatic dampers into the new design ovens. Install new type of alarm</td>
</tr>
<tr>
<td>Stuck</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Damper</td>
<td>2</td>
<td>10</td>
<td>80</td>
<td>None</td>
<td>SAA</td>
<td>Eng. Eric.R 6/4/03 SAA Install automatic shut off temp control</td>
</tr>
<tr>
<td>Defective fans</td>
<td>2</td>
<td>10</td>
<td>80</td>
<td>None</td>
<td>SAA</td>
<td>Eng. James R. 6/4/03 SAA Install automatic shut off temp control</td>
</tr>
<tr>
<td>Clogged supply lines</td>
<td>2</td>
<td>10</td>
<td>80</td>
<td>None</td>
<td>SAA</td>
<td>Eng. Carla S. 6/4/03 SAA Install automatic shut off temp control</td>
</tr>
<tr>
<td>Defective fans</td>
<td>2</td>
<td>10</td>
<td>80</td>
<td>None</td>
<td>SAA</td>
<td>Eng. Tim S. 6/4/03 SAA Install automatic shut off temp control</td>
</tr>
<tr>
<td>Broken belt</td>
<td>4</td>
<td>10</td>
<td>160</td>
<td>None</td>
<td>SAA &amp; review procedures for maintenance manual</td>
<td>SAA 6/4/02 SAA Install automatic shut off temp control</td>
</tr>
</tbody>
</table>

**Figure 91** An example of a machinery FMEA.
REFERENCES


This chapter provides an overview of the FMEA and the electromechanical (EM) industry and tries to identify some of the special concerns in its utilization.

The FMEA is a method of reliability analysis intended to identify failures that have significant consequences affecting the system performance in the application considered. These failures may be potential or known (through warranty failures, internal rework records, inspection records, customer feedback and/or complaints, and so on). The potential failures may be suspect based on similar designs, processes, products, services, and so on.

In general terms, failures of any component will affect system performance adversely (Eachus 1992). When one studies the system reliability, safety, and availability, however, both qualitative and quantitative analyses are required as they complement each other. Quantitative analysis methods allow calculation or prediction of performance indices of the system while satisfying a specific task, or in long-term operation under specific conditions. Typical indices denote reliability, safety, availability, maintainability, failure rates, mean time between failure (MTBF), and so on.

On the other hand, qualitative methods may be used to identify the failures, categorize them, understand them better, and help in the priority of quantification process. Typical tools used in such cases are brainstorming, affinity charts, force field analysis, cause-and-effect charts, Pareto charts, and so on.

Generally, the FMEA in the EM industry is based on a specific component or subassembly level where the basic failure criteria (primary failure modes) are available. Starting from the basic element failure characteristics and the functional system structure, the FMEA determines the relationship between the element failures and the system failures, malfunctions, operational constraints, and degradation of performance or integrity. To evaluate secondary and higher-order system and subsystem failures, the sequences of events in time may also have to be considered. A process flowchart or a block diagram may be used to facilitate this sequence.

FMEA is a method primarily adapted for material and equipment failures. It can be applied to categories based on different technologies (hydraulic, mechanical, electrical, and so on) and combinations of technologies.

In a narrow sense, the FMEA is limited to a qualitative analysis of failure modes of hardware and does not include human errors/performance and software errors, despite the fact that current systems usually are subject to both. In a wider sense, these factors can be included. Indeed one can perform FMEA for a system, design, process, service (in other words, customer service, software applications, and so on). See Chapter 11 for more information on this.

The severity of the consequences of a failure is described by criticality. Criticality is designated by categories or levels that are functions of the dangers and losses of system capabilities and sometimes of the probability of their occurrence. (These categories sometimes are defined by the customer or are given by a standard, such as MIL-STD 1629A.) This probability is best identified separately. A logical extension of the FMEA is consideration of the criticality and probability of occurrence of the failure modes. This criticality analysis of the identified failure modes is widely known as failure mode effect and critical analysis (FMECA).

The FMEA in the EM industry is an important technique for a reliability assurance program which can be applied to a wide range of problems and may be encountered in technical systems with varying depths and modifications to suit the purpose (Kececioglu 1991). The analysis is carried out in a limited way during conception, planning, and definition phases; and conducted more fully in the design and development phase, followed by the process phase and occasionally the product phase. In the case of service application, the FMEA may be used or developed during the implementation phase or concurrently with the problem. In any case, the FMEA is an inductive method of performing a qualitative system reliability or safety analysis from a low to high level (Blanchard 1988; Bass 1991). To accomplish this, the FMEA uses a variety of tasks and activities to derive appropriate results.
The application of the FMEA within the framework of the specific project is very important and one must plan how and for what purpose the FMEA will be used. Always remember that the requirements for FMEA originate with the need, wish, and expectancy to understand a problem’s behavior and its implications, and ultimately to remove the root cause for that unwanted behavior. Look for continual improvement. Because behaviors vary, the FMEA can vary widely from one project to another and from company to company.

Furthermore, the FMEA is a technique for design review support and for assurance and assessment, which should be employed from the first steps of system and subsystem design. FMEA is appropriate to all levels of system, design, process, service, and software development. Special training of personnel performing FMEA is required; the FMEA team must have the close collaboration of systems engineers, designers, operators, manufacturing engineers, and anyone who is close to the project. The FMEA must be updated as the project progresses and as the system, design, process, software, and service are modified. By the end of the project, FMEA is used to check the overall system, design, process, software; and service and may be essential for demonstration of conformity of a design system to required standards, regulations, and user’s requirements.

Information from the FMEA identifies priorities for process controls and inspection tests during manufacturing and installation, and for qualification, approval, acceptance, and start-up tests. It provides essential information for diagnostic and maintenance procedures, and it should be identified in the reliability program and/or the control plan. This identification will make the FMEA even more effective.

In deciding on the extent and manner in which FMEA should be applied to an item, one should consider the specific purposes for which FMEA results are needed, the time phasing with other activities, and the importance of establishing a predetermined degree of awareness and control over unwanted failure modes and effects. This leads to the planning of FMEA in qualitative terms at specified levels (item, component, code, subsystem, system, process, task) to relate to the iterative design and development process.

**USES OF FMEA**

Some of FMEA’s benefits are:

- To identify failures that, when they occur alone, have unacceptable or significant effects, and to determine the failure modes which may seriously affect the expected or required operation. Such effects may include secondary failures.
• To determine the need for:
  – Redundancy
  – Designing features which increase the probability of fail-safe outcomes of failures
  – Further derating and/or design simplification (This may be done in conjunction with concurrent engineering and/or the poka-yoke method of designing.)
  – Improvement of task, failure, and so on

• To determine the need for selecting alternative materials, parts, devices, components, and tasks. (This may be done in conjunction with DOE—classical or Taguchi.)

• To identify serious failure consequences and hence the need for design review and revision.

• To provide the logic model required to evaluate the probability of anomalous operating conditions of the system.

• To disclose safety hazard and liability problem areas, or noncompliance with regulatory requirements.

• To ensure that the test program prototype can detect potential failure modes.

• To establish duty cycles which anticipate and avoid wear-out failures.

• To focus upon key areas in which to concentrate quality, inspection, and manufacturing process controls.

• To avoid costly modifications by the early identification of design deficiencies.

• To establish the need for data recording and monitoring during testing, checkout, and use.

• To provide information for selection of preventive or corrective maintenance points and development of troubleshooting guides, built-in test equipment, procedures for testing, and/or inspection and suitable test points.

• To facilitate or support the determination of test criteria, test plans, and diagnostic procedures (for example, performance testing, reliability testing).

• To identify circuits requiring worst case analysis (frequently required for failure models involving parameter shifts).
• To support the design of fault isolation sequences and to support the planning for alternative modes of operation and reconfiguration.

• To facilitate communication between:
  – General and specialized engineers
  – General and specialized attorneys
  – General and specialized healthcare personnel
  – Operators (doers) and management
  – Equipment manufacturer and suppliers and customers
  – System user and the designer or manufacturer
  – System, design, process, product, service personnel

• To enhance the analyst’s knowledge and understanding of the behavior of the equipment, task, process, software, service, product, system, and design studied.

• To provide a systematic and rigorous approach to the study of system facilities.

**LIMITATIONS OF FMEA**

FMEA is extremely efficient when it is applied to the analysis of elements that cause a failure of the entire system; however, FMEA may be difficult and tedious for the case of complex systems that have multiple functions consisting of a number of components. This is because of the quantity of detailed system information which must be considered. This difficulty can be increased by the number of possible operating modes, as well as by considerations of the repair and maintenance policies.

Another limitation is that the results of human error usually are not included. Studies of machine interactions are the subject of specific methods (for example, task analysis). Generally, human errors appear during operation systems in a sequential mode and the study of their impact has to be made by methods such as cause-consequence analysis. Nevertheless, the FMEA can identify components most sensitive to human factors. A further limitation is apparent when the effects of the environment are significant. The consideration of these effects requires a thorough knowledge of the characteristics and performance of the different components of the system.

Note that human error and environmental effects constitute a major source of common mode or common cause failure, especially in the process, service, and software FMEA.
THE PRINCIPLES OF FMEA

Terminology

The terminology is the same as the generic FMEA.

Concepts

All FMEAs require:

- The system breakdown into elements—the smallest component or individual task
- Diagrams of the system functional structure and identification of the various data that are needed to perform the FMEA
- The failure mode concept
- The criticality concept (if criticality analysis is required)

Definition of the System Functional Structure

The analysis is initiated by selecting lowest level of interest (usually the part, circuit, or module/task level) at which sufficient information is available. At this lowest level, the various failure modes that can occur for each item at that level are tabulated. The corresponding failure effect for each (taken singly and in turn) is interpreted as a failure mode for consideration of the failure effect at the next higher functional level. Successive iterations result in the identification of the failure effects in relation to specific failure modes.

It is important to determine the breakdown level that will be used for the analysis. For example, systems can be broken down into subsystems, least replaceable items, or detailed parts (components). The same can be said about a process, which can be broken into the areas of labor, machine, method, material, measurement, and environment. These areas can be broken into smaller items. In the case of the service (customer service) FMEA one must break down each task into a single unit relevant to the entire job. Some good tools for such a breakdown may be the use of the process flowchart, task analysis, brainstorming, or cause-and-effect analysis. An example of a design FMEA using the cause-and-effect diagram with certain criteria is shown in Figures 10.1 and 10.2 and Tables 10.1 and 10.2.
## The development of the FMEA
### Step 1: The criteria

<table>
<thead>
<tr>
<th>Project number:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Description:</strong> Industrial-grade, all-plastic connector for nonmetallic conduit</td>
</tr>
</tbody>
</table>

**Products designed must meet the following minimum requirements.**


2. Compatible with UL-listed type B nonmetallic conduit and UL-recognized flexible corrugated tubing (type EFC style).

3. Resistance to chemical found in the following:
   - Machine tool-related environments
   - Food processing-related environments
   - Automotive-related environments
   - Determine suitability for use in marine environments

4. Suitable and marked for outdoor use (UV/sunlight resistant).

5. Consistently meets UL requirements for pullout and liquid tightness on both LTC and EFC styles.


7. Install connector on conduit without disassembly.

8. Conduit should not rotate as gland nut is tightened.

9. 90-degree connector to easily allow wire pulling similar to the established 2680 series.

10. Include sealing ring (not standard product) and metallic locknut.

11. Connectors to be black in color.

12. UL listing and CSA certification required. It is desirable to meet NEMA 4, NEMA 6, and NEMA 12 specs.

---

**Figure 101** Criteria for a product.
Figure 10.2  Cause-and-effect diagram. (Based on information from Figure 10.1.)
### Table 10.1  Design FMEA. (Based on information from Figures 10.1 and 10.2.)

#### Step 3: Fill in the Design Form

<table>
<thead>
<tr>
<th>Product requirement</th>
<th>Potential failure mode</th>
<th>Potential effects of failure</th>
<th>SPC SYM</th>
<th>Potential causes of failure</th>
<th>Existing conditions</th>
<th>Recommended actions and status</th>
<th>Resulting</th>
<th>Responsible activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seal at the enclosure</td>
<td>Leakage at enclosure</td>
<td>&quot;O&quot; Ring</td>
<td>Visual</td>
<td>&quot;O&quot; Ring</td>
<td>Visual</td>
<td>Review design of &quot;O&quot; ring for color and fit</td>
<td>Design team</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Cert.</td>
<td>Size</td>
<td>1</td>
<td>6</td>
<td>96</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Visual</td>
<td>Cracked</td>
<td>1</td>
<td>3</td>
<td>94</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Visual</td>
<td>Out of groove</td>
<td>2</td>
<td>6</td>
<td>36</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Body</td>
<td>Visual</td>
<td>Cracked hub</td>
<td>1</td>
<td>2</td>
<td>10</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Gauge</td>
<td>Undersize hub</td>
<td>1</td>
<td>4</td>
<td>36</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Flash on stopping shld.</td>
<td>Visual</td>
<td></td>
<td>1</td>
<td>4</td>
<td>9</td>
<td>36</td>
</tr>
</tbody>
</table>

(Continued)
### Table 10.1  Design FMEA. (Based on information from Figures 10.1 and 10.2.)  

<table>
<thead>
<tr>
<th>Product requirement</th>
<th>Potential failure mode</th>
<th>Potential effects of failure</th>
<th>SPC SYM</th>
<th>Potential causes of failure</th>
<th>Existing conditions</th>
<th>Recommended actions and status</th>
<th>Resulting</th>
<th>Responsible activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seal at the conduit</td>
<td>Leakage at conduit</td>
<td>1. Equipment failure (physical)</td>
<td>Conduit Size</td>
<td>Industry standard</td>
<td>OCC 5 SEV 6 DET 8</td>
<td>RSK PRT NO. 240</td>
<td>Look for new vendor</td>
<td>Design team</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Fire</td>
<td>Conduit Burrs</td>
<td>Stuffer</td>
<td>2 3 9</td>
<td>5</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Equipment failure (electric)</td>
<td>Body Scratched</td>
<td>Visual</td>
<td>1 3 9</td>
<td>27</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Cracked Control chart</td>
<td>1 3 9</td>
<td>27</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dimensional</td>
<td>Partial insertion</td>
<td>Stuffer</td>
<td>4 3 9</td>
<td>108</td>
<td>Review design to allow wider range of cond. I.D.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

Product: Industrial grade APC connector  
FMEA date (original): 11/21/89  
Rev.: Orig. Scheduled production release: _______________  
Prepared by: __________________ Design team: __________________  
Approved by: __________________
<table>
<thead>
<tr>
<th>Product requirement</th>
<th>Potential failure mode</th>
<th>Potential effects of failure</th>
<th>SPC SYM</th>
<th>Potential causes of failure</th>
<th>Existing conditions</th>
<th>Recommended actions and status</th>
<th>Resulting RSK PRT NO.</th>
<th>Responsible activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strain relief</td>
<td>Strain relief and pullout resistance</td>
<td>1. Loss of conductor protection</td>
<td>Parts cracked</td>
<td>1. Over torque</td>
<td>Stuffer</td>
<td>1</td>
<td>8</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>...Vibration</td>
<td>None</td>
<td>1</td>
<td>8</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>...Abuse</td>
<td>None</td>
<td>2</td>
<td>8</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dimensional</td>
<td>...Gland/ body thread</td>
<td>Control chart</td>
<td>1</td>
<td>8</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>...Unfilled parts</td>
<td>Visual</td>
<td>1</td>
<td>8</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Installation</td>
<td>...Not tight</td>
<td>Stuffer</td>
<td>3</td>
<td>8</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>...Contaminant</td>
<td>Stuffer</td>
<td>2</td>
<td>8</td>
<td>2</td>
</tr>
</tbody>
</table>

FMEA date (original): 11/21/89  Rev.: Orig.  Scheduled production release:  

Prepared by: __________ Design team: __________________

Approved by: ____________________________

Project no.: ____________________________

Table 10.1 Design FMEA. (Based on information from Figures 10.1 and 10.2.) (Continued)
### Table 10.1  Design FMEA. (Based on information from Figures 10.1 and 10.2.)

#### Step 4: Fill in the Process Form

**Product:** Industrial grade APC connector  
**FMEA date (original):** 11/21/89  
**Project no.:**  
**Prepared by:**  
**Design team:**  
**Scheduled production release:**  
**Approved by:**

<table>
<thead>
<tr>
<th>Product requirement</th>
<th>Potential failure mode</th>
<th>Potential effects of failure</th>
<th>SPC SYM</th>
<th>Potential causes of failure</th>
<th>Existing conditions</th>
<th>Recommended actions and status</th>
<th>Resulting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ease of installation</td>
<td>Hard to install (without disassemble)</td>
<td>1. Inefficient installation</td>
<td>Assemble</td>
<td>Note on drawing</td>
<td>OCC 9 SEV 3 DET 1 RSK PRT NO. 27</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Environmental integrity</td>
<td>Environmental outdoor/industrial degradation</td>
<td>1. Equipment failure</td>
<td>Weather</td>
<td>Review M&amp;E</td>
<td>OCC 1 SEV 8 DET 8 RSK PRT NO. 64</td>
<td>Note on drawing</td>
<td></td>
</tr>
</tbody>
</table>

** Ease of installation:**
- **Hard to install (without disassemble):**
  - 1. Inefficient installation
    - Assemble
    - Note on drawing
    - OCC 9 SEV 3 DET 1 RSK PRT NO. 27

**Environmental integrity:**
- **Environmental outdoor/industrial degradation:**
  - 1. Equipment failure
  - 2. Rework/maintenance
  - 3. Equipment damage
  - Weather
  - Stuffer
  - Note on drawing
  - OCC 1 SEV 8 DET 8 RSK PRT NO. 64
  - Review M&E
  - Conduct design experiments

**Recommended actions:**
- Actions taken
- OCC
- SEV
- DET
- RSK PRT NO.

**Resulting activity:**
- Responsible activity
- Production Manager
- Design team
<table>
<thead>
<tr>
<th>Product requirement</th>
<th>Potential failure mode</th>
<th>Potential effects of failure</th>
<th>SPC SYM</th>
<th>Potential causes of failure</th>
<th>Existing conditions</th>
<th>Recommended actions and status</th>
<th>Resulting</th>
<th>Responsible activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meet agency requirement</td>
<td>Fail agency requirement</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1. Delist/decertified</td>
<td></td>
<td></td>
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<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>2. Recall</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Requalification</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>4. Loss of business</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5. Customer rework</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Failure to meet agency performance requirements</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lack of proper identification</td>
<td>Drawings specs/ process/ control</td>
<td></td>
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Table 10.1 Design FMEA. (Based on information from Figures 10.1 and 10.2. (Continued)
Table 10.2  Process FMEA. (Based on information from Figures 10.1 and 10.2, and Table 10.1.)

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(Continued)
Table 10.2  Process FMEA. (Based on information from Figures 10.1 and 10.2, and Table 10.1.)

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<th>Potential failure mode</th>
<th>Potential effects of failure</th>
<th>SPC SYM</th>
<th>Potential causes of failure</th>
<th>Existing condition</th>
<th>Recommended actions and status</th>
<th>Responsible person</th>
<th>Resulting</th>
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### Table 10.2  Process FMEA. (Based on information from Figures 10.1 and 10.2, and Table 10.1.)  

Product: **Industrial grade APC connector**  
FMEA date (original): **11/21/89**  
Rev.: **Orig.**  
Scheduled production release: 

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<td>Recommended actions and status</td>
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Table 10.2  Process FMEA. (Based on information from Figures 10.1 and 10.2, and Table 10.1.)
**Table 10.2**  Process FM EA. (Based on information from Figures 10.1 and 10.2, and Table 10.1.)  
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<td>Screwdriver malfunction</td>
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### Table 10.2  Process FMEA. (Based on information from Figures 10.1 and 10.2, and Table 10.1.) (Continued)

Part name: **Industrial grade connector**

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### Table 10.2  Process FMEA. (Based on information from Figures 10.1 and 10.2, and Table 10.1.)

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</tbody>
</table>
Where relevant, nonelectrical items must be considered. When quantitative results are required, the level chosen must be one at which it is possible to obtain adequate and dependable failure rate data on each failure mode or error mode; or to make reasonable identified assumptions of such failure rates. The chosen breakdown level requires a dependable and detailed knowledge of the failure modes of the elements. Apart from this requirement, it is neither possible nor desirable to set strict rules about the choice of the breakdown level.

**INFORMATION NECESSARY TO PERFORM THE FMEA**

**System Structure**

The following information is required:

- The different system elements with their characteristics, performances, roles, and functions
- The connections between elements, tasks, components
- Redundancy level and nature of the redundant systems
- Location of the system within the entire facility (if possible)
- Data pertaining to functions, characteristics, and performances are required for all levels considered, up to the highest level.

**System Initiation, Operation, Control, and Maintenance**

The status of the different operating conditions of the system should be specified, as well as the changes in the configuration or the position of the system and its components during the different operational phases. The minimum performances demanded of the system should be defined and such specific requirements as availability or safety should be considered in terms of specified levels of performance and levels of damage or harm.

It is necessary to know the following:

- The duration of each task
• The time interval between periodic tests
• The time available for corrective action before serious consequences occur to the system
• The entire facility, the environment, and/or the personnel repair conditions including corrective actions and the time, equipment, and/or personnel to achieve them

Further information is required on:
• Operating procedures during system start-up
• Control during operational phases
• Preventive and/or corrective maintenance
• Procedures for routine testing, if employed

System Environment

The environmental conditions of the system should be specified, including ambient conditions and those created by other systems in the facility. The system should be delineated as to its relationships, dependencies, or interconnections with auxiliary or other systems and human interfaces.

Usually at the design stage these facts are not (all) known and therefore approximations and assumptions will be needed. As the project progresses, the data will have to be augmented and the FMEA modified to allow for new information or changed assumptions or approximations.

FMEA or any other analysis requires certain modeling of the system (in other words, a simplification of the relevant information on the system). Some assumptions may be made about the nature of failure modes, and the seriousness of their consequences. For example, in safety situations conservative hypotheses may be made concerning the impact of certain failures on the system.

An FMEA conducted on hardware may result in decisions on effects, criticality, and conditional probabilities that involve identifying software elements and their nature, sequence, and timing. When this is the case, the facts must be clearly identified because any subsequent alteration or improvement of the software may modify the FMEA and the assessments derived from it. Approval of software development and change may be conditional upon revision of the FMEA and the related assessments.
Representation of System Structure

Symbolic representations of the system structure and operation, especially diagrams, can be used. Usually block diagrams are adopted highlighting all the functions essential to the system.

In the diagram, the blocks are linked together by lines that represent the inputs and outputs for each function. Usually, the nature of each function and input must be precisely described. There also may be several diagrams to cover different phases of system operation.

Generally, graphical presentations, including those closely related to analytical methods (such as failure trees or cause-consequence diagrams) contribute to a better understanding of a system, its structure, and its operation. Their use, however, raises the problem of the relationship between FMEA and these methods.

Failure Modes

A failure mode is the effect by which a failure is observed in a system component. It is important that all possible or potential failure modes of a system be listed as this is the essential basis of the FMEA.

Component or equipment manufacturers should take part in the identification of the failure modes of their products because of the following:

- For new components, reference can be made to other components with similar functions and structures and to tests performed on them.
- For commonly used components already in service, records on their performance, reported failures, and laboratory tests can be consulted.
- Complex components that can be broken down into elements can be analyzed qualitatively, treating each as a system.
- Potential failure modes can be deduced from functions and physical parameters typical of the component operation.

Classification of failure modes should be performed. Two common ways of classifying failure modes are:

1. Identification of general failure modes, such as:
   - Premature operation
   - Failure to operate at a prescribed time
   - Failure to cease operation at a prescribed time
   - Failure during operation
2. By listing, as completely as possible, all generic failure modes. Some of these failure modes follow.

- Structural failure (rupture)
- False actuation
- Physical binding or jamming
- Fails to stop
- Vibration
- Fails to start
- Fails to remain in position
- Fails to switch
- Fails to open
- Premature operation
- Fails to close
- Delays operation
- Erroneous input—increase
- Internal leakage
- Erroneous input—decreased
- Loss of input
- Erroneous output—increased
- Loss of output
- Erroneous output—decreased
- Shorted (electrical)
- Fails out of tolerance (high)
- Open (electrical)
- Fails out of tolerance (low)
- Erratic operation
- Intermittent operation
- Leakage (electrical)
- Inadvertent operation
- Erroneous indication
- Restricted flow
- Communications
- No power
- Code errors
- Restricted flow
- Security issues

**Common Cause Failures**

In a reliability analysis, it is not sufficient to consider only random and independent failures. Some common cause failures can occur, which cause system performance degradation or failure through simultaneous deficiency in several system components, due to single source such as design error, human error, and so on. An FMEA analysis does just that.

A common cause failure is the result of an event that (because of dependencies) causes a coincidence of failure states in two or more components (excluding secondary failures caused by the effects of a primary failure).

A common cause can be subjected to qualitative analytical techniques using FMEA. FMEA is a methodology to successively examine each failure mode and associated causes and to identify all periodic tests, preventive maintenance measures, and so on. It makes possible a study of all the causes, including potential common cause failures.

These causes can be classified into five main categories:

1. Environmental effects (normal, abnormal, and accidental)
2. Design deficiencies
3. Manufacturing defects

4. Assembly errors

5. Human errors (during operation and/or maintenance)

A checklist based on these categories may be developed and used to identify in a detailed manner all possible causes that may include common cause failure. Chapter 11 provides a structure to help develop a specific checklist given a set of parameters.

The tendency is to build redundant systems to avoid failures. One must be careful because redundancy alone does not solve or eliminate all the common cause failure problems. What is necessary and highly encouraged is to combine several methods in dealing with these failures (functional diversity, redundancies of different types, physical separation, tests, and so on).

**Human Factors**

Some systems must be designed to allow for human error (for example, by providing mechanical interlocks on railway signals, passwords for computer usage or data retrieval). Where such provisions exist in a system, the effect of failure of the provisions will depend on the type of error. Some modes of human error also should be considered for an otherwise fault-free system, to check the effectiveness of the provisions. Although incomplete, even a partial listing of these modes is beneficial.

**Software Errors**

There will be effects from malfunctions due to software errors or inadequacies. Criticality will be determined by both hardware and software design. The postulation of such errors or inadequacies and the analysis of their effects is possible only to a limited extent and is beyond the scope of the FMEA; however, the effects upon associated hardware of possible errors in software may be estimated. For specific guidelines in this area see Chapter 11.

**Criticality Concept**

The degree of concern appropriate to any failure situation is clearly related both to its probability of occurrence and the seriousness of its effects. The criticality concept quantifies analysis and complements FMEA. There are no general criteria for criticality applicable to a system, because this concept is fundamentally linked to that of the severity of consequences and
their probability of occurrence. The severity concept itself can be defined in various ways depending on whether the objective is related to safety of life, consequential damage or loss, or service availability.

The criticality concept adds greatly to the benefits of the FMEA process by considering:

- Items to be given more intensive study to eliminate a particular hazard, to increase the probability of a fail-safe outcome, or reduce the failure rate or extent and risk of resultant damage
- Items requiring special attention during manufacture and stringent quality assurance or special control of handling
- Special requirements in purchasing specifications concerning design, performance, reliability, safety, or quality assurance
- Acceptance standards for subcontractors’ products including parameters that should be stringently tested
- Any special procedures, safeguards, protective equipment, monitoring devices, or warning systems
- The most cost-effective application of accident prevention resources

In order to define criticality, there must be a value scale to judge the severity of the consequences in terms of the criteria considered. The following is an example of definition, based on a classification of consequence severity of four levels (MIL-STD-1629A 1980).

**Criticality Levels and Criticality Conditions**

1. Any event that could cause degradation of system performance function(s) resulting in negligible damage to either system or its environment and no damage to life or limb
2. Any event that degrades system performance function(s) without appreciable damage to system, life, or limb
3. Any event that potentially could cause the loss of primary system function(s) resulting in significant damage to the said system or its environment and negligible hazard to life or limb
4. Any event that potentially could cause the loss of primary system function(s) resulting in significant damage to the said system or its environment and significant hazard to life or limb
The actual number of the selected levels is arbitrary. In this example, the levels are based on the combination of criteria considered relevant and concerning, respectively:

- Harm to personnel (injuries, death)
- Loss of system function(s)
- Environmental impact and material damage

The terms catastrophic, critical, major, and minor are widely used, but their definition in IEC Publication 271 may or may not suit particular FMEA usage. Words such as these could be specifically defined in individual cases.

**Procedure**

The wide variation in complexity of system designs and applications may require the development of highly individualized FMEA procedures consistent with the information available. The following are the fundamental steps used in FMEA cases in the EM industry.

1. Definition of the system and its functional and minimal operating requirements.
   a. A complete definition of a system includes its primary and secondary functions, its use, expected performance, system constraints, and explicit conditions that constitute a failure.
   b. In addition, it may be necessary to define the acceptable functional performance of the system as a whole and of its constituent elements, as well as those performance characteristics considered unacceptable. Part of this definition should also account for regulatory requirements, especially those governing production, use, and by-products.
   c. The functional requirements should include a definition of acceptable performance for all desired or specified characteristics, in all operating and nonoperating modes, for all relevant periods of time, and for all environmental conditions.
   d. The environmental conditions such as temperature, humidity, radiation, vibration, and pressure should be clearly defined, specifically for the environment that the system will operate in (exposed and/or stored). For cybernetic systems consideration also should be given to further factors, psychological, physiological, and environmental, insofar as they affect human performances and system design or operation.
2. Development of functional and reliability block diagrams and other diagrammatic or mathematical models and descriptions.
   a. Diagrams showing the functional elements of the system are necessary both for technical understanding of the functions and the subsequent analysis. The diagrams should display any series and redundant relationships among the elements and the functional interdependencies between them. This allows the functional failures to be tracked through the system. More than one diagram may be needed to display the alternative modes of system operation. Separate logic diagrams may be required for each operational mode. As a minimum, the block diagram should contain:
      – Breakdown of the system into major subsystems including functional relationships
      – All appropriately labeled inputs and outputs and identification numbers by which each subsystem is consistently referenced
      – All redundancies, alternative signal paths, and other engineering features that provide fail-safe measures
      – Establishment of basic principles and corresponding documentation in performing the analysis

Basic principles for selecting the system levels for analysis depend on the results desired and the availability of design information. The following may be of help:

- The highest system level is selected from the design concept and specified output requirements.

- The lowest system level at which the analysis is effective is that level for which information is available to establish definition and description of functions. The lowest system level is influenced by previous experience. Less-detailed analysis can be justified for any system having a mature design, good reliability, maintainability, and safety record. Conversely, greater detail and a correspondingly lower system level is indicated for any newly designed system or system with unknown reliability history.

- The specified or intended maintenance and repair level may be a valuable guide in determining lower system levels. The lowest system level at which system maintenance will be performed should first be identified. An analysis is then made of the level immediately above the lowest system level at which maintenance will be performed. On critical system elements, the analysis is performed down to the least replaceable element.

As for documentation, it is recommended that the FMEA be done in a form that is designed to meet the requirements of the system and is consistent
with the set objectives. No standard form exists. Each company must design its own with its specific objectives in mind. (For a variety of FMEA forms see Appendix E on the CD.)

**Identification of failure modes, their causes and effects, their relative importance, and their sequence**

The operation of a successful FMEA is dependent on the performance of certain critical system elements. The key to evaluation of system performance is the identification of critical elements. The procedures for identifying failure modes, their causes, and effects can be effectively enhanced by the preparation of a list of failure modes anticipated in view of:

- System usage
- Particular system element involved
- Mode of operation
- Pertinent operation specifications
- Time constraints
- Environment

It is important to remember that in the FMEA the definitions of failure modes, causes, and effects depend on the level of analysis and they may be interchanged depending on the level addressed. For example, a failure may be an effect, and a cause may be a failure depending on the level of analysis. Furthermore, as the analysis progresses, the failure effects identified at the lower level may become failure modes at the higher level. Similarly, the failure modes at the lower level may become the failure causes at the higher level and so on.

**Identification of failure detection and isolation provisions and methods**

The methods of detection of the failure mode are described. Failure modes other than the one being considered which give rise to an identical indication are analyzed and listed. The need for separate failure detection of redundant elements during operation should be considered.

**Identification of design and operating provisions against particularly undesirable events**

The relative significance of the failure should be recorded on the FMEA form. The idea is that the form will clearly show the true behavior of the equipment in the presence of an internal malfunction. Other provisions include:
• Redundant items that allow continued operation if one or more elements fail
• Alternative means of operation
• Monitoring or alarm devices
• Any other means permitting effective operation or limiting damage

When the functional elements (either the hardware or software) are rearranged or reconfigured in the design, the capability will change. Following this, the relevant failure modes should be reexamined before repeating the FMEA.

Special remarks also may be incorporated in the FMEA form to denote:
• Any unusual conditions
• Effects of redundant element failures
• Recognition of especially critical design features
• Any remarks to amplify the line entry
• References to other FMEAs or entries for sequential failure analysis
  – Determination of event criticality (FMECA only)
  – Evaluation of failure probability (FMECA only)
  – Search for specific combinations of multiple failures to be considered (optional)
  – Recommendation

Note that one may conduct an FMEA with full benefits without completing an FMECA.

REFERENCES

Chapter 2 provided a general overview of what the FMEA is and how it works. Chapters 4 through 7 discussed the specific mechanics of the FMEA. This chapter focuses on the computer industry. The focus is as specific as possible without being too rigid. Thus, this chapter will identify the entire concept of hardware and software and will address specific issues dealing with the FMEA.

As discussed earlier, the fundamental reason for conducting an FMEA is to prevent known and potential failures from reaching the customer. Indeed, if an organization wants to be world-class it has to be a market-driven organization with the emphasis of satisfying the customer through process improvement.

This section addresses this prevention mode of operation using the FMEA approach. It will not, however, repeat the methodology that is identical to that for system, design, process, and service. Rather it will focus on the thought process for identifying possible problems.

Failure has been defined as something that fails to meet customer expectations. In the computer industry that may be interpreted as:

- Day-to-day problems
- Process problems (writing a software program is a process)
- Communications
- Rework defect removal
- Coding
- Creative analysis
• Meetings with functional (users) customers
• Paperwork
• Integration
• Clerical support
• Field failures
• Scheduling
• Late delivery
• Lost order
• Customer dissatisfaction
• Software error
• Typing errors

Although all of these may not be present in all situations, they do represent a major portion of the problems that are being faced in the industry. Figures 11.1 and 11.2 represent failures that could have been avoided if proper planning and an FMEA had been conducted.

To prevent these irregularities from happening repeatedly, the focus must be on three basic concepts:

1. What is the cause of the error?
2. What will prevent it in the future?
3. Implement the preventive actions.

The moral of these three concepts is that everyone should learn from every error.

The learning process will begin with appropriate planning and appropriate definition of the needs, wants, and expectations of the defined customer. To make sure that this learning process starts with a chance of being completed one must assemble a team, and the team must define the work items under three categories:

1. Product strategy
2. Objectives and goals of the project
3. Statement of requirements

Look at these work items from a specific functional perspective.
• AT&T’s entire long distance network was once shut down.
• The bank of New York once had to borrow $21 billion in emergency overnight funds from the Federal Reserve, incurring a cool $5 million in interest charges.
• Because of a decimal point error, Wells Fargo Bank in California overstated the income of 22,000 employees in statements to the IRS.
• International lenders could lose up to $650 million because of inadequate software used to process student loans.
• According to the General Accounting Office (GAO) only 2 percent of a sample group of $6.77 million in software projects was used as delivered.

<table>
<thead>
<tr>
<th>Percentage</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 percent used as delivered</td>
<td>$119,000</td>
</tr>
<tr>
<td>3 percent usable after changes</td>
<td>$198,000</td>
</tr>
<tr>
<td>29 percent paid but never delivered</td>
<td>$1,950,000</td>
</tr>
<tr>
<td>47 percent delivered but never used</td>
<td>$3,200,000</td>
</tr>
<tr>
<td>19 percent used after extensive rework</td>
<td>$13,000,000</td>
</tr>
</tbody>
</table>

• Technical failures per 1000 lines of source code during the first year.
  - Japan  1.96
  - United States  4.44

• Lines debugged source code delivered per person year of work.
  - Japan  12,447
  - United States  7,290

• $1 in design = $100 fix in the field

**Figure 11** Software failures.

**Information Development**

• Book plan—may be incomplete
• Documentation standards—standards may not be clear
• Examples—documentation does not match the code
• Books—documentation is late
• Responses to reader comment form—spelling errors

**Testers**

• Test plan—does not specify the environment
• Test cases—cases not updated to latest release level
1. The PCjr
2. Top View, the company’s first attempt at multitasking software
3. Losing early members of its original PC design team to competitors such as Compaq, Apple, and Dell Computer
4. The second release of the 3270 PC Control program, which consumed so much memory that users could not run applications
5. Early problems with PC AT hard disk drives
6. A design oversight in the XT 286 meant that add-in cards designed for the PC AT were too tall to be inserted in the XT 286
7. The company’s failure to introduce the first 80386-based PC, which gave Compaq a competitive edge as a high-technology innovator
8. Ceasing production of the best-selling PC AT without having an effective PS/2 available to replace it
9. Failure to keep abreast of rapid technological and market changes in the laptop/portable markets; case in point: IBM’s portable and convertible
10. The failure to competently and unequivocally demonstrate to users the benefits of the Micro Channel Architecture, which led to its slow acceptance in the market
11. Delivery problems with the PS/2 Model 80-111 in early 1989
12. Hard drive and early delivery problems with the 25MHz PS/2 Model 70

**Figure 11.2** IBM’s 12 biggest PC blunders.
As reported in “IBM’s PC Strategies for the 1990s,” a report by the Computer Technology Research Corp, Holtsville, N.Y.

- Documentation—test escapes or inadequate test coverage
- Verified code—test and build plan conflict

**Developers**

- Design material—design built on self-expectations rather than the customer’s
- Documentation—incorrect level of design
- Unit tests—build or driver content lists incomplete
- Plans, schedules—escapes from unit tests
- Team assignments—unit test scaffolding incorrect
- Fixes—design or programming tips not documented
Managers

- Evaluations—late evaluations
- Development plans—lengthy transition of trainees and/or new hires
- Education plans—development plans not done; education plans not up to date
- Budgets—budget did not include software purchases
- Status—status information is missing and/or is incorrect

Early Support Program

- Support program—support has not been planned
- Customer selection criteria—the true customer has not been identified
- Requirements documentation—not all requirements have been understood; fixes not delivered to all sites; documentation not kept up to date with fixes

Defect Description

What is the error? Can it be defined? Is it really the problem? Can it be quantified? To answer these questions, a team with a leader must work together for a resolution of which everyone will have ownership. To do that, an understanding of group dynamics must be in place. For example, similar to any situation of a team environment, a leader will conduct the meeting.

First, the leader must establish the role by physical, verbal, or procedural methods. In each case the leader must communicate that she or he is in charge of the team process, not the content. This is very important because a team does not have to prove its expertise. The leader is there to facilitate the process.

Second, the leader must establish the role of the team members again through physical, verbal, or procedural means. In no uncertain terms the leader must communicate to the team members the importance of their contribution as well as make them feel important and that their opinions count (Stamatis 1992). Reestablish the commitment of no fear for whatever the opinion is (Deming 1986).
The leader always must ask probing questions—and in some cases leading questions—to make the team start the thinking process. Some questions may be in the form of the following:

1. *Communications*—What was not communicated from whom to whom? Some of the considerations may be:
   - Circulate reports on...
   - Provide tools that will...
   - Define common focal points for...
   - Get correct information to the right people at the right time
   - Embedded communication requirements in process for...
   - Communicate process changes to...

2. *Education*—What was not understood? Some of the considerations may be:
   - Document education requirements that will...
   - Provide back-ups for key jobs that will...
   - Target to job responsibility by...
   - Use forms (standard whenever possible) to share information
   - Make education timely by...
   - Focus on projects, *not* people, titles, and organizations

3. *Oversight*—What was overlooked or not considered? Some of the considerations may be:
   - Improve process by streamlining...
   - Reduce distractions when...
   - Add to common error list...
   - Help peer reviews that...
   - Reduce interruptions when...
   - Develop a tool to...
   - Create a checklist to...
   - Centralize communication for...
4. Process—How did the process require or encourage introduction of the error? Some of the considerations may be:

- Make processes flexible by...
- Recognize the need for continual improvement by...
- Reduce complexity through...
- Automate the task of...
- Communicate changes in... to...
- Evaluate processes versus schedule when...
- Improves inputs by...
- Allocate resources to...
- Define ownership of processes for...
- Develop a work item focus by...

5. Transcription—What technique or procedure was used? Some of the considerations may be:

- Eliminate need for...
- Develop tools to ease the task of…
- Reduce interruptions during...
- Specify training for...

If, on the other hand, an error has been identified, the leader must ask leading questions for confirmation and understanding of the problem. The leader may probe or guide the discussion in the areas of who, what, where, agreement, disagreement, and possible alternatives to the problem. At all times the leader must be careful not to use the why, address a problem on a personal level, or put people on the defensive.

Another function of the leader is to summarize the events of the meeting, so that benchmarks in the progress of resolution may be established for future reference. All that is going on in the meeting must be recorded by either the leader or a secretary. The FMEA may contribute the following benefits from a development perspective to the software industry considering
the relative effectiveness of the team effort in conjunction with the specific methodology of the FMEA:

<table>
<thead>
<tr>
<th><strong>Type of action</strong></th>
<th><strong>Effectiveness (percent)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Improve or extend testing</td>
<td>0</td>
</tr>
<tr>
<td>Improve or introduce inspections</td>
<td>0</td>
</tr>
<tr>
<td>Do it better next time</td>
<td>0–30</td>
</tr>
<tr>
<td>Improve product documentation</td>
<td>30–60</td>
</tr>
<tr>
<td>Improve process documentation</td>
<td>30–60</td>
</tr>
<tr>
<td>Add to common errors list</td>
<td>30–60</td>
</tr>
<tr>
<td>Education</td>
<td>30–60</td>
</tr>
<tr>
<td>Redesign/rewrite code</td>
<td>60–100</td>
</tr>
<tr>
<td>Redesign part/subassembly</td>
<td>60–100</td>
</tr>
<tr>
<td>Tool (avoid or remove)</td>
<td>60–100</td>
</tr>
<tr>
<td>Improve system or production</td>
<td>60–100</td>
</tr>
</tbody>
</table>

To generate specific actions the team must be willing to ask specific questions about the project at hand. For example:

- If the team could change anything at all, what would it change to prevent this error in the future?
- How could the team automatically eliminate this error?
- How could the team remove this error where it exists in other parts of the product?

The questions seem easy and straightforward, but the experience of the author indicates that the answers to these questions are the heart of the team effort for improvement. The answers to these questions will depend on the time allotted for discussion and the willingness of the team to participate. To encourage participation, the leader may want to make sure that each suggested action is:

- Specific and clearly understood
- Stated with an active verb
- Expressed as a complete thought
- As effective and understandable as the team can make it
- Practical
- Usable right now
- Based on sound rationale
• Justifiable
• Data driven

One example as to where and how an FMEA may be used is in the data processing system (DPS). Some of the concerns at the starting point follow.

**Implementation of the System**

• Summary files (open, close, action, archive)
• Control tables for customization
  – Product control tables
  – Verification tables
  – Configuration tables
  – Search synonyms

**Security**

• Lock files
• System passwords
• Authorizations to specific points

**Installation, Customization, and Operation**

• Set up disconnected identification
• Set up tool and database disks
• Customize DPS configuration
• Customize product control table
• Customize verification table

For software, the following may be addressed:

• Documented development process
• Focus on customer
• Verification and validation
• Early software manufacturing involvement
• Benchmarking
• Dependency management
• In-process measurements
• Defect prevention
• Robust change control
• Tools
• Education
• Reuse
• Linkage to other product
• Productivity and cycle time

The model follows for performing an FMEA on software.

Figure 11.3 shows the overview software structure for an FMEA application. It is interesting to note that the possibility exists to conduct an FMEA in the development stage, changing control stage, and evaluation and implementation stage.

In each case one can follow up with evaluation to determine if effectiveness has been accomplished. If not the cycle can start over again.

For a detailed example of a software analysis, examine the code. Some questions and/or possibilities that the FMEA may address are:

• Is the code completed?
• Does the code meet the customer’s requirements?
• Is the first draft evaluated?
• Are the appropriate standards applied?
• Is the appropriate library initialized?
• Have the appropriate drivers and macros for the drivers been finalized?
• Has the clear del been created?
• Is the code placed in the appropriate clear del?
• Have all the test tools been developed?
• Are the tools appropriate?
• Have the project and product databases been updated?
**Figure 11.3** Software structure overview for FMEA application.
• Have all the technical and publication inspectors been identified?
• Have all the unnecessary calculations been removed?
• Have all path lengths been identified?
• Is the path length appropriate?
• Does the code meet the product’s coding conventions?
• Have all the reinspection criteria been followed?
• Have all deviations been accounted for?
• Does the code follow the structure programming?

A checklist of specific issues and/or concerns may be developed based on the above questions. Examples of checklists in specific areas are:

**Logic Missing**

• Are all constants defined and used?
• Are all defaults checked explicitly (for example, blanks in an input stream)?
• If character strings are created, are they complete? Are delimiters used as necessary?
• If a key word has many unique values, are they all checked?
• Are all key words tested in a macro?
• Are all key word related parameters tested in a service routine?
• Are all increment counts properly initialized (0 or 1)?
• After processing a table entry, should any value be decremented/incremented?
• Is provision made for possible processing at logical checkpoints in the program (end-of-file, end-of-volume, and so on)?
• If a queue is being manipulated, can the execution be interrupted? If so, is the queue protected by a locking structure? Can the queue be destroyed over an interrupt?
• After queueing/dequeueing, should any value be decremented or incremented?
• Should any registers be saved on entry?
• Should registers be restored on exits?
Logic Wrong

- Are literals used where there should be constant data names?
- On comparison of group items, should all fields be compared?
- Are internal variables unique?

Logic Extra

- Are all data areas necessary?
- Does this module contain redundant logic (tests for something already screened out)?

Linkage

- Are all correct linkage macros used:
  - When a module is an external subroutine?
  - When a module is the last module to be called?

Control Block Definition/Usage Missing

- Are pointers declared as XX bit pointers?
- Is the bit configuration for input/output parameters defined?
- Is the field property defined in the control block/data area?
- If the design is dependent on building/creating/deleting various control blocks/data areas, is it provided for in the code?

Common Errors in the Code Stage

- Coded incorrect copyright
- Consider all operating environments when developing code
- Consider all possible error conditions
- Fiche flag all code changes
- Communicate all changes to components with dependencies on the organization
- When changing a macro, make sure all affected modules are paralleled
- Compare each stage of development against previous stage(s) to prevent oversights
Bits, Bytes, Ptrs, or Regnot Reset After Processing (This Is Very Common)

- Initialize all variables before usage—never assume zeroes
- Initialize all fields of a control block; do not leave garbage
- *Reserved* fields must be initialized to zero
- Early termination—pointer, values not reset
- First buffer released, but not others

Be Concerned with Data Types and Variable Lengths

- When defining counters, make sure boundaries are sufficient—try to predict possible future size changes
- Make code data independent whenever possible
- Control block not fullword aligned
- DCL not properly aligned
- Field definition as FIXED (XX) based later on CHAR string (which is not properly aligned, causing bugs)
- Bit versus mask equate used
- FIXED (XX) versus CHAR (X)

Consider All Permutations of Parameter Values

- Parms passed in wrong order
- Update return code on error conditions

Open and Close All I/O Files Properly

- Use a different work area for each I/O file
- When changing I/O file Irecls and blksizes, make sure file definitions reflect these changes

Duplicate Labels

- Made up labels as coder went along
- Names misunderstood or confused with others
- Do not assume control block bit meanings
Parenthesis Missing in Parameter

- Comma missing
- Did not understand implications of in-line macros
- Register destroyed by in-line macro
- Macro assumed space for save area
- Moved code (copied code) is very error prone. Deleted code is very error prone. Check all paths and instructions (this is very common)
- Easy code change near complex code change is error prone
- Use positive logic whenever possible

Loop Logic Errors

- Consider all flags on each iteration
- Consider three loop conditions: first pass, last pass, and middle iteration
- Initialize all flags and counters before entering loop
- Increment counters on each iteration
- Update all pointers on each iteration
- Wrong bit checked

Resetting of Bits in Wrong Place

- Flag set in control block at wrong time

DO WHILE Instead of DO UNTIL

- OR instead of AND on IF statement
- Tested OFF instead of ON
- X‘YY’ should have been X‘10’

Assembler 1/2 Word Usage

- Make sure data will always fit in 2 bytes
- Make sure high-order bytes are cleared
- Registers clobbered (this is very common)
Wrong registers used
No addressability established
Save areas not bumped; register does not point to save area

How to Get Started

The sequence for performing an FMEA in the computer industry with the intent of (1) identifying the problem, (2) providing for a solution, and (3) providing for follow-up is:

- Form a team
- Select a leader
- Collect or anticipate error data
- Have a kickoff meeting(s)
- Do a causal analysis
- Conduct the FMEA
- Utilize the action team
- Gather feedback and other communications
- Analyze results
- Confirm results
- Gain publicity
- Extend application
- Monitor improvements

A SYSTEM APPROACH TO IMPLEMENTATION

A complete system development methodology outline using the six phases of project management follows (Kerzner 1992). Please note that within each phase there is a tremendous opportunity to develop an FMEA.
**Phase 1—Project Initiation Phase**

<table>
<thead>
<tr>
<th>Activity task</th>
<th>Approvals required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prepare direction of project</td>
<td>Project management administrator, QA, project manager, project leader</td>
</tr>
</tbody>
</table>

**Project assessment**

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Approvals required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Define the education requirements</td>
<td>ISD training and development</td>
</tr>
<tr>
<td>Education schedule</td>
<td>Project manager, project leader</td>
</tr>
</tbody>
</table>

**Prepare project plan**

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Approvals required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Management objectives</td>
<td>Project manager, project leader</td>
</tr>
<tr>
<td>Assumptions and constraints</td>
<td>Project manager, project leader</td>
</tr>
<tr>
<td>Current system resource requirements</td>
<td>Project manager, project leader</td>
</tr>
<tr>
<td>Proposed system resource requirements</td>
<td>Project manager, project leader</td>
</tr>
<tr>
<td>Cost-benefit analysis</td>
<td>Project manager, project leader</td>
</tr>
<tr>
<td>Design considerations</td>
<td>Project manager, project leader</td>
</tr>
<tr>
<td>Approval mechanism</td>
<td>Requisition approvals as noted</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Milestone</th>
<th>Approvals required</th>
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</thead>
<tbody>
<tr>
<td>Major milestones Planning</td>
<td>Project manager, project leader</td>
</tr>
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</table>

**Authorization to proceed**

<table>
<thead>
<tr>
<th>Activity</th>
<th>Approvals required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Review project initiation phase</td>
<td>Project management administrator, QA, information services director, Non-ISD director or chair</td>
</tr>
</tbody>
</table>

**Phase 2—General Analysis Phase**

<table>
<thead>
<tr>
<th>Activity task</th>
<th>Approvals required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prepare general system design proposal</td>
<td>Project manager, project leader</td>
</tr>
<tr>
<td>Prepare cover sheet, table of contents</td>
<td>Project manager, project leader</td>
</tr>
<tr>
<td>Interview schedule</td>
<td>Project manager, project leader</td>
</tr>
<tr>
<td>Interview the functional areas</td>
<td>Project manager, project leader, interviewee</td>
</tr>
<tr>
<td>Current system/subsystem description</td>
<td>Project manager, project leader</td>
</tr>
<tr>
<td>Project objectives</td>
<td>Project manager, project leader</td>
</tr>
</tbody>
</table>
Assumptions and constraints: Project manager, project leader
Proposed system/subsystem description: Project manager, project leader
Data requirements analysis: Project manager, project leader, data administrator
Security analysis: Project manager, project leader, security administrator, department managers
Resource requirements analysis: Project manager, project leader, department managers
Expected benefits: Project manager, project leader, department managers
Cost-benefit analysis: Project manager, project leader
Future considerations: Project manager, project leader
Alternatives evaluation: Project manager, project leader
Planning: Project manager, project leader, department managers

Authorization to proceed
Review general analysis phase: Project management administrator, QA, information service director, Non-ISD director or chair

Phase 3—System/Subsystem Design Phase

<table>
<thead>
<tr>
<th>Activity task</th>
<th>Approvals required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prepare system/subsystem design specs</td>
<td></td>
</tr>
<tr>
<td>Prepare cover sheet, table of contents</td>
<td>Project manager, project leader</td>
</tr>
<tr>
<td>Define the purpose</td>
<td>Project manager, project leader</td>
</tr>
<tr>
<td>Functional comparison</td>
<td>Project manager, project leader</td>
</tr>
<tr>
<td>Detail comparison (external devel)</td>
<td>Project manager, project leader</td>
</tr>
<tr>
<td>Function analysis</td>
<td>Project manager, project leader, interviewee</td>
</tr>
<tr>
<td>Data requirements analysis</td>
<td>Project manager, project leader, data administrator, database administrator</td>
</tr>
<tr>
<td>Data element analysis</td>
<td>Project manager, project leader, data administrator</td>
</tr>
<tr>
<td>Processing analysis</td>
<td>Project manager, project leader</td>
</tr>
<tr>
<td>Control requirements</td>
<td>Project manager, project leader</td>
</tr>
<tr>
<td>Task</td>
<td>Responsible Party</td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>-----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Application analysis</td>
<td>Project leader, data administrator, database administrator</td>
</tr>
<tr>
<td>Simulation development</td>
<td>Project manager, project leader, data administrator</td>
</tr>
<tr>
<td>Simulation walk-through</td>
<td>Department managers</td>
</tr>
<tr>
<td>Normalize data</td>
<td>Data administrator</td>
</tr>
<tr>
<td>Define logical file structure design</td>
<td>Data administrator</td>
</tr>
<tr>
<td>Define physical file structure design</td>
<td>Database administrator</td>
</tr>
<tr>
<td>Informal file structure design review</td>
<td>Data administrator, database administrator, project leader, system analyst</td>
</tr>
<tr>
<td>Doc. file structure design assumptions</td>
<td>Data administrator, database administrator</td>
</tr>
<tr>
<td>Define file structure install req</td>
<td>Database administrator</td>
</tr>
<tr>
<td>Define file structure security</td>
<td>Data administrator</td>
</tr>
<tr>
<td>Formal file structure review</td>
<td>Data administrator, database administrator, project leader, system analyst</td>
</tr>
<tr>
<td>Integrated application and file structure</td>
<td>Project leader, data administrator, database administrator</td>
</tr>
<tr>
<td>Procedure analysis</td>
<td>Project manager, project leader</td>
</tr>
<tr>
<td>System acceptance criteria</td>
<td>Project manager, project leader, department managers</td>
</tr>
<tr>
<td>Final resource requirements analysis</td>
<td>Project manager, project leader, department managers</td>
</tr>
<tr>
<td>Expected benefits</td>
<td>Project manager, project leader, department managers</td>
</tr>
<tr>
<td>Cost-benefit analysis</td>
<td>Project manager, project leader</td>
</tr>
<tr>
<td>Planning</td>
<td>Project manager, project leader, department managers</td>
</tr>
<tr>
<td>Authorization to proceed</td>
<td></td>
</tr>
<tr>
<td>Review system/subsystem design phase</td>
<td>Project management administrator, QA, information service director, Non-ISD director or chair</td>
</tr>
</tbody>
</table>
## Phase 4—Development Phase

<table>
<thead>
<tr>
<th>Activity task</th>
<th>Approvals required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acquire resources for implementation</td>
<td>Project manager, project leader</td>
</tr>
<tr>
<td>Prepare user procedures</td>
<td>Project manager</td>
</tr>
<tr>
<td>Develop training plan</td>
<td>Project manager, project leader</td>
</tr>
<tr>
<td>Prepare system test plan</td>
<td>Project manager, project leader</td>
</tr>
<tr>
<td>Prepare installation plan</td>
<td>Project leader, database administrator</td>
</tr>
<tr>
<td><strong>File structure install (test)</strong></td>
<td></td>
</tr>
<tr>
<td>Define file structure elements</td>
<td>Data administrator</td>
</tr>
<tr>
<td>Define file structure records</td>
<td>Data administrator, database administrator</td>
</tr>
<tr>
<td>Physical file description</td>
<td>Database administrator, database administrator</td>
</tr>
<tr>
<td>File restructure</td>
<td>Database administrator</td>
</tr>
<tr>
<td>Create new files</td>
<td>Database administrator</td>
</tr>
<tr>
<td>Prepare file backups</td>
<td>Database administrator, department managers</td>
</tr>
<tr>
<td>Programming specifications</td>
<td>Project leader</td>
</tr>
<tr>
<td><strong>Application roundtable</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Program coding</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Unit testing</strong></td>
<td></td>
</tr>
<tr>
<td>Revise specifications</td>
<td>Project leader</td>
</tr>
<tr>
<td><strong>Document operations procedures</strong></td>
<td></td>
</tr>
<tr>
<td><em>(see operations documentation req)</em></td>
<td></td>
</tr>
<tr>
<td>Planning</td>
<td>Project manager, project leader, department managers</td>
</tr>
<tr>
<td><strong>Authorization to proceed</strong></td>
<td></td>
</tr>
<tr>
<td>Review system development phase</td>
<td>Project management administrator and QA, information service director, Non-ISD director or chair</td>
</tr>
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</table>
Phase 5—System Acceptance and Implementation Phase

<table>
<thead>
<tr>
<th>Activity task</th>
<th>Approvals required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Execute system test plan</td>
<td>Project manager, project leader, project management administrator, QA</td>
</tr>
<tr>
<td>Execute training plan</td>
<td>Project management administrator, QA</td>
</tr>
<tr>
<td>Execute conversion</td>
<td>Project management administrator, QA</td>
</tr>
<tr>
<td>Execute parallel</td>
<td>Project management administrator, QA</td>
</tr>
<tr>
<td>Review the documentation</td>
<td>Project administrator, and QA</td>
</tr>
<tr>
<td>Planning</td>
<td>Project manager, project leader, department managers</td>
</tr>
</tbody>
</table>

Authorization to proceed

Review system acceptance and implementation phase

Implementation

Notification

Install files

Install operations documentation

Implementation summary report

Phase 6—Postimplementation Audit Phase

<table>
<thead>
<tr>
<th>Activity task</th>
<th>Approvals required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interview schedule</td>
<td></td>
</tr>
<tr>
<td>Interview the functional areas</td>
<td></td>
</tr>
<tr>
<td>Prepare summary report</td>
<td></td>
</tr>
<tr>
<td>Authorization to close the project</td>
<td>ISD director, Non-ISD director or chair</td>
</tr>
<tr>
<td>Review postimplementation audit phase</td>
<td>ISD director, Non-ISD director or chair</td>
</tr>
</tbody>
</table>

The team composition for the hardware design and process FMEA may reflect the cross-functionality and multidisciplines of the appropriate personnel for the design and/or the process. It may follow the general guidelines discussed in the section on team development.
The team composition for the software FMEA should follow the general guidelines of the team composition of cross-functionality and multi-disciplines as appropriately defined. In this team, however, it must be emphasized that the team must reflect a makeup of developers who work on the same release or line item; or who go through development stages at approximately the same time. Logically, the person who may be the leader is the chief programmer because he or she is responsible for the ultimate product. A typical software FMEA team may include:

- Programmer  
- Security  
- Data administrator  
- System analyst  
- Developer  
- Database administrator

Other appropriate personnel may be added or consulted as needed. For example:

- Code personnel  
- Project manager  
- Supplier  
- Information system personnel  
- Customer  
- Release coordinator

REFERENCES


The main focus of the FMEA in the semiconductor industry is to determine the cause for device malfunction or parametric degradation. This entails experienced technical personnel pursuing a disciplined analytical approach leading to a root cause of failure. This approach is the FMEA.

Although the methodology of conducting an FMEA is the same as that discussed, there are some distinct differences in the failure mode identification, causes of failure, and control mechanisms in preventing these failure modes.

This chapter addresses some of these differences and presents a summary of possible failure modes testing mechanisms.

Some of the major failure modes in the semiconductor industry are:

- Electrostatic discharge (ESD)
- Thermal changes
- Oxide ruptures
- Current heating
- Hot or cold sites on ICs
- Reclaim scrap
- Purity of gold bullion
- Plating uniformity
- Wafer surface problems
- Organic contaminants
- Powder or residue problems
• Solvent or liquid contamination
• Molding compound contamination
• Over/undercuring
• Identification
• Dimensional problems
• Solder bump thickness
• Composition ratios of binary thin films
• Plating thicknesses
• Thicknesses of multilayer backmetal systems
• Trace metals in process solutions and waters
• Concentration of major, minor, and trace elements in:
  – Alloys
  – Thin films
  – Solders
  – Residues
• Oxide and junction defects
• Silicon lattice defects
• Grain size
• Oxide slope
• Surface topography
• Bonding defects
• Construction parameters
• Composition
• Intermetallic formation and degree of wire bond deformation
• Surface leakage
• Visual rejects
• Bond voids
• Discoloration
• Flaking
• Dewetting
• Bridging
• Pinhole defects
• Field oxide
  – Patterning/etching defect
• Foreign matter/particulate
  – Interlevel oxide
• Passivation
  – Cracks/crazing
• Defusion
  – N type, doping level
• Scratch
  – Pre-interlevel oxide
  – Mechanical surface damage
• Dielectric breakdown
• Oxide in contact
• Physical damage
• Substrate
  – Dislocations
  – Stacking fault
• Broken leads
• Off bond
• Lifted bond and die
• Lifted bond and post/lead/frame
• Swept wipes
• Broken wire bond
• Heel break and wedge/stitchbond
• Neck break and ball bond
• Improper wire dress
• Scribe grid short
• Wire package short
• Handling damage
• Contamination on external leads
• Flow in mask
• Foreign matter on die
• C-S leakage
• Underetched metal
• Wrong EPI
• Overetched VIA(s)/PREOHMICS
• Passivation pinholes
• Interlayer passivation cracks
• Visual contamination
• Break/reversible leakage
• Mixed product
• EOS
• Metal deformation
• Mechanical surface damage
• Intermetallics
• Retest with specification
• Undetermined
• Equipment malfunction
• Lost units
• Hermeticity rejects
• Metal shorts
• Probe defects
• Corrosion
• Chopped bond
• Silicon defect in collector junction
• Excess photoresist pattern
• C E leakage/short
This list is not exhaustive, but meant as an example of the complex failure modes and/or causes one may encounter in pursuing FMEA in the semiconductor industry. The list should provide the reader with a starting point of investigating problems to seek improvements to existing and/or future designs and/or processes.

As an example of using the list in a prevention mode, consider the problem of ESD. ESD is the process of accumulation of large amounts of charge on a body—resulting in high electric potential and rapid, uncontrolled discharge through another body at lower electric potential with the possibility of damage occurring. There are at least three models developed that describe the methods by which ESD damage can be induced to semiconductor devices (Motorola 1992). They are:

1. **The human body model**—It consists of a 100 pF capacitor in series with 1500 ohm resistor and typifies the characteristics of the human body.

2. **The machine model**—It consists of only a 200 pF capacitor with no series resistance.
   <note> These two models are based on the premise that a high potential outside source inflicts an ESD event upon the semiconductor with the possibility of causing damage.

3. **The charged device model**—With this model the device develops voltage potential and upon contact with a lower potential object discharges to cause the ESD event.
   
   After one isolates the problem, the potential for damage is recognized. Based on that knowledge one should plan accordingly for the elimination of the failure either through design changes or process changes. These changes may be incorporated into the company’s system of improvement by defining a prevention course for the specific failure or incorporating any one of the tests explained later in this chapter.

   First, examine the prevention mode of operation by focusing on the prevention of ESD. The process of prevention for the ESD may be as follows:

   • Training of personnel for development of ESD prevention culture

   • Special studies for development of ESD resistance structures, materials, and design rules

   • Measurement/characterization program using human body and machine models/simulation

   • System audit for assuring compliance to ESD policy process
After the skeleton of the policy has been established, the FMEA team may focus on very specific outcomes for prevention. The following specific items may be considered:

- What should the specification documenting minimum ESD prevention procedure cover?
- What specific materials for ESD prevention should be considered? Why? Why not?
- Are specification documenting assessment procedures for compliance verifiable? How?
- Do all areas (wafer fab, assembly, and so on) implement ESD prevention procedures?
- Are individual wafers packed in vacuum-scaled envelopes made of conductive materials?
- Do all working stations have conductive tabletops, properly grounded?
- Are wrist straps for static control used appropriately?
- Are ionization devices used where appropriate for neutralizing static charges?
- Are the floors conductive or antistatic?
- Are shoe straps used by personnel when appropriate? How is one assured that the practice is followed?
- Do antistatic envelopes for storage accompany the product?
- Are antistatic packaging practices followed for transport of the product?
- Are high dielectric materials avoided?
- Are soldering irons grounded properly?

These questions are only a sample of possibilities for one failure in the ESD. One can further the probe with additional reliability questions and testing.

The quest for a superior product in the semiconductor industry is emphasized by a serious focus on quality and reliability. To reach this superior product, superior designs with conservative design rules and process checkpoints must be in place. Even though this superior product is achievable, much planning has to be done in both the design and process FMEA. The reason for this so-called excessive planning is because in the semiconductor devices there is an inherently very low failure rate (Motorola 1992). As a result, the industry uses techniques with accelerating testing to assess
the reliability, functionality, and performance of the semiconductors before they reach the customer.

Some of the guidelines to achieve this superior quality with accelerated testing are:

- Minimum levels of latch-up protection are required.
- Guidelines are in place to reduce the effects of hot carrier injection.
- All design work is based on simulation.
- Testability must be realistic in new designs.
- There are minimum levels of input protection for ESD.
- Stress relief design rules must be communicated to all appropriate personnel to reduce the effects of packaged induced stress.
- Specific guidelines must be in place for maximum current density allowed in metal lines, contacts, and vias to eliminate electro migration concerns.

Although this text will not discuss in detail each of the available statistical techniques and all the individual testing techniques used today in the industry, it will focus on a summary presentation of such tests for both the design and process FMEA to detect individual failures. This does not suggest that all the tests identified here have to be used in a given FMEA to control failures. Rather, they are presented as brief descriptions to help the engineer plan for controlling the design and/or process. Some of these tests available for design control follow.

**Temperature Cycle.** This test accelerates the effects of thermal expansion mismatch among the different components within a specific die and packaging system. This test is performed based on MIL-STD 883 or MIL-STD 750.

**High Temperature Operating Life.** This test accelerates failure mechanisms that are thermally activated through the application of extreme temperatures and the use of biased operating conditions.

**Autoclave.** This environmental test measures device resistance to moisture penetration and the resultant effects of galvanic corrosion.

**Thermal Shock.** This test is similar to temperature cycle testing. It emphasizes differences in expansion coefficients for components of the packaging system. This test also is based on MIL-STD 883 and MIL-STD 750.

**Temperature Humidity Bias.** This test is designed to measure resistance of plastic-encapsulated circuits.
HAST/PTHB (Pressure-Temperature-Humidity-Bias). This test accelerates the effects of moisture penetration with the dominant effect being corrosion.

Cycled Temperature Humidity Bias. This test is used to examine a device’s ability to withstand the combined effects of temperature cycling, high humidity, and voltage (test can be run without bias).

Power Temperature Cycling. This test determines the effects of alternate exposures to extremes of high and low temperature with operating voltages periodically applied and removed.

Low Temperature Operating Life. This test is performed to accelerate hot carrier injection (HCI) effects in semiconductor devices by exposing them to room ambient or colder temperatures with the use of biased operating conditions.

Power Cycling. This test is performed at a constant ambient temperature with operating voltage(s) periodically applied and removed, producing a DTJA, typically between 50 degrees and 150 degrees Celsius.

Salt Atmosphere. This test evaluates the corrosive effects of a seacoast-type atmosphere on device and package elements. It is performed based on MIL-STD 883 or MIL-STD 750.

Lead Integrity. This test examines the mechanical properties of a device’s leads, welds, and seals. It is performed based on MIL-STD 883 or MIL-STD 750.

Solder Heat. This test examines the device’s ability to withstand the temperatures present in soldering over a more extended period as compared to the typical exposure levels in a production process.

Constant Acceleration. This test is used to indicate structural or mechanical weaknesses in a device/packaging system by applying a severe mechanical stress. It is based on MIL-STD 883 or MIL-STD 750.

Variable Frequency Vibration. This test is used to examine the ability of the device to withstand deterioration due to mechanical resonance. It is based on MIL-STD 883 or MIL-STD 750.

Write/Erase Cycling of EEPROMs. This test evaluates the effects of repeated programming and erasing excursions on EEPROM devices without corruption of data.

High Temperature Storage/Data Retention. This test measures the stability of semiconductor devices, including the data-retention characteristics
of EPROM and EEPROM devices, during storage at elevated temperatures with no electrical stress applied.

**System Soft Error.** This test detects errors caused by impact ionization of silicon by high-energy particles.

**Mechanical Shock.** This test is used to examine the ability of the device to withstand a sudden change in mechanical stress, typically due to abrupt changes in motion as seen in handling, transportation, or actual use. It is based on MIL-STD 883 or 750.

These tests are a good starting point to make sure that the design has built-in mechanisms that control performance, reliability, and function. When one reaches the process, however, one may want to do a failure analysis of an existing (known) problem. If that is the case, one might proceed with some of the following nondestructive tests.

**X-ray Inspection.** Check for voids and uniformity, component and wire placement.

**Acoustic Imaging.** Check for package or internal component voiding or delamination.

**Hermeticity Testing.** Check for hermetic integrity of the package.

**Device Bake or Stress.** Check for parametric shifts or recovery.

**Electrical Retest.** Check for failure if it is present or if it has recovered.

**Residual Gas Analysis (RGA).** Used to analyze the internal atmosphere of a hermetic cavity device.

**Wet or Dry Chemical Decapsulation.** Used to remove the encapsulant with acids or solvents to expose the internal components or die surface.

**Thermal/Mechanical Decapsulation.** Used to remove the lids on either metal or ceramic packages by either remelting the lid-attached material or by grinding into the package.

**Microcross Sectioning.** Used to reveal various features of the assembly.

**Internal Inspection.** Used to check if the failure mechanism is still present.

**Internal Diagnostic Testing.** These techniques are readily used for failure identification. All are considered to be nondestructive.

**Liquid Crystal Testing.** Used to identify localized spots during device operation.
Voltage Contrast. Used to observe voltage level variations on internal interconnects. It also may be used in a dynamic mode.

Electron Beam Induced Current (EBIC). Used to induce current in relation to its location.

Emission Microscopy. Used as a diagnostic instrument to image the light emission of specific device features.

Thermal Imaging. Used to give a graphical representation of the surface temperature of the device/component under test.

Electrical Probing and Isolation. Used to determine further electrical characterization.

E-Beam Testing. Used to induce and measure localized signals to diagnostically evaluate internal circuitry on a semiconductor.

Focused Ion Beam (FIB). Used for localized material removal to allow access to underlying features for subsequent evaluation. This method also may be used to allow for electrical connection and device troubleshooting.

Electron Microscopy. A generic term to denote the types of electrons or x-rays generated using an electron microscope.

Secondary Electrons. Used for imaging of the specimen.

Backscattered Electrons. Dispersive X-ray Spectroscopy. Chemical-Surface Analysis. These tests are used to evaluate the composition of materials in the course of an analysis.

Secondary Ion Spectroscopy (SIMS). Used to depict profiling of trace contamination of surfaces, thin films, thick films, multilayer structures, and interfaces.

Auger Microscopy. Used for characterization of surface containments which may inhibit bondability and solderability, contribute to surface leakage, or constitute visual rejects.

Electron Spectroscopy for Chemical Analysis (ESCA). X-ray Fluorescence (XRF). Used for qualitative elemental screening of unknown samples often for subsequent characterization by other methods.

Chemical Deprocessing. There are many methods available for removal of various layers and materials for the deprocessing of semiconductor devices; however, the primary technique is the use of wet chemicals such as acids or solvents for selective etching. Plasma etching or dry etching can be used when wet chemicals are not preferred.

Failure Simulations. Used to evaluate failures under control conditions in which the device was perceived to have failed. Information gained can point to a device weakness or even specific application-related stress.

REFERENCES

The proliferation of the ISO 9000 standards and the related Product Liability Directives have caused acceptance of these standards by both companies and countries. The United States is no different. Even though in 1991 the United States accounted for 40 percent of the overall $18 billion market it must comply with the new European Commission (EC) directives (Kolka 1992).

In the process of complying, however, there are some questions that should be addressed:

- Which standards apply to medical devices and to what extent?
- Will certification be required?
- What kind of testing is required?
- Who is going to perform the testing?
- Are there applicable directives for medical devices? What do they require?
- How are the compliance procedures going to be met? Are there considerations for detail?
- What is the overall plan of EC in the area of medical devices?

Although these questions are some of the most critical ones, this chapter will address the applicability of several standards to the reliability of safe products in the medical device industry. Furthermore, the FMEA is recommended on the basis that it will contribute much toward the safety of the products.
First, one must define what a medical device is. A medical device is an instrument, apparatus, implement, appliance, implant, or other similar or related article, that is intended for use in the treatment of humans, contraception, or in diagnosis (Kolka 1992). (A device achieving its principal intended purpose through chemical action within or on the body is excluded from the definition.)

Second, one must study the appropriate standards relating to medical devices:

- European Norm (EN) 46000 for medical devices
- BS 5750: Part 1 Quality Systems: Specification for design, manufacture, and installation
- BS 5781: Part 1 Specification for measurement and calibration systems
- BS 6000: Guide to the use of BS 6001, sampling procedures and tablets for inspection by attributes
- BS 6001: Sampling procedures and tablets for inspection by attributes
- BS 6002: Sampling procedures and charts for inspection by variables for percent defective
- HMSO (Guide to Good Manufacturing Practice—GMP)
- U.S. Current GMP: Part 210–211 Pharmaceuticals
- U.S. Current GMP: Part 820 Medical Devices
- U.S. Controlled Substances Regulations: Part 1301–1304.

The Active Implantable Medical Devices Directive (AIMDD) was adapted in June 1990 and became effective January 1, 1993. The AIMDD was given two years for full implementation. By definition, an AIMD is: “Any active device which is intended to be totally or partially introduced, surgically or medically, into the human body or any medical intervention into a natural orifice and which is intended to remain after the procedure.”

The directive also covers:

- Custom-made active implantable medical devices developed for individuals by medical specialists
- Any active implantable medical devices intended for clinical investigation.
The implications of the AIMDD to FMEA are in Procedure A (Article 1a). To complete this procedure, a manufacturer must take into account the language and requirements of:

- ISO 9001
- Annex 2
- EN 46001
- EN 50103

For the requirements of an FMEA program in ISO 9001, see Chapter 15. The requirements of Annex 2 ask that verification and declaration of conformance be present in the design and manufacturing. The requirements of the EN standards request:

- Surveillance systems
- System consistency
- Record maintenance
- Safety
- Complaint feedback

The Medical Devices Directive (MDD) was proposed on August 30, 1991. The implementation date was set for July 1, 1994, with a three-year transition period.

As for liability concerns, the MDD raises the same issues as the AIMDD and the In Vitro Diagnostics Directive (IVDD). Specifically, Annex 1: Essential Requirements, Section 2 of all three directives states, “The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles taking account of the generally acknowledged state of the art.”

In addition, the MDD raises the following concerns:

- Personnel responsibility for product quality
- Labeling
- Warnings
- Complaints
- Recalls
- Feedback system
- Environmental control and manufacturing conditions
- Maintenance of quality records
One of the most relevant clauses for FMEA application is in Annex 1, paragraph 1, regarding “acceptable risk,” which states “Devices must be designed and manufactured in such a way that … any risk which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.”

The In Vitro Diagnostics Directive was introduced in August 1992 and is still considered a draft proposal. It is designed for noninvasive use with body fluids or tissues, however, and it is considered to be one of the preventive law programs that will help reduce liability exposure. The Food and Drug Administration (FDA) medical device developments essentially are regulations for the manufacturers in pursuing quality standards. These regulations are called Good Manufacturing Practices (GMP) for Medical Devices. Some of the requirements of GMPs are:

- Equipment service reports
- Process validation
- Design control

The intent of the requirements is to reduce the number of defects and whenever possible improve the design and/or process.

The issue of all the mentioned standards and directives is product liability prevention. As such, manufacturers dealing with medical devices can prevent accidents and liability issues by:

- Providing safe products with legally adequate warning labels and instruction manuals (appropriate for their intended users).
- Creating safety committees to analyze relevant data and to determine whether or not some action is necessary. The some may be changes or modifications in design or process.
- Establishing document retention policies (not only for legalistic reasons) to track improvements, changes, and to document the process from a historical perspective.

Is all this relative to FMEA? The answer is a definite yes. Why? Because, as already shown, product liability creates defenses for manufacturers. Generally, the availability of data (especially for improvement) will make it easier to defend against a claim of defective product. An FMEA is precisely the instrument that will define the need for the data and determine how the data should be implemented as part of the design or process improvement.
In addition, an FMEA is part of a prevention mechanism within the organization that includes analysis of standards and laws as they apply to a given product. This application in the medical device industry allows the FMEA to help identify current or potential problems.

Is the FMEA applicable to the medical device industry? Yes. The medical device industry is becoming a global market. As such, the standards that it is going to follow for continual improvement and elimination of problems are the ISO 9000 series. Specifically, ISO 9001 and ISO 9004 call for some important and critical issues relating to medical devices. Some of these issues include:

- Risks
- Problem analysis
- Health and safety
- Complaints
- Problem prevention
- Corrective action
- Incorporation of new technologies
- Unintended use and misuse
- Regulation requirements
- Documentation
- Record keeping
- Reporting

Obviously, the FMEA has a very strong role to play in the medical device industry. As for the FDA and the GMPs, the FDA is moving toward harmonizing the new GMPs and the EC medical device directive.

**REFERENCES**


For a long time, the auto industry has used FMEA to improve customer satisfaction and reduce nonconformances. In fact, since early 1980 some of the American automotive companies have included the FMEA as part of their own standards in defining quality.

To be sure, even though the FMEA has been around, that does not mean that it was used continuously or appropriately with exceptional results. To the contrary, because it was viewed as a tremendous time consuming activity corners were cut and the spirit of the FMEA was not really followed.

The status quo continued until the mid 1990s. About that time, the FMEA was more or less finally identified as a methodology that could prevent problems and improve quality. Whereas the FMEA was indeed part of standards and requirements as early as the 1970s in some cases, now it became the methodology of choice. Auditors in ISO 9000 and QS-9000 were beginning to ask for appropriate documentation and organizations began to systematically follow appropriate guidelines for its appropriate implementation.

The FMEA finally became a very important item in the toolbox of quality. So much so that Six Sigma methodology, Advanced Product Quality Planning (APQP), Production Part Approval Process (PPAP), Tooling and Equipment (TE 9000), ISO 9000, QS-9000, and ISO/TS16949 specifically identified the FMEA as a mandatory methodology for improvement.

This chapter focuses on the uniqueness of the FMEA as used in the automotive industry and as such the background and other generic information will not be repeated in here. So let us begin our discussion with the definition of the FMEA as viewed primarily in the automotive world.
DEFINITION OF FMEA

FMEA is an *engineering reliability tool* that:

1. Helps to define, identify, prioritize, and eliminate known and/or potential failures of the system, design, or manufacturing process before they reach the customer. The goal is to eliminate the failure modes or reduce their risks.

2. Provides structure for a cross functional critique of a design or a process.

3. Facilitates inter-departmental dialog. (It is much more than a design review.)

4. Is a mental discipline engineering teams go through when critiquing what might go wrong with the product or process.

5. Is a living document that reflects the latest product and process actions.

6. Ultimately helps prevent, and not react to problems.

7. Identifies potential product or process related failure modes before they happen.

8. Determines the effect and severity of these failure modes.

9. Identifies the causes and probability of occurrence of the failure modes.

10. Identifies the controls and their effectiveness.

11. Quantifies and prioritizes the risks associated with the failure modes.

12. Develops and documents action plans that will occur to reduce risk.

Types of FMEAs

*System/Concept*—S/CFMEAs. These are driven by system functions. A system is an organized set of parts or subsystems designed to accomplish one or more functions. System FMEAs are typically done very early, before specific hardware has been determined.

*Design*—DFMEA. A design FMEA is driven by part or component functions. A design/part is a unit of physical hardware that is considered a single replaceable part with respect to repair. Design FMEAs are typically done later in the development process when specific hardware has been determined.
Manufacturing or Process—PFMEA. A process FMEA is driven by process functions and part characteristics. A manufacturing process is a sequence of tasks that is organized to produce a product. A process FMEA can involve fabrication as well as assembly.

Service—A service FMEA is a standardized technique for evaluating systems and components during the concept and design phase to improve the serviceability of the product.

Environmental—An environmental FMEA is used to check whether environmental objectives are fulfilled by the analyzed design, process, or machinery. Generally the design form is followed, although in some cases (for example, toxicology) the process FMEA form may be used.

Machinery—A machinery FMEA is a methodology to assure that potential failure modes and their associated causes and/or mechanisms have been addressed for tooling and equipment. Generally it is an extension of a design FMEA.

Software—A software FMEA is also a variation of a design FMEA focusing on software issues, especially intermittent and unintended failure modes.

Attribute—An attribute FMEA is a methodology that translates customer driven product attribute targets into a coordinated design and verification plan by integrating target cascade processes and robustness tools.

Is FMEA Needed?

In the automotive world especially, the emphasis is always on reducing complexity and engineering changes. Therefore, if any answer to the following questions is positive, then an FMEA is needed:

- Are customers becoming more quality conscious?
- Are reliability problems becoming a big concern?
- Are regulatory requirements harder to meet?
- Is too much time being spent problem solving?
- Is there an addiction to problem solving? This is a very important consideration in the application of an active FMEA program, because when the thrill and excitement of solving problems become dominant, an organization is addicted to problem solving rather than preventing the problem to begin with. A proper FMEA will help break that addiction by:
  - Reducing the percent of time in problem solving
  - Increasing the percent of time in problem prevention
  - Increasing the efficiency of resource allocation
Benefits of FMEA

In the automotive industry, when properly conducted, FMEAs should lead to:

1. Confidence that all risks have been identified early and appropriate actions have been taken
2. Priorities and rationale for product and process improvement actions
3. Reduction of scrap, rework, and manufacturing costs
4. Preservation of product and process knowledge
5. Reduction of field failures and warranty cost
6. Documentation risks and actions for future designs and or processes
7. Identification of potential failure modes
8. Identification of effects of the failure mode
9. Rating the severity of each effect
10. Determination of the potential causes of the failure starting with the highest severity rating
11. Identification of robust designs or controls that will prevent the failure from occurring
12. Identification of corrective actions required to prevent or mitigate failures, or improve the likelihood of detecting failures early
13. Establishment of a priority for design improvement actions

By way of comparison of FMEA benefits and the quality lever, Figure 14.1 may help. The figure identifies the payback effort in relation to the product development cycle of a typical organization. The earlier the planning, the more the return. One will notice that as we move closer to “job 1” point, the return is less than the investment.

In essence, one may argue that the most important benefit of an FMEA is that it helps identify hidden costs that are quite often greater than visible costs early on in the product development cycle.

Some of these costs may be identified through:

- Customer dissatisfaction
- Development inefficiencies
Lost repeat business (no brand loyalty)

High employee turnover

**Initiation of the FMEA**

Perhaps one of the most interesting facts about FMEAs in the automotive world is the fact that history has shown that a majority of product warranty campaigns and automotive recalls could have been prevented by thorough FMEA studies. It is this knowledge that leads one to the conclusion that regardless of the type, all FMEAs should be conducted as early as possible. FMEA studies can be carried out at any stage during the development of a product or process. However, the ideal time to start the FMEA is:

- When new systems, designs, or processes are being designed, but before they are finalized
- When systems design or process modifications are being contemplated
- When new applications are used for the systems, designs, or processes
- When quality concerns become visible

It is imperative to remember that once the FMEA is initiated, it becomes a living document, is updated as necessary, and is never really complete. Therefore:

- *FMEA type thinking* is central to reliability and continual improvement in products and manufacturing processes to remain
competitive in our global marketplace. It must be understood that an FMEA conducted after production serves as a reactive tool and the user has not taken the full benefit of the FMEA process.

• A typical system FMEA should begin even before the program approval stage. The design FMEA should start right after program approval and continue to be updated through prototypes. A process FMEA should begin just before prototypes and continue through pilot build and sometimes into product launching. It is imperative for a user of an FMEA to understand that information is not always available. In these situations, the user must do the best they can with what they have, recognizing that the document itself is indeed a living document and will change as more information become available.

**Getting Started**

In the introduction we discussed the four generic assumptions for any FMEA. In this section we are going to address the assumptions specifically for the automotive industry. They are:

1. **Understand your customers and their needs**
   
   A product or a process may perform functions flawlessly, but if the functions are not aligned with the customer’s needs, the company may be wasting its time. Therefore:

   • Determine all (internal and or external) relevant customers.
   
   • Understand the customer’s needs better than the customers understand their own needs.
   
   • Document the customer’s needs and develop concepts. For example, customers need:
     – Chewable toothpaste
     – Smokeless cigarettes
     – Celery flavored gum

   In FMEA, a customer is anyone/thing that has functions/needs from your product or manufacturing process. An easy way to determine customer needs, is to understand the Kano model (see Figure 14.2). The model facilitates understanding of all customer needs.

   **Excitement needs:** Generally, these are the *unspoken wants* of the customer.
Performance needs: Generally, these are the *spoken needs* of the customer. They serve as the neutral requirements of the customer.

Basic needs: Generally, these are the *unspoken needs* of the customer. They serve as the very minimum of requirements.

It is important to understand that the three needs are always in a state of change. They move (over time) from excitement needs to performance needs to basic needs depending on the product and/or expectation, as well as value to the customer. For example:

*System* customers may be viewed as: other systems, whole product, government regulations, design engineers, and end user.

*Design* customers may be viewed as: higher assembly, whole product, design engineers, manufacturing engineers, government engineers, and end user.

*Process* customers may be viewed as: the next operation, operators, design and manufacturing engineering, government regulations, and end user.

Another way to understand the FMEA customers is through the FMEA team, which must in no uncertain terms determine:

1. Who the customers are
2. What their needs are
3. Which needs will be addressed in the design/process

![The Kano model](image-url)
The appropriate and applicable response will help in developing both the function and effects.

2. Know the function
The dictionary definition of a function is: The natural, proper, or characteristic action of any thing. This is very useful because it implies performance. After all, it is this performance that one is focusing on in the FMEA.

Specifically, a function from an FMEA perspective is the task that a system, part, or manufacturing process performs to satisfy a customer. To understand the function and its significance means that the team for conducting the FMEA must have a thorough list of functions to evaluate. Once this is done, the rest of the FMEA process is a mechanical task.

3. Understand the concept of priority
One of the outcomes of an FMEA is the prioritization of problems. It is very important for the team to recognize and resist the temptation to address all problems, just because they have been identified. That action, if taken, will diminish the effectiveness of the FMEA. Rather, the team should concentrate on the most important, based on performance, cost, quality, or any characteristic identified a priori through the risk priority number.

4. Develop and evaluate conceptual designs/processes based on customer’s needs and business strategy
There are many methods to assist in developing concepts. Some of the most common ones are:

1. Brainstorming
2. Benchmarking
3. TRIZ (the theory of inventive problem solving)
4. Pugh concept selection (an objective way to analyze and select/synthesize alternative concepts)

A typical Pugh matrix for the concept of shaving with a base of razor may look like Table 14.1.

5. Be committed to continual improvement
Everyone in the organization—especially management—must be committed to continual improvement. In FMEA, that means, once recommendations have been made to increase effectiveness and/or to reduce cost, defects, or any other characteristic, a proper corrective action must be developed and implemented, provided it is sound and it complements the business strategy.
6. Create an effective FMEA team

Perhaps one of the most important issues in dealing with the FMEA is that an FMEA must be done with a team. An FMEA completed by an individual is only that individual’s opinion and does not meet the requirements or the intent of an FMEA.

The elements of an effective FMEA team are:

- Expertise in subject (5 to 7 individuals)
- Multi-level/consensus based
- Representing all relevant stakeholders (those who have ownership)
- Cross-functional and multidisciplined (one person doing his or her best cannot approach the knowledge of an effective cross-functional and multidisciplined team)
- Appropriately and applicably empowered

---

**Table 141** A typical Pugh matrix.

<table>
<thead>
<tr>
<th>Evaluation criteria</th>
<th>Razor</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
<th>G</th>
<th>H</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stubble length</td>
<td>D</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain level</td>
<td>A</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mfg. costs</td>
<td>T</td>
<td>–</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>–</td>
<td>S</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Price/use</td>
<td>U</td>
<td>–</td>
<td>S</td>
<td>–</td>
<td>+</td>
<td>–</td>
<td>S</td>
<td>S</td>
<td></td>
</tr>
<tr>
<td>Etc.</td>
<td>M</td>
<td>+</td>
<td>S</td>
<td>–</td>
<td>S</td>
<td>–</td>
<td>S</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Etc.</td>
<td>S</td>
<td>S</td>
<td>S</td>
<td>–</td>
<td>S</td>
<td>–</td>
<td>+</td>
<td>–</td>
<td></td>
</tr>
<tr>
<td>Totals</td>
<td>–</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>+</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S</td>
<td>1</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Evaluation criteria: These are the criteria that we are comparing to the razor with the other approaches.

Datum: These are the basic razor characteristics that we are comparing the other concepts to.

A: Chemical
B: Electric
C: Electrolysis
D: Duct tape
E: Epilady
F: Laser beam
G: Straight edge
H: ?

+: Better than the basic razor requirement
–: Worse than the basic razor requirement
S: Same as the basic razor requirement
The structure of the FMEA team

Core team: The experts of the project and the closest to the project. They facilitate honest communication and encourage active participation. Membership may change as work progresses, and support membership may vary depending on the stage of the project.

Champion/sponsor:

• Provides resources and support
• Attends some meetings
• Supports team
• Promotes team effort and implements recommendations
• Shares authority/power with team
• Kicks off team
• Higher up in management the better

Team leader: A team leader is the “watchdog” of the project. Typically, this function falls upon the lead engineer. Some of the ingredients of a good team leader are:

• Possesses good leadership skills
• Respected by team members
• Leads but does not dominate
• Maintains full team participation

Recorder: Keeps documentation of team’s efforts. The recorder is responsible for coordinating meeting rooms and times, as well as distributing meeting minutes and agendas.

Facilitator: The watchdog of the process. The facilitator keeps the team on track and makes sure that everyone participates. In addition, it is the facilitator’s responsibility to make sure that team dynamics develop in a positive environment. For the facilitator to be effective it is imperative that he or she has no stake in the project, possesses FMEA process expertise, and communicates assertively.

Team considerations:

• Continuity of members
• Receptive and open minded
• Committed to success
• Empowered by sponsor
• Cross-functionality
• Multidiscipline
• Consensus
• Positive synergy

Ingredients of a motivated FMEA team:

• Realistic agendas
• Good facilitator
• Short meetings
• Right people present
• Reach decisions based on consensus
• Open minded, self initiators, volunteers
• Incentives!!
• Establish ground rules, etc.

One individual must be responsible for coordination and accountability of the FMEA project. Typically for the design FMEA, the design engineer is that person; for the process FMEA, the manufacturing engineer accounts for that responsibility.

To make sure the effectiveness of the team is sustained throughout the project, it is imperative that everyone concerned with the project bring useful information into the process. Useful information may be derived from education, experience, training, or a combination of these.

At least two areas that are usually underutilized for useful information are (1) background information and (2) surrogate data.

1. *Background information and supporting documents* that may be helpful in completing the system, design, or process FMEAs are:
   • Customer specifications (OEMs)
   • Previous or similar FMEAs
   • Historical information (warranty/recalls and so on)
   • Design reviews and verification reports
   • Product drawings/bill of material
   • Process flow charts/manufacturing routing
• Test methods
• Preliminary control and gage plans
• Maintenance history
• Process capabilities

2. Surrogate data are data that are generated from similar projects and may help in the initial stages of the FMEA. When surrogate data are used, extra caution should be taken.

Potential FMEA team members:

• Design engineers • Manufacturing engineers
• Quality engineers • Test engineers
• Reliability engineers • Maintenance personnel
• Operators (from all shifts) • Equipment suppliers
• Customers • Suppliers
• Anyone who has a direct or indirect interest

Note the following:

• In any FMEA team effort, the individuals must have interaction with manufacturing and/or process engineering while conducting a design FMEA. This is important to ensure that the process will manufacture per design specification.

• On the other hand, interaction with design engineering while conducting a process or assembly FMEA is important to ensure that the design is right.

• In either case, group consensus will identify the high risk areas which must be addressed to assure that the design and/or process changes are implemented for improved quality and reliability of the product.

Obviously, these lists are typical menus to choose an appropriate team for your project. The actual team composition for any organization will depend upon the individual project and resources.

Once the team is chosen for the given project, 15–20 minutes spent creating a list of the biggest (however biggest is defined) concerns for this product or process is vital. This list will be used later to make sure a complete list of functions is available.
7. Define the FMEA project and scope
Teams must know their assignment. That means that they must know:

- *What* they are working on (scope)
- *What* they are not working on (scope)
- *When* they must complete the work
- *Where* and how often they will meet

In essence, part of the responsibility to define the project and scope has to do with *how broad is the focus?* Another way to define project and scope, is to answer the question of *how detailed must one be?* This is much more difficult than it sounds and it needs some heavy discussion from all the members. Obviously, consensus is imperative. As a general rule, the focus depends upon the project and the experience or education of the team members.

Let us look at an example. It must be recognized that sometimes, due to the complexity of the system, it is necessary to narrow the scope of the FMEA. In other words, break down the system into smaller pieces (see Figure 14.3 and Figure 14.4).

**THE FMEA FORM**

The FMEA form for the automotive industry is somewhat standardized. A typical FMEA form consists of the header information (see Figure 14.5) and the main body (see Figure 14.6). One must remember that this information may be customized to reflect one’s organization, but a typical reader may include the following information:

- Type of FMEA study
- Subject description
- Responsible engineer
- FMEA team leader
- FMEA core team members
- Suppliers
- Appropriate dates (original issue, revision, production start, and so on)
- FMEA number
- Assembly/part/detail number
- Current dates (drawings, specifications, control plan, and so on)
Safety: Injury is the most serious of all failure effects. Therefore, safety is handled either with an FMEA, a fault tree analysis (FTA), and/or a failure mode critical analysis (FMCA). In the traditional FTA the starting point is the list of hazard or events for which the designer must provide some solution. Each hazard becomes a failure mode and thus requires an analysis.

Effect of downtime: The FMEA may incorporate maintenance data to study the effects of downtime. It is an excellent tool to be used in conjunction with total preventive maintenance.

Repair planning: The FMEA may provide preventive data to support repair planning as well as predictive maintenance cycles.

Access: In the world of recycling and environmental conscience, the FMEA can provide data for tear downs as well as information about how to get at the failed component. It can be used with mistake-proofing for some very unexpected positive results.

A typical body of an FMEA form—description: (Part Name/Process Step and Function [Verb/Noun]): In this area the actual description is written in a concise, exact, and simple language.
Developing the function: A fundamental principle in writing functions is the notion that they must be written either in action verb format or as a measurable noun. Remember, a function is a task that a component, subsystem, or product must perform, described in a language that everyone understands.

Legend:  
L: Low Risk  
M: Medium Risk  
H: High Risk

[Note: Just as in design FMEA, sometimes it is necessary to “narrow the scope” of the process FMEA.]

Figure 14.4 Scope for PFMEA—printed circuit board screen printing process.

FMEA worksheet

<table>
<thead>
<tr>
<th>System FMEA:</th>
<th>Design FMEA:</th>
<th>Process FMEA:</th>
<th>FMEA Number:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Subject:</th>
<th>Team Leader:</th>
<th>Page:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Part/Proc. ID No.:</td>
<td>Date Orig.:</td>
<td>Date Rev.:</td>
<td></td>
</tr>
<tr>
<td>Key Date:</td>
<td>Team Members:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figure 14.5 A typical FMEA header.
<table>
<thead>
<tr>
<th>Description</th>
<th>Failure mode analysis</th>
<th>Action plan</th>
<th>Action results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Part name or process step &amp; function</td>
<td>Potential failure mode</td>
<td>Potential effect of failure mode</td>
<td>Potential cause of failure mode</td>
</tr>
</tbody>
</table>

**Figure 14.6**  A typical FMEA body.
Stay away from jargon. To identify appropriate functions, leading questions such as the following may help.

- What does the product/process do?
- How does the product/process do that?
- If a product feature or process step is deleted, what functions disappear?
- If you were this task, what are you supposed to accomplish? Why do you exist?

The priority of asking function questions for a system/part FMEA are:
1. A system view
2. A subsystem view
3. A component view

Typical functions are:
- Position
- Support
- Seal in, out
- Retain
- Lubricate

Organizing product functions: After the brainstorming is complete, a function tree (see Figure 14.7) can be used to organize the functions. This is a simple tree structure to document and help organize the functions.

Purposes for the function tree:
1. To document all the functions
2. To improve team communication
3. To document complexity and improve team understanding of all the functions

Steps:
1. Brainstorm all the functions
2. Arrange functions into function tree
3. Test for completeness of function (how/why)

Questions to ask when building the function tree:
- What does the product/process do?
- Which component/process step does that?
- How does it do that?
Primary functions provide a direct answer to these questions without conditions or ambiguity. Secondary functions explain how primary functions are performed. Continue until the answer to how requires using a part name, labor operation, or activity. Ask why in the reverse direction and add additional functions as needed.

**Function Tree Process Summary**

1. Identify the task function
   
   *Place on the far left side of a chart pad.*

2. Identify the supporting functions
   
   *Place on the top half of the pad.*

3. Identify enhancing functions
   
   *Place on the bottom half of the pad.*

4. Build the function tree
   
   *Include the secondary/tertiary functions. Place these to the right of the primary functions.*

5. Verify the diagram: ask how and why
Let us examine an example of a function tree for a ball point pen (tip). See Figure 14.8.

**Failure mode analysis:** The second portion of the FMEA body form deals with the failure mode analysis. A typical format is shown in Figure 14.9.

**Understanding failure mode:** Failure mode (a specific loss of a function) is the inability of a component/subsystem/system/process/part to perform to design intent. In other words, it may potentially fail to perform its function(s).

---

**Figure 14.8** Function tree for a ball point pen.

**Axial force function**
- The inside diameter of the barrel tip end transmits axial force to the tip system housing sheath O.D.
- The tip system housing tip retainer I.D. transmits axial force to the ball housing
- The ball housing I.D. (ball) transmits axial force on the ball
- The ball transmits axial force to the marking surface, however, the marking surface is stationary, which causes the ball rotational motion
- The ball rotates through the ink supply, picking up a film of ink on the ball surface
- The ink is transferred from the ball surface to the marking surface
- The ink remains on the marking surface (3mm width) area drying in 3 seconds

**Vector force function**
- The end of the barrel and the barrel I.D. (tip end) simultaneously apply force to the tip system housing end and sheath.
- The tip assembly housing transmits the vector force to the O.D. of the ball housing
- The ball housing transmits the vector force to the ball, the ball moves up into the ball housing creating a gap between the ball and ball housing
- The ink flows through the ink tube contacting the ball surface
For the design failure mode: A technical description of how the system, subsystem, or part may not adequately perform its function. On the other hand, for the process failure mode: A technical description of how the manufacturing process may not perform its function, or the reason the part may get rejected.

**Failure Mode Questions:** Brainstorming Failure Modes:

**DFMEA**
- Considering the conditions in which the product will be used, how can it fail to perform its function?
- How have similar products failed in the past?

**PFMEA**
- Considering the conditions in which the process will be used, what could possibly go wrong with the process?
- How have similar processes failed in the past?
- What might happen that would cause a part to get rejected?

**Determining potential failure modes:** Failure modes are when the function is not fulfilled in five major categories. Some of these categories may not apply. As a consequence, use these as **thought provokers** to begin the process and then adjust them as needed.

1. Absence of function
2. Incomplete, partial, or decayed function

<table>
<thead>
<tr>
<th>Potential failure mode</th>
<th>Potential effects of failure mode</th>
<th>S E V E R I T Y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identify the potential failure</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Figure 14.9** A typical format for the failure mode analysis.
3. Related unwanted *surprise* failure mode

4. Function occurs too soon or too late

5. Excess or too much function

Failure mode examples using the above categories and applied to the pen case:

1. Absence of function:
   – DFMEA: Make marks
   – PFMEA: Inject plastic

2. Incomplete, partial, or decayed function:
   – DFMEA: Make marks
   – PFMEA: Inject plastic

3. Related unwanted *surprise* failure mode
   – DFMEA: Make marks
   – PFMEA: Inject plastic

4. Function occurs too soon or too late
   – DFMEA: Make marks
   – PFMEA: Inject plastic

5. Excess or too much function
   – DFMEA: Make marks
   – PFMEA: Inject plastic

General examples of failure modes in design FMEAs:

- No power
- Failed to open
- Water leaking
- Partial insulation
- Open circuit
- Loss of air
- Releases too early
- No spark
- Noise
- Insufficient torque
- Vibration
- Paper jams
- Doesn’t cut

Process FMEA: Four categories of process failures:

1. Fabrication failures
2. Assembly failures
3. Testing failures
4. Inspecting failures
Examples for these failures are: warped, too hot, RPM too slow, rough surface, loose part, misaligned, poor inspection, hole too large, leakage, fracture, fatigue, and so on.

Note: at this stage, you are ready to transfer the failure modes in the FMEA form (see Figure 14.10).

**Failure Mode Effect**

- A description of the consequence/ramification of a system, part, or manufacturing process failure. A typical failure mode may have several effects depending on which customer(s) are considered.
- Consider the effects/consequences on all the customers, as they are applicable.

**SFMEA**
- System
- Whole product
- End user
- Other systems
- Government regulations

**DFMEA**
- Part
- Whole product
- End user
- Higher assembly
- Government regulations

<table>
<thead>
<tr>
<th>Potential failure mode</th>
<th>Potential effects of failure mode</th>
<th>Severity</th>
<th>Class</th>
<th>Potential causes of failure mode</th>
<th>Occurrence</th>
<th>Current controls</th>
<th>Detection</th>
<th>Risk priority number (RPN)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does not transfer ink</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Partial ink</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Figure 14.10** Failure modes in the FMEA form.
PFMEA

- Part
- Equipment
- Operators
- Next operation
- Government regulations
- End user

**Effects and severity rating:** Effects and severity are very related items. As the effect increases, so does the severity. In essence, two fundamental questions have to be raised and answered:

1. What will happen if this failure mode occurs?
2. How will customers react if these failures happen?

- Describe as specifically as possible what the customer(s) might notice once the failure occurs.
- What are the effects of the failure mode?
- How severe is the effect on the customers?

**Progression of function, cause, failure mode, effect, and severity:**

- In function: What is the individual task intended by design?
- In failure mode: What can go wrong with this function?
- In cause: What is the *root cause* of the failure mode?
- In effect: What are the consequences of this failure mode?
- In severity: What is the seriousness of the effect?

**DFMEA and PFMEA effects examples:**

<table>
<thead>
<tr>
<th>Customer gets wet</th>
<th>Loss of performance</th>
</tr>
</thead>
<tbody>
<tr>
<td>System failure</td>
<td>Scrap</td>
</tr>
<tr>
<td>Loss of efficiency</td>
<td>Rework</td>
</tr>
<tr>
<td>Reduced life</td>
<td>Becomes loose</td>
</tr>
<tr>
<td>Degraded performance</td>
<td>Hard to load in next operation</td>
</tr>
<tr>
<td>Can’t assemble</td>
<td>Operator injury</td>
</tr>
<tr>
<td>Violate Gov. Reg. XYZ</td>
<td>Noise, rattles</td>
</tr>
<tr>
<td>Damaged equipment</td>
<td></td>
</tr>
</tbody>
</table>

Please note that the effect remains the same for both DFMEA and PFMEA.

**Severity Rating (Seriousness of the Effect)**

- Severity is a numerical rating of the impact on customers. (See Table 6.1 in Chapter 6 and 7.1 in Chapter 7.)
- When multiple effects exist for a given failure mode, enter the worst case severity on the worksheet to calculate risk.

- In cases where severity varies depending on timing, use the worst case scenario.

There is nothing special about these guidelines. They may be changed to reflect the organization, the product/design, and or process. To modify these guidelines, keep in mind:

1. List the entire range of possible consequences (effects)
2. Force rank the consequences from high to low
3. Resolve the extreme values (rate 10 and rate 1)
4. Fill in the other ratings
5. Use consensus

At this point the information should be transferred to the FMEA form (see Figure 14.11).

The column identifying the class is the location for the placement of the critical characteristic. The appropriate response is only “Yes” or “No.” A Yes in this column indicates that the characteristic is critical, if No, that indicates that the characteristic is not critical.

**Failure cause and occurrence:** The analysis of the cause and occurrence is based on two questions:

1. What design or process choices were already made that may be responsible for a failure to occur?
2. How likely is the failure mode to occur because of this?

For each failure mode, the possible mechanism(s) and/or cause(s) of failure are listed. This is an important element of the FMEA since it points the way toward preventive/corrective action. It is after all, a description of the design or process deficiency that results in the failure mode. That is why it is important to focus on the *global* or *root* cause. Root causes should be specific and in the form of a characteristic that may be controlled or corrected. Caution should be exercised not to overuse the *operator error* or *equipment failure* as a root cause even though they are both tempting and easy to assign blame.
You must look for causes not symptoms of the failure. Most failure modes have more than one potential cause. An easy way to probe into the causes is to ask:

- What design choices, process variables, or circumstances could result in the failure mode(s)?

DFMEA failure causes are typically specific system, design, or material characteristics.

PFMEA failure causes are typically process parameters, equipment characteristics, environmental, or incoming material characteristics.

**Popular Ways (Techniques) to Determine Causes:**

- Brainstorm
- Why’s
- Fishbone diagram
• Fault tree analysis (FTA)—A model that uses a tree to show the cause-and-effect relationship between a failure mode and the various contributing causes. The tree illustrates the logical hierarchy branches from the failure at the top to the root causes at the bottom.

• Classic 5-step problem solving process
  1. What is the problem?
  2. What can I do about it?
  3. Put a star on the best plan.
  4. Do the plan!
  5. Did your plan work?

• Kepner Trego (What is, what is not analysis)

• Discipline (8 D)

• Experience
  – Knowledge of physics and the sciences
  – Knowledge of similar products

• Experiments—When many causes are suspect or specific cause is unknown
  – Classical
  – Taguchi methods

Occurrence rating: Is an estimate number of frequencies or cumulative number of failures (based on experience) that will occur (in our design concepts) for a given cause over the intended life of the design. Example: Cause of Staples Falling Out ... Soft Wood. Likelihood of occurrence is a 9 if we picked Balsa wood but a 2 if we chose oak.

Just like severity, there are standard tables for occurrence for each type of FMEA. The ratings on these tables are estimates on experience and/or similar products or processes. Non-standard occurrence tables may also be used, based on specific characteristics. However, reliability expertise is needed to construct occurrence tables. (Typical characteristics may be historical failure frequencies, Cpk, theoretical distributions, and reliability statistics.) Two sample tables are shown in Tables 6.2 in Chapter 6 and 7.2 in Chapter 7 for design and process respectively.

At this point the data for causes and their ratings should be transferred to the FMEA form (see Figure 14.12).

Current controls and detection ratings: Design and process controls are the mechanisms, methods, tests, procedures, or controls that we have in place to prevent the cause of the failure mode or detect the failure mode or
cause should it occur. (The controls currently exist.) Design controls prevent or detect the failure mode prior to engineering release. On the other hand, process controls prevent or detect failure mode prior to the part or assembly leaving the area.

A good control prevents or detects causes or failure modes:

- As early as possible (ideally before production or prototypes)
- Using proven methods

So, the next step in the FMEA process is to:

- Analyze planned controls for the system, part, or manufacturing process.
- Understand the effectiveness of these controls to detect causes or failure modes.

**Figure 14.12** Causes and their ratings placed on the FMEA form.

<table>
<thead>
<tr>
<th>Potential failure mode</th>
<th>Potential effects of failure mode</th>
<th>SEVERITY</th>
<th>CLASS</th>
<th>Potential causes of failure mode</th>
<th>OCCURRENCE</th>
<th>Current controls</th>
<th>DETECTION</th>
<th>Risk priority number (RPN)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does not transfer ink</td>
<td>Pen does not work; customer tries and eventually tears paper and scraps the pen</td>
<td>8 N</td>
<td></td>
<td>Ball housing I.D. deformed</td>
<td>2</td>
<td></td>
<td>9</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ink viscosity too high</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Debris build-up</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Partial ink</td>
<td>Old pen stops writing, customer scraps pen</td>
<td>7 N</td>
<td></td>
<td>Inconsistent ball rolling due to deformed housing</td>
<td>2</td>
<td></td>
<td>7</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Customer has to retrace</td>
<td></td>
<td></td>
<td>Ball does not / always pickup ink due to ink viscosity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Writing or drawing looks bad</td>
<td>7</td>
<td></td>
<td>Housing I.D. variation due to mfg</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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**Detection rating:** Detection rating is a numerical rating of the probability that a given set of controls will discover a specific cause or failure mode to prevent bad parts from leaving the operation/facility or getting to the ultimate customer. Typical ratings are shown in Tables 6.3 in Chapter 6 and 7.3 in Chapter 7 for design and process respectively.

- Assuming that the cause of the failure did occur, assess the capabilities of the controls to find the design flaw or prevent the bad part from leaving the operation/facility. In the first case, the DFMEA is at issue. In the second case the PFMEA is of concern.

- When multiple controls exist for a given failure mode, record the best (lowest) to calculate risk.

- In order to evaluate detection, there are appropriate tables for both design and process. Just as before, however, if there is a need to alter them, remember that the change and approval must be done by the FMEA team with consensus.

At this point the data for current controls and their ratings should be transferred to the FMEA form (see Figure 14.13). There should be a current control for every cause. If there is not, that is a good indication that there might be a problem.

**Understanding and calculating risk:** Without risk, there is very little progress! Risk is inevitable in any system, design, or manufacturing process. However, as Abraham Lincoln said long ago, the probability that we may fail in the struggle ought not to deter us from the support of a cause we believe to be just. The FMEA process aids in identifying significant risks, then helps to minimize the potential impact of risk. It does that through the risk priority number, or as it is commonly known, the RPN index. (We must remind the reader here that there is a good chance that most people confuse the issues of excellence and perfection. Excellence we can reach, however, perfection is in the domain of God. FMEA, we believe, is a tool/methodology that can get us to excellence.) In the analysis of the RPN, make sure to look at risk patterns rather than just a high RPN.

The RPN is always the product of severity, occurrence, and detection or:

$$RISK = RPN = S \times O \times D$$

Obviously the higher the number of the RPN the more the concern. A good rule of thumb analysis to follow is the 95 percent rule. That means that you will address all failure modes with a 95 percent confidence. It turns out the magic number is 50 \((S=10 \times O=10 \times D=10) - (1000 \times .95)\). This number of course is only relative to what the total FMEA is all about.
and it may change as the risk increases in all categories and in all causes. Obviously, special risk priority patterns require special attention, through specific action plans that will reduce or eliminate the high risk factor. Yet another way of identifying high risk is the evaluation of:

1. High severity (9–10)
2. Criticality \((S \times O)\) where \(S = 5–8\) and \(O\) is greater than 3
3. Higher RPN

(Some automotive companies focus on the three path approach. This identifies the priority 1\textsuperscript{st} based on the severity 2\textsuperscript{nd} the criticality [severity times occurrence] and 3\textsuperscript{rd} detection.)

At this stage let us look at our FMEA project calculate and enter the RPN (see Figure 14.14).

![Figure 14.13](image-url)  
Current controls and their rating placed on the FMEA form.
### Action plans and results:

The third portion of the FMEA form deals with the action plans and results analysis. A typical format is shown in Figure 14.15.

The idea of this third portion of the FMEA form is to generate a strategy that reduces severity, occurrence and/or detection or a general strategy that is best to reduce the total RPN.

**Reducing the severity rating** (or reducing the severity of the failure mode effect):

- Design or manufacturing process changes are necessary
- Much more proactive than detection rating

**Figure 14.14**  RPN placed on the FMEA form.

<table>
<thead>
<tr>
<th>Potential failure mode</th>
<th>Potential effects of failure mode</th>
<th>SEVERITY</th>
<th>CLASS</th>
<th>Potential causes of failure mode</th>
<th>OCCURRENCE</th>
<th>Current controls</th>
<th>DETECTION</th>
<th>Risk priority number (RPN)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does not transfer ink</td>
<td>Pen does not work; customer tries and eventually tears paper and scraps the pen</td>
<td>8</td>
<td>N</td>
<td>Ball housing I.D. deformed</td>
<td>2</td>
<td>Life test Test # X</td>
<td>2</td>
<td>32</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Ink viscosity too high</td>
<td>9</td>
<td>Test # X</td>
<td>10</td>
<td>720</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Debris build-up</td>
<td>5</td>
<td>Design review Prototype test # XY</td>
<td>7</td>
<td>280</td>
</tr>
<tr>
<td>Partial ink</td>
<td>Old pen stops writing, customer scraps pen</td>
<td>7</td>
<td>N</td>
<td>Inconsistent ball rolling due to deformed housing</td>
<td>2</td>
<td>Test # X</td>
<td>10</td>
<td>140</td>
</tr>
<tr>
<td></td>
<td>Customer has to retrace</td>
<td></td>
<td></td>
<td>Ball does not always pickup ink due to ink viscosity</td>
<td>7</td>
<td>None</td>
<td>10</td>
<td>490</td>
</tr>
<tr>
<td></td>
<td>Writing or drawing looks bad</td>
<td></td>
<td></td>
<td>Housing I.D. variation due to mfg</td>
<td>1</td>
<td>None</td>
<td>10</td>
<td>70</td>
</tr>
</tbody>
</table>
Reducing the occurrence rating (or reducing the frequency of the cause):

- Design or manufacturing process changes are necessary
- Much more proactive than detection rating

Reducing the detection rating (or increasing the probability of detection):

- Improving the detection controls is generally costly, reactive, and doesn’t do much for quality improvement, but it does reduce risk.
- Increased frequency of inspection, for example, should only be used as a last resort. It is not a proactive corrective action.

Classification and characteristics: In the automotive industry this classification is very important and is identified as special characteristics. There are two kinds: a) Critical and b) Significant. In the design FMEA they are known as potential and in the process FMEA they are designated as critical or significant. These characteristics must be classified according to risk impact:

- Severity 9, 10: highest classification (Critical)

These kinds of characteristics are product or process related that:
- May affect compliance with government or federal regulations (Environmental Protection Agency [EPA], Occupational Safety and Health Administration [OSHA], Food and Drug Administration [FDA], Federal Communications Commission [FCC], Federal Aviation Administration [FAA], and so on)
- May affect safety of the customer
- Require specific actions or controls during manufacturing to ensure 100 percent compliance

![Figure 14.15](image-url) Action plans and results analysis.
• Severity between 5–8 and occurrence greater than 3: secondary classification (Significant)
  *These characteristics are product or process related that:*
  – Are non-critical items that are important for customer satisfaction (for example, fit, finish, durability, appearance)
  – Should be identified on drawings, specifications, or process instructions to ensure acceptable levels of capability

• High RPN: secondary classification

**Product characteristics/root causes:** Examples include size, form, location, orientation, or other physical properties such as color, hardness, strength.

**Process parameters/root causes:** Examples include pressure, temperature, current, torque, speeds, feeds, voltage, nozzle diameter, time, chemical concentrations, cleanliness of incoming part, ambient temperature.

### SPECIAL AUTOMOTIVE CHARACTERISTICS

**DaimlerChrysler Characteristics**

**The Shield:**

• Government/safety characteristic

**The Diamond:**

• Special characteristics
• Process driven and require SPC
• Product verification required but not SPC

**The Pentagon:** (Affects tooling):

• Critical tooling characteristics

**Significant Characteristics:**

• Supplier designated—no symbol
Ford Motor Characteristics

Critical Characteristics:

• Government regulations/safety compliance (\(\vee\)—inverted delta)

• Significant characteristics (SC designation—no symbol)
  – Product requirements/process parameters
    = Impact customer satisfaction & require quality planning actions
    = Included in control plans

GM Characteristics

Safety/Compliance:

• Government safety characteristic

Fit/Function:

• Customer satisfaction: fit, function, ability to process, mount, assemble, or appearance

Standard (no symbol):

• Variation is unlikely to affect government/safety compliance or fit/function

DRIVING THE ACTION PLAN

• For each recommended action, the FMEA team must:
  – Plan for implementation of recommendations
  – Make sure that recommendations are followed, improved, and completed

• Implementation of action plans requires answering the classic questions:
  – Who … (will take the lead)
  – What… (specifically is to be done)
  – Where… (will the work get done)
  – Why… (this should be obvious)
  – When… (should the actions be done)
  – How… (will we start)
• Accelerate implementation by getting buy-in (ownership).

• Drawing out and addressing objections is important.

• When plans address objections in a constructive way, stakeholders feel ownership in plans and actions. Ownership aids in successful implementation!

• Typical questions that begin a fruitful discussion are:
  – Why are we…?
  – Why not this?
  – What about this?
  – What if…?

• Timing and actions must be reviewed on a regular basis to:
  – Maintain a sense of urgency
  – Allow for ongoing facilitation
  – Ensure work is progressing
  – Drive team members to meet commitments
  – Surface new facts that may affect plans

• Fill in the actions taken
  – The Action Taken column should not be filled out before the actions are totally complete.

• Record final outcomes in the action plan and action results section of the FMEA form (see Figure 14.16). Remember, because of the actions you have taken you should expect changes in severity, occurrence, detection, RPN, and new characteristic designations. Of course, these changes may be individual or in combination.

After the FMEA is completed, it is imperative that the recommendations, controls, and critical as well as significant characteristics should be followed with a control plan. The flow and linkages of the FMEA to control plan are shown in Figure 14.17.

**GETTING THE MOST FROM FMEA**

1. Common team problems

  • Poor team composition. (Not cross-functional or multidisciplined.)
    – Low expertise in FMEA
    – Not multi-level
    – Low experience/expertise in product
    – One person FMEA
<table>
<thead>
<tr>
<th>Description</th>
<th>Failure mode analysis</th>
<th>Action plan</th>
<th>Action results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>RPN</td>
<td>Recommended action &amp; responsibility</td>
<td>Target finish date</td>
</tr>
<tr>
<td></td>
<td>32</td>
<td>No action required</td>
<td>2/22/03</td>
</tr>
<tr>
<td></td>
<td>720</td>
<td>DOE - Taguchi</td>
<td>2/18/03</td>
</tr>
<tr>
<td></td>
<td>280</td>
<td>Develop accel. test (thermal vibration)</td>
<td>2/3/03</td>
</tr>
<tr>
<td></td>
<td>140</td>
<td>Develop a new test # ABC</td>
<td>2/2/03</td>
</tr>
<tr>
<td></td>
<td>490</td>
<td>DOE - Taguchi optimize viscosity</td>
<td>5/3/03</td>
</tr>
<tr>
<td></td>
<td>70</td>
<td>Evaluate machining process</td>
<td>TBD</td>
</tr>
</tbody>
</table>

**Figure 1416** Record final outcomes in the action plan and action results.

- Lack of management support.
- Not enough time.
- Too detailed, could go on forever.
- Arguments between team members. Base opinions on facts and data.
- Lack of team enthusiasm/motivation.
- Getting team to start and stay with the process.
- Proactive vs. reactive (a *before the event* not *after the fact* exercise).
- Doing it for the wrong reason.

### 2. Common procedural problems

- Confusion about, poorly defined, or incomplete functions, failure modes, effects, or causes.
- Sub-group discussion.
• Using symptoms or superficial causes instead of root causes.

• Confusion about ratings as estimates, and not absolutes. It will take time to be consistent.

• Confusion about the relationship between causes, failure modes, and effects.

• Using *customer dissatisfied* as failure effect.

• Shifting design concerns to manufacturing and vice versa.

• Doing FMEAs by hand.
  – Dependent on the engineer’s printing skills
  – RPNs or criticality can’t be ranked easily
  – Hard to update
  – Complicated FMEAs take up much space
  – Time consuming
  – No one wants to be the recorder when done manually
  – Inefficient means of storing and retrieving info

Note: With FMEA software these are all eliminated.
• Working non-systematically on the form. (It is suggested that the failure analysis should progress from left to right, with each column being completed before the next begins.)

• No one wants to assume responsibility for recommended actions.

• Doing a reactive FMEA as opposed to a proactive FMEA. (FMEAs are best applied as a problem prevention tool, not problem solving tool, although one may use it for both. However, the value out of a reactive FMEA is much less.)

• Not having robust FMEA terminology: A robust communication process is one that delivers its function (imparting knowledge and understanding) without being affected by noise factors (varying degrees of training). Simply stated, the process should be as clear as possible with minimum possibility for misunderstanding.

3. Institutionalizing FMEA

Institutionalizing FMEA is challenging and its success is largely dependent upon the culture in the organization as well as why it is being utilized. Below are some main considerations:

• Selecting pilot projects (start small and build successes)

• Identifying team participants

• Developing and promoting FMEA successes

• Developing templates (databases of failure modes, functions, controls, and so on)

• Addressing training needs

• The learning stages (see Figure 14.18)

<table>
<thead>
<tr>
<th>Stages of learning</th>
<th>Stages of FMEA maturity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unconscious incompetence</td>
<td>Never heard of FMEA</td>
</tr>
<tr>
<td>Conscious incompetence</td>
<td>We talked about it</td>
</tr>
<tr>
<td>Conscious competence</td>
<td>Customer made us do it</td>
</tr>
<tr>
<td>Unconscious competence</td>
<td>Some small successes</td>
</tr>
</tbody>
</table>

The direction of the arrows indicates the increased level.

**Figure 14.18** The learning stages.
Strategies For Lowering Risk: (System/Design)—High Severity or Occurrence

Change the product design to:

- Eliminate the failure mode cause or decouple the cause and effect
- Eliminate or reduce the severity of the effect
- Make cause less likely or impossible to occur
- Eliminate function or eliminate part!!! (functional analysis)

Some tools to consider:

- Quality function deployment (QFD)
- Fault tree analysis (FTA)
- Benchmarking
- Brainstorming
- TRIZ

Evaluate ideas using Pugh Concept Selection:

Some specific examples:

- Change material, increase strength, decrease stress
- Add redundancy
- Constrain usage (exclude features)
- Develop fail safe designs, early warning system

Strategies For Lowering Risk: (System/Design)—High Detection Rating

Change the evaluation/verification/tests to:

- Make failure mode easier to perceive
- Detect causes prior to failure
Some tools to consider:

- Benchmarking
- Brainstorming
- Process control (automatic corrective devices)
- TRIZ

Evaluate ideas using Pugh Concept Selection:

Some specific examples:

- Change testing and evaluation procedures
- Increase failure feedback or warning systems
- Increase sampling in testing or instrumentation
- Increase redundancy in testing

Manufacturing Process Functions:

Just as products have functions, manufacturing processes also have functions. The goal is to concisely list the function(s) for each process operation. The first step in improving any process is to make the current process visible by developing a process flow diagram (a sequential flow of operations by people and/or equipment). This helps the team understand, agree on, and define the scope. Three possibilities exist for any existing process:

1. What you think is happening
2. What is actually happening
3. What should be happening

Special reminder for manufacturing process functions: if the process flow diagram is too extensive for a timely FMEA, a risk assessment may be done on each process operation to narrow the scope.
The PFMEA Function Questions

For each manufacturing step, there is typically one or more functions (see Figure 14.19). Determine what functions are associated with each manufacturing process step and then ask:

- What does the process step do to the part?
- What are you doing to the part/assembly?
- What is the goal, purpose, or objective of this process step?

1. Inject Ink into Ink Tube.
   \(0.835 \text{ cc}\)
2. Insert Ink Tube into Tip Assembly Housing.
   \(12 \text{ mm}\)
3. Insert Tip Assembly into Tip Assembly Housing.
   \(\text{full depth until stop}\)
4. Insert Tip Assembly Housing into Barrel.
   \(\text{full depth until stop}\)
5. Insert End Cap into Barrel.
   \(\text{full depth until stop}\)
6. Insert Barrel into Cap.
   \(\text{full depth until stop}\)
7. Move to Dock.
   \(\text{to dock within 8 seconds}\)
8. Package and Ship.
   \(12 \text{ pens per box}\)

Note: At the end of this function analysis you are ready to transfer the information to the FMEA form.

Remember that another way to reduce the complexity or scope of the FMEA is to prioritize the list of functions, and then take only the ones that the team collectively agree are the biggest concerns.

Describing the failure mode anticipated—The team must pose the questions “How could this process fail to complete its intended function? Could the resulting workpiece be oversize, undersize, rough, eccentric, misassembled, deformed, cracked, open, shorted, leaking, porous, damaged, omitted, misaligned, out-of-balance?” The team is trying to anticipate how the workpiece might fail to meet engineering requirements; at this point in their analysis they should stress how it could fail and not whether or not it will fail.
Strategies For Lowering Risk: (Manufacturing)—High Severity or Occurrence

Change the product or process design to:

- Eliminate the failure cause or decouple the cause and effect
- Eliminate or reduce the severity of the effect (recommend changes in design)
Some tools to consider:

- Benchmarking
- Brainstorming
- Mistake proofing
- TRIZ

Evaluate ideas using Pugh Concept Selection:

Some specific examples:

- Developing a robust design (insensitive to manufacturing variations)
- Changing process parameters (time, temperature, and so on)
- Increase redundancy, add process steps
- Alter process inputs (materials, components, consumables)
- Use mistake-proofing (Poka-Yoke), reduce handling

Strategies For Lowering Risk: (Manufacturing)—High Detection Rating

Change the process controls to:

- Make failure mode easier to perceive
- Detect causes prior to failure mode

Some tools to consider:

- Benchmarking
- Brainstorming

Evaluate ideas using Pugh Concept Selection:

Some specific examples:

- Change testing and inspection procedures/equipment
- Improve failure feedback or warning systems
• Add sensors/feedback or feed forward systems
• Increase sampling and/or redundancy in testing
• Alter decision rules for better capture of causes and failures (that is, more sophisticated tests)

At this stage, enter a brief description of the recommended actions, including the department and individual responsible for implementation, as well as both the target and finish dates on the FMEA form. If the risk is low and no action is required, write: no action needed.

• For each entry that has a designated characteristic in the class (classification) column.
• Review the issues that impact cause/occurrence, detection/control, or failure mode.
• Generate recommended actions to reduce risk.
• Special RPN patterns suggest that certain characteristics/root causes are important risk factors that need special attention.

AFTER THE FMEA

1. Review the FMEA.
2. Highlight the high risk areas based on severity, criticality, and finally detection. The RPN should not be used as a criteria for setting priority failures.
3. Identify the critical and/or major characteristics based on your classification criteria.
4. Ensure that a control plan exists and is being followed.
5. Conduct capability studies.
6. Work on processes which have $C_{pk}$ of less or equal to 1.33.
7. Work on processes which have $C_{pk}$ greater than 1.33 to reduce variation and reach a $C_{pk}$ of greater or equal to 2.0.
Finally, the team leader must make sure that the following essential questions are addressed by all engineers (team members) in governing the product development process using the FMEA:

1. What are your top ten failure modes?
2. What steps have you taken in the new design to address them?
3. What are your five sources of noise?
4. Has the team taken a refresher in the tools/methods?
5. What are the root causes/most important failure modes?
6. Do you have a viable plan for achieving robustness?
7. Have you completed an elementary reliability guide worksheet, covering basic reliability issues?
8. Are your experiments designed and planned; are they necessary?
9. Are the results of your experiments satisfactory?
10. Do you have a failure resolution plan?
11. Have you updated your FMEA and Design Verification Plan (DVP)?
12. Does your FMEA consider sources of noise and subsystem interaction?
13. Does your DVP/Key Life Testing (KLT) address all noise sources?
14. Do your tests recreate the failure modes that field returns exhibit?
15. Does the System Design Specifications (SDS) reflect your real world usage profile?
16. Does your management support your efforts to design a quality product?
17. Have your suppliers supported robust and reliable design processes?
18. Have you demonstrated the reliability of your new design?

REFERENCES


This chapter focuses on the liability of products as defined by the ISO 9000 standards and the need of the application of an FMEA to fulfill the specific requirements of ISO 9001:2000. By no means is this an exhaustive discussion on the issue of liability and the European Union (EU) and/or the ISO 9000 standards. In addition this chapter will address the importance of FMEA as it is identified through the ISO 9004:2000.

The Product Liability Directive was passed in 1985. Its aim is to provide consumers with a measure of liability protection. Prior to this directive, EU product liability protection did not exist and European consumers had little protection under a few national laws. Generally, when a consumer was injured by a defective product, the old principle of *caveat emptor* (buyer beware) prevailed (Kolka 1992).

The Product Liability Directive changed the system. If someone is injured and can prove that a defective product caused the injury, the manufacturer is strictly liable, regardless of fault. In 1989, the EU council adopted the Machinery Safety Directive that creates uniform design and safety requirements for machinery. Its purpose is to promote safety and to eliminate barriers to trade that arise from different safety standards between the community states. In June 1992, the EU adopted the Product Safety Directive. This directive lays out basic principles of product safety and is meant to complement the Product Liability Directive.

In addition to all these directives, the EU has proposed a Services Liability Directive, for the service industry in Europe. This is considered a critical element for the economic success of Europe. The proposed directive seeks to protect consumers and to resolve legal differences between community states. The present and proposed directives have important
implications for any company that does business with the EU in either regulated or non-regulated products. It is expected that these new liability and safety laws will bring the EU more in line with consumerism and more closely related to the United States (Harral 1993; Middleton 1993; Stamatis 1992).

The legal issues of the directives raise some very important questions. For example:

- The Product Liability Directive employs the theory of strict liability. It holds a manufacturer liable, regardless of fault or negligence. What is the full scope of this law?

- The Product Liability Directive does not require proof that a product is both defective and unreasonably defective, as in the case of U.S. law. As such, it will be easier to prove a defect under the EU law than under U.S. law. What preventive steps can companies take to reduce their liability exposure?

- The Product Safety Directive requires manufacturers to mark and monitor the safety of their products. What kind of duty is required by this monitoring process?

- How broad is the scope of the law concerning service supplier liability?

- Does the definition of service supplier in the proposed directive include agencies that certify quality assurance systems, certify and endorse products, or create standards? What about the liability of ISO 9000 consultants?

These questions raise more questions and concerns for European and U.S. companies, and for the international companies at large. The Product Liability Directive has changed the climate in new and profound ways. For example, Article 1 of the Product Liability Directive states, “The producer shall be liable for damage caused by a defect in his product.” On the other hand, Article 2 of the directive defines a product as, “all movables, with the exception of primary agricultural products and game … product includes electricity.” A movable is an attached to or part of real property.

In addition, in Article 3 of the directive a producer is defined as “the manufacturer of a finished product, the producer of any raw material or the manufacturer of a component part, and any person who, by putting his name, trademark or other distinguishing features on the product, presents himself as its producer.”
Finally, Article 6 of the directive defines defective product as:

1. A product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including:
   a. The presentation of the product
   b. The use to which it could reasonably be expected that the product would be put, and
   c. The time when the product was put into circulation.

2. A product shall not be considered defective for the sole reason that a better product is subsequently put into circulation.

With this limited overview of the directive and the concept of liability from an ISO perspective, we hope that is quite obvious that domestic and multinational companies must change the way they do business.

One way to change is to require specific responses to distinct laws in reference to liability. One such response is the failure mode and effect Analysis (FMEA). The FMEA was indeed recognized in the ISO 9001:1994 as a way to focus on both reduction in failures and continual improvement in several elements of the standard (4.4, 4.9 and elsewhere). Furthermore, the ISO 9004:1994 was full of references that one could interpret as the application of an FMEA (11.2, 14.2, 14.6 and elsewhere).

ISO 9004:2000

The ISO 9004 is a quality system guideline. Therefore, it is not a certifiable standard. It is, however, a complete model for a quality system. This model recommends and encourages the use of FMEA in several of its elements either directly or indirectly. The following are a sample of the recommendations, without any commentary:

1 Scope: “...to consider both the effectiveness and efficiency of a quality management system, and consequently the potential for improvement of the performance of an organization. When compared to ISO 9001, the objectives of customer satisfaction and product quality are extended to include the satisfaction of interested parties and the performance of the organization.”

4.1 Managing systems and processes: (b) by ensuring effective and efficient operation and control of processes and the measures and data used to determine satisfactory performance of the organization (for example, using suitable methods to evaluate process improvement, such as self-assessments and management review).
4.2 Documentation: “...The nature and extent of the documentation should satisfy the contractual, statutory and regulatory requirements, and the needs and expectations of customers and other interested parties and should be appropriate to the organization ... information about the needs and expectations of interested parties ... current and future requirements related to managing knowledge ... interfaces used by organization’s customers, suppliers and other interested parties.”

4.3 Use of quality management principles: (a) Customer focus— Organizations depend on their customers and therefore should understand current and future customer needs, should meet customer requirements and strive to exceed customer expectations. (f) Continual improvement— ... Continual improvement of the organization’s overall performance should be a permanent objective of the organization. (g) Factual approach to decision making— ... Effective decisions are based on the analysis of data and information.

5.1.1 Introduction: ...it is necessary to establish, sustain, and increase customer satisfaction (participating in improvement projects, searching for new methods, solutions and products; identifying the product realization processes that provide added value to the organization).

5.1.2 Issues to be considered: Understanding current and future customer needs and expectations, in addition to requirements; top management should identify the organization’s product realization processes, as these are directly related to the success of the organization (identifying and managing risks, and exploiting performance improvement opportunities; conducting data analysis to facilitate continual improvement of processes; identifying process owners and giving them full responsibility and authority).

5.2.1 General: Every organization has interested parties, each party having needs and expectations (society in terms of the community and the public affected by the organization or its products).

5.2.2 Needs and expectations: ...In order to understand and meet the needs and expectations of interested parties, an organization should identify its interested parties and maintain a balanced response to their needs and expectations; translate identified needs and expectations into requirements; communicate the requirements throughout the organization ... and determine key product characteristics for its customers and end-users. (Examples of customer and end-user needs and expectations, as related to the organization’s products, include: conformity, dependability, availability, delivery, post-realization activities, price and life-cycle costs, product safety, product liability, and environmental impact.)

In considering its relationships with society, the organization should demonstrate responsibility for health and safety, consider environmental
impact, including conservation of energy and natural resources, identify applicable statutory and regulatory requirements, and identify the current and potential impacts on society in general, and the local community in particular, of its products, processes, and activities.

5.2.3 Statutory and regulatory requirements: Management should ensure that the organization has knowledge of the statutory and regulatory requirements that apply to its products, processes, and activities and should include such requirements as part of the quality management system. Consideration should also be given to the promotion of ethical, effective and efficient compliance with current and prospective requirements; the benefits to interested parties from exceeding compliance; and the role of the organization in the protection of community interests.

5.3 Quality policy: Top management should use the quality policy as a means of leading the organization toward improvement of its performance … In establishing the quality policy, top management should consider the level and type of future improvement needed for the organization to be successful.

5.4.1 Quality objectives: …The objectives should be capable of being measured in order to facilitate an effective and efficient review by management. When establishing these objectives, management should also consider: relevant findings from management reviews … opportunities for improvement, and objectives should be systematically reviewed and revised as necessary.

5.4.2 Quality planning: “…defined needs and expectations of the customers and other interested parties; evaluation of statutory and regulatory requirements; lessons learned from previous experience; indicated opportunities for improvement, and related risk assessment and mitigation data.”

5.6.1 General: “…review activity beyond verification of the effectiveness and efficiency of the quality management system into a process that extends to the whole organization, and which also evaluates the efficiency of the system. Management reviews should be platforms for the exchange of new ideas, with open discussion and evaluation of the inputs being stimulated by the leadership of top management … assessing opportunities for improvement and the need for changes to the quality management…”

5.6.2 Review input: Inputs to evaluate efficiency as well as effectiveness of the quality management system should consider the … new opportunities for improvement; control of process and product nonconformities; and … financial, social or environmental conditions, relevant statutory and regulatory changes.

5.6.3 Review output: “…Top management can use this review process as a powerful tool in the identification of opportunities for performance improvement of the organization … Selected output should be communicated
to demonstrate to the people in the organization how the management review process leads to new objectives that will benefit the organization. Typical examples are: performance objectives for products and processes; loss prevention and mitigation plans for identified risks.”

6.2.2.2 Awareness and training: …To support the achievement of the organization’s objectives and the development of its people, planning for education and training should consider: teambuilding; problem solving… the organization’s impact on society.

6.3 Infrastructure: The process to define the infrastructure necessary for achieving effective and efficient product realization should include the following: (a) provision of an infrastructure, defined in terms such as objectives, function, performance, availability, cost, safety … (d) consideration of environmental issues associated with infrastructure, such as conservation, pollution, waste, and recycling. (Natural phenomena that cannot be controlled can impact the infrastructure. The plan for the infrastructure should consider the identification and mitigation of associated risks and should include strategies to protect the interests of interested parties.)

6.6 Suppliers and partnerships: “…cooperating with suppliers in validation of the capability of their processes; monitoring the ability of suppliers to deliver conforming products with the aim of eliminating redundant verifications; involving suppliers in the organization’s design and development activities to share knowledge and effectively and efficiently improve the realization and delivery processes for conforming products.”

6.8 Financial resources: “…Improving the effectiveness and efficiency of the quality management system can influence positively the financial results of the organization, for example: (a) internally, by reducing process and product failures, or waste in material and time, or (b) externally, by reducing product failures, costs of compensation under guarantees and warranties, and costs of lost customers and markets.”

7.1.2 Issues to be considered: Understanding that a process can be represented as a sequence of activities aids management in defining the process inputs … Results from verification and validation of processes and outputs should also be considered as inputs to a process … to achieve continual improvement of performance and the promotion of excellence throughout the organization. Continual improvement of the organization’s processes will improve the effectiveness and efficiency of the quality management system and the organization’s performance. Processes should be documented to the extent necessary to support effective and efficient operation (for example, significant features of the processes; to ensure the health and safety of people). Also, the drive for continual improvement of the organization’s performance should focus on the improvement of the
effectiveness and efficiency of processes as the means by which beneficial results are achieved. Increased benefits, improved customer satisfaction, improved use of resources and reduction of waste are examples of measurable results achieved by greater effectiveness and efficiency of processes.

7.1.3.1 General: An operating plan should be defined to manage the processes, including: verification and validation of processes and products, analysis of the process including dependability, identification, assessment and mitigation of risk, corrective and preventive actions.

7.1.3.2 Process inputs, outputs and review: The organization should identify significant or critical features of products and processes in order to develop an effective and efficient plan for controlling and monitoring the activities within its processes (for example, equipment capability and monitoring, and health, safety and work environment).

7.1.3.3 Product and process validation and changes: Validation activities include modeling, simulation and trials, as well as reviews involving customers or other interested parties (for example, environmental impact of the product and impact of the use of natural resources including materials and energy). Process validation should be carried out at appropriate intervals to ensure timely reaction to changes impacting the process. Particular attention should be given to validation of processes for high value and safety critical products, and where deficiency in product will only be apparent in use.

Any changes in the process affecting product characteristics should be recorded and communicated in order to maintain the conformity of the product and provide information for corrective action or performance improvement of the organization. Risk assessment should be undertaken to assess the potential for, and the effect of, possible failures or faults in (for example, fault modes and effects analysis; fault tree analysis; relationship diagrams; simulation techniques, and reliability prediction).

7.3.1 General guidance: Top management should ensure that the organization has defined, implemented and maintained the necessary design and development processes to respond effectively and efficiently to the needs and expectations of its customers and other interested parties ... the organization should consider life cycle, safety and health, testability, usability, user-friendliness, dependability, durability, ergonomics, the environment, product disposal and identified risks ... to identify and mitigate potential risk to the users of the products and processes of the organization. Risk assessment should be undertaken to assess the potential for, and the effect of, possible failures or faults in products or processes. The results of the assessment should be used to define and implement preventive actions to mitigate the identified risks (for example, design fault modes and effects analysis; fault tree analysis; reliability prediction; relationship diagrams; ranking techniques, and simulation techniques).
7.3.2 Design and development input and output: Considerations should be given to: customer’s needs; statutory and regulatory requirements; past experience; physical parameters and the environment. In addition the output should include information to enable verification and validation to planned requirements (for example, testing specifications).

7.3.3 Design and development review: Top management should ensure that appropriate people are assigned to manage and conduct systematic reviews to determine that design and development objectives are achieved. These reviews may be conducted at selected points in the design and development process as well as at completion. These include evaluation of potential hazards or fault modes in product use; identification and correction of problems; opportunities for design and development process improvement, and potential impact of the product on the environment … Sufficient data should be generated through verification and validation activities to enable design and development methods and decisions to be reviewed (for example, failure investigation activities, and future design and development process needs).

7.4.1 Purchasing process: Purchasing processes should consider several activities including identification and mitigation of risks associated with the purchased product.

7.5.1 Operation and realization: Top management should go beyond control of the realization processes in order to achieve both compliance with requirements and provide benefits to interested parties (for example, reducing waste; preventing problems).

8.2.1.4 Financial measures: Management should consider the conversion of data from processes to financial information in order to provide comparable measures across processes and to facilitate improvement of the effectiveness and efficiency (for example, internal and external failure cost analysis, and life-cycle cost analysis).

8.2.2 Measurement and monitoring of processes: The organization should identify measurement methods and should perform measurements to evaluate process performance (for example, capability, cycle time or throughput, measurable aspects of dependability, yield, waste reduction).

8.2.3 Measurement and monitoring of product: …The organization should consider the following: (e) customer established points for witness or verification of selected characteristics of a product; (f) inspections or testing required to be witnessed or performed by statutory and regulatory authorities; (g) where, when, and how the organization intends, or is required by the customer or statutory and regulatory authorities, to engage qualified third parties to perform (type testing, in-process inspections or testing, product verification); (i) final inspection to confirm that verification and validation activities have been completed and accepted.
8.3.1 General: ...Where practical, nonconformities should be recorded, together with their disposition, to assist learning and to provide data for analysis and improvement activities. The organization may also decide that nonconformities to both product realization and support processes should be recorded and controlled.

8.3.2 Nonconformity review and disposition: The management of the organization should ensure the establishment of an effective and efficient process to provide for review and disposition of identified nonconformities.

8.5.2 Corrective action: Top management should ensure that corrective action is used as a tool for improvement. Corrective action planning should include evaluation of the significance of problems, and should be in terms of the potential impact.

8.5.3 Loss prevention: To be effective and efficient, planning for loss prevention should be systematic. This should be based on data from appropriate methods, including evaluation of historical data for trends, and criticality relative to the performance of the organization and its products, in order to generate data in quantitative terms. Data can be generated from: use of risk analysis tools such as fault mode and effects analysis, lessons learned from past experience. Such data will provide information to develop an effective and efficient plan for loss prevention and prioritization appropriate to each process and product, in order to satisfy the needs and expectations of interested parties.

ISO 9001:2000

Whereas the ISO 9004 serves as a guideline for a quality system, the ISO 9001 is the certifiable standard for quality. As such, it offers both direct and indirect requirements for the usage of FMEA. Without commentary the following elements have been identified as the ones that relate to FMEA. The reader should be aware of their implication as the third party auditors will audit FMEAs based on these requirements in addition to customer defined requirements.

4.1 General requirements: (b) determine the sequence and interaction of these processes.

4.2 Documentation requirements: (d) documents needed by the organization to ensure the effective planning, operation and control of its processes. (Where the term “documented procedure” appears within this International Standard, this means that the procedure is established, documented, implemented and maintained.)

4.2.3 Control of documents: A documented procedure shall be established to define the controls needed (a) to approve documents for adequacy prior to issue, (b) to review and update as necessary and re-approve
documents, (c) to ensure that changes and the current revision status of documents are identified.

5.1 **Management commitment:** (d) conducting management reviews.

5.2 **Customer focus:** …ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction.

5.3. **Quality policy:** (b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system (c) provides a framework for establishing and reviewing quality objectives (e) is reviewed for continuing stability.

5.4. **Quality objectives:** …that quality objectives, including those needed to meet requirements for product, are established at relevant functions and levels within the organization.

5.4.2 **Quality management system planning:** …management system is carried out in order to meet the requirements given in 4.1, as well as … and (b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.6.2 **Review input:** The input to management review shall include information on … (c) process performance and product conformity, (d) status of preventive and corrective actions, (e) follow-up actions from previous management reviews, and (g) recommendations for improvement.

5.6.3 **Review output:** The output from the management review shall include any decisions and actions related to … improvement of product related to customer requirements.

7.2.1 **Determination of requirements related to the product:** The organization shall determine: (b) requirements not stated by the customer but necessary for specified or intended use, where known, (c) statutory and regulatory requirements related to the product, and (d) any additional requirements determined by the organization.

7.3.1 **Design and development planning:** The organization shall plan and control the design and development of product … During the design and development planning the organization shall determine: (a) the design and development stages, (b) the review, verification and validation that are appropriate to each design and development stage. The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility. Planning output shall be updated, as appropriate, as the design and development progresses.

7.3.2 **Design and development inputs:** Inputs include: applicable statutory regulatory requirements and … information from previous similar designs.

7.3.3 **Design and development outputs:** Outputs include: specify the characteristics of the product that are essential for its sale and proper use.
7.3.4 **Design and development review:** …(a) to evaluate the ability of the results of design and development to meet requirements, and (b) to identify any problems and propose necessary actions.

7.3.7 **Control of design and development changes:** The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered.

7.5.1 **Control of production and service provision:** The organization shall plan and carry out production and service provision under controlled conditions. For example, (a) the availability of information that describes the characteristics of the product.

7.5.2 **Validation of processes for production and service provision:** …Validation shall demonstrate the ability of these processes to achieve planned results. For example, (a) defined criteria for review and approval of the processes, (c) use of specific methods and procedures and (e) revalidation.

8.3 **Control of nonconforming product:** The organization shall deal with nonconforming product by one or more of the following ways: (a) by taking action to eliminate the detected nonconformity; (c) by taking action to preclude its original intended use or application. When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.

8.4 **Analysis of data:** The organization shall determine, collect, and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made.

8.5.1 **Continual improvement:** The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions, and management review.

8.5.2 **Corrective action:** The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. For example, (c) evaluating the need for action to ensure that nonconformities do not recur, (d) determining and implementing action needed, (f) reviewing corrective action taken.

8.5.3 **Preventive action:** The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems. For example, (a) determining potential nonconformities and their causes, (b) evaluating the need for action to prevent occurrence of nonconformities, (c) determining and implementing action needed, (d) records of results of action taken, and (e) reviewing preventive action taken.
One can see that the rationale for improvement, customer satisfaction, and failure reduction continues in the ISO 9001:2000 as well as in the ISO 9004:2000. In fact, the specific language of ISO 9001:2000 as well as the language of ISO 9004:2000 is full of either direct or indirect implications that may greatly expand liability issues. Issues such as “Risks, Costs, and Benefits” are abundantly much clearer in the 2000 version than the 1994 version. From all the clauses of ISO 9004:2000 and ISO 9001:2000 addressed here it is evident that the International Organization for Standardization has made it clear that the principle focus in the product liability area is on product liability prevention, rather than on liability per se.

This prevention may be accomplished by audits, tests, and reliability studies. One specific method is the FMEA. In fact, FMEA is specifically called out in several of the elements. The reason for the applicability of the FMEA into the system of ISO 9000 standards is because FMEA is a prevention tool in both design and manufacturing.

Finally, the reason why the FMEA applies to all the aforementioned clauses of ISO 9001 and ISO 9004 is that the FMEA lives the intent and spirit of the prevention mode of the entire standard. One must always remember that the FMEA by definition is a methodology that wants to optimize the system, design, process, and/or service by modifying, improving, and/or eliminating any known or potential problems. Even though it does that, it also recognizes that the optimization is not without risk. The FMEA, no matter what the level, always recognizes the relationship of 
\[ R(t) = 1 - F(t) \]
which tells us that reliability can never be 100 percent, rather by focusing on the minimization of the failure rate we can come close to a designated reliability based on some predefined confidence.

REFERENCES


Much has been said about the define, measure, analyze, improve, control (DMAIC) and the define, characterize, optimize, verify (DCOV) models in the Six Sigma methodology. However, as important as fixing problems are, there seems to be a tendency to stay away from the real source of problems. We all have a preference to fix problems rather than prevent problems from occurring. In the Six Sigma methodology, both in the traditional sense and the design for Six Sigma (DFSS), the FMEA plays a very important role. The mechanics and the process, of course, do not change; however, the role of the design review, especially in the DFSS approach, takes an extra dimension. In this chapter we will focus on this design review in somewhat of a detailed fashion and provide the reader with a guideline that may be used in their own environment.

**GENERAL**

The predominant reason for any design review is to:

1. Provide a guideline for design reviews utilizing peer-oriented assessment and coaching.
2. Provide a method to assess status and drive implementation of corporate timing guidelines of quality and reliability methods.
3. Serve as a requirement for assessing and scoring product development. It does that by the fact that a design review is an integral part of one of three components of any quality system for
product engineering requirements. The three component requirements are:

a) System assessment: satisfactory score(s) on the quality assessment criteria questions.

b) Results metrics: satisfactory trends on the specified engineering results metrics.

c) Customer endorsements: written endorsement from specified engineering customers.

QUALITY SYSTEM ASSESSMENT (QSA) — PRODUCT DEVELOPMENT (PD)

The quality system assessment, which is part of the design review, emphasizes the high-leverage quality and reliability disciplines in the corporate timing schedule. It should be organized in categories that reflect the organizational objectives and each of the categories should have subsections that describe the requirements. A warning here is appropriate: make sure that the specified requirements are in tandem with the organizational culture, values, and mission.

APPLICABILITY AND SCOPE

The design review may be applied to:

1. Product design organizations or activities. For example, department, section, or Program Module Team (PMT). The PMT approach is of special interest if the organization is dealing with specific products or brand orientation.

2. Internal and external engineering activities of the organization.

It is intended for all levels of product design activity (component, subsystem, and complete system programs) and supporting manufacturing engineering activity. It also may be used for both large product programs and minor design changes.
DESIGN REVIEW FUNDAMENTALS

Perhaps the most important ingredients for any design review are the following:

1. Focused on engineering for quality and reliability—not program status.

2. Peer reviewed by another assigned PMT—not attended by senior management.

3. Working documents distributed to coaching PMT in advance of the review—not a walk-in cold and shoot from the hip review.

4. Honest discussion and learning from each other so both PMTs improve—not presentation.

5. Most of all, it is for the company’s benefit.

Without understanding and internalizing these five fundamental, a design review is bound to be another show in the parade of other tools.

DESIGN REVIEW OPERATION

The timing schedule of a given organization is the rudder for any design review content. Without a solid understanding of the organization’s timing requirements, the product development cycle is going to be like a sail boat without a captain. It is imperative that the timing not only be in place, but is reasonable, attainable, realistic, and measurable. Therefore, the following procedural requirements must be understood and implemented as needed:

- The QSA focuses the design team on the vital quality and reliability practices that must be implemented for the relevant phase of the timing milestones. (Every organization must have timing and milestone requirements.)

- Every PMT should be assigned a peer coach. These teams will assess and coach one another with respect to QSA. The peer coaching PMT assigned pairings will rotate every X months. (Obviously, this is a function of the timing and product cycle for the individual organization.)

- The quality team leaders will attend each other’s PMT meetings in an effort to get to know the other team’s scope, open issues, and current status. This should occur in the first few weeks after the teams conduct their self-assessment training sessions. Also during
this timeframe, agreements should be reached for the scheduling of the first design reviews. Agreements are also reached between each team as to which sections of the QSA will be assessed at the first design review, depending on the relevant timing and milestone.

- Two weeks prior to the design review (this is a general guideline), the quality team being coached produces the appropriate documents required to support the relevant timing milestone. The quality coaching team uses the next week to study the documents in detail and prepare constructive comments relative to the QSA criteria to be evaluated.

- One week prior to the design review, the quality coaching team reviews their comments/critiques with members of the steering team. An agenda for the design review is produced at this point.

- The design review is held. No scoring is conducted at this point, only constructive dialogue as to strengths and weaknesses of the team within the framework of the QSA quality and reliability parameters, found in the initial design review.

- For the next several months, the teams continue their work, focusing on the relevant timing disciplines, but emphasizing improvement in the weaknesses found in the initial design review.

- At this point, the quality teams agree on a second design review date and follow the same preparation process as in the initial design review. After completion of this design review, the peer coaching team leader uses the questions in the QSA to score and assess the timing quality of event. This is the relevant score for the design team at that point in time.

At this point, the teams will be reassigned new coaching partners by the coordinating activity and the cycle will repeat (see Table 16.1).

**QSA SCORING GUIDELINES**

Now that we have discussed some of the overall goals and roles/responsibilities for a typical design review, let us examine the QSA process. Our intent here is not to give a cookbook approach but rather to give a guideline as to what is important and how one may go on and evaluate the design review for optimum results. It is of paramount importance to recognize that
Table 161  Roles and responsibilities—design review process.

<table>
<thead>
<tr>
<th>Roles</th>
<th>Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>PMTs (when being coached)</td>
<td><strong>Meeting frequency:</strong> Determine the frequency of design reviews in collaboration with the PD peer. Coaching PMT (Target is to conduct at least 2 PD design reviews over an X month time period.)</td>
</tr>
<tr>
<td></td>
<td><strong>Scheduling:</strong> Develop design review schedules with input from PD peer coaching team leader.</td>
</tr>
<tr>
<td></td>
<td>Ensure scheduled meeting times are communicated.</td>
</tr>
<tr>
<td></td>
<td><strong>Agenda:</strong> Develop agenda for design reviews based on the appropriate elements of the QSA and the PD design review timing relationship to your organization's timing milestones.</td>
</tr>
<tr>
<td></td>
<td><strong>Collect/distribute working documents:</strong> Per the guidelines provided in the PD design review, collect relevant timing working documents and send them to the assigned coaching PMT team leader a minimum of two weeks before the scheduled design review.</td>
</tr>
<tr>
<td></td>
<td><strong>Design reviews:</strong> Listen, answer questions, receive input to improve the quality of event of the engineering process and the system design.</td>
</tr>
<tr>
<td></td>
<td><strong>Improvement workplan:</strong> Develop the workplan to implement constructive ideas, and develop actions to close the gap between the actual and desired QSA score.</td>
</tr>
<tr>
<td>PMTs (when coaching)</td>
<td><strong>Facilitation and coaching:</strong> Attend selected meetings of the coached PMT review working documentation package of team being coached and prepare to review with PD steering team (elapsed time approximately one week from receipt of documentation package).</td>
</tr>
<tr>
<td></td>
<td>Meet with members of the steering team approximately one week in advance of the scheduled design review to discuss the contents and quality of the documentation package provided by the PMT being coached.</td>
</tr>
<tr>
<td></td>
<td>Conduct design reviews per the formal agenda and provide team being coached with recommendations and constructive comments.</td>
</tr>
<tr>
<td></td>
<td><strong>Evaluation:</strong> Score the relevant portions of QSA and provide feedback to the design team being coached.</td>
</tr>
<tr>
<td>Reliability implementation engineer (RIE)</td>
<td><strong>Prework:</strong> Review system/subsystem documentation provided by the PMT being coached in advance of the scheduled design review(s).</td>
</tr>
<tr>
<td></td>
<td>Help coaching PMT prepare questions and recommendations in advance for discussion at the scheduled review.</td>
</tr>
<tr>
<td></td>
<td><strong>Support:</strong> Provide coaching, knowledge, experience/expertise, and act in an advisory role to the PMT leader/team in areas related to:</td>
</tr>
<tr>
<td></td>
<td>• PD processes and philosophies</td>
</tr>
<tr>
<td></td>
<td>• Reliability/robustness methods, disciplines, tools, and their implementation.</td>
</tr>
<tr>
<td></td>
<td><strong>Improvement workplan:</strong> Work with the PMT leader/team being coached and PMT peer coach team leader to develop a roadmap/workplan for the team being coached which identifies the basic improvement actions that the team should consider implementing to achieve pre-specified levels of performance.</td>
</tr>
</tbody>
</table>
each organization is unique and each design review is unique and must be thought out completely.

A very general format of a scoring guideline (shown in Table 16.2) shall be used to demonstrate the scoring process. (It is not the only way.) Scoring may be used as a means of establishing a baseline and measure improvement in performance to the QSA. The scoring may be performed as a self-assessment by an individual or organization, or by a peer(s). It is imperative that this scoring must not be confused with the criteria guidelines of the FMEA.

<table>
<thead>
<tr>
<th>Item</th>
<th>Level</th>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approach</td>
<td>None</td>
<td>0</td>
<td>The organization is not familiar with the concept/criteria and has no relevant approach in this area.</td>
</tr>
<tr>
<td></td>
<td>Low</td>
<td>1</td>
<td>The organization is familiar with the concept/criteria and a systematic approach is less than 50% developed.</td>
</tr>
<tr>
<td></td>
<td>Medium</td>
<td>2</td>
<td>The organization is familiar with the concept/criteria and a systematic approach is greater than 50% developed.</td>
</tr>
<tr>
<td></td>
<td>High</td>
<td>3</td>
<td>The organization is familiar with the concept/criteria and the approach is greater than 90% developed.</td>
</tr>
<tr>
<td>Deployment</td>
<td>Low</td>
<td>4</td>
<td>A systematic approach is developed and deployment has started in some major areas.</td>
</tr>
<tr>
<td></td>
<td>Medium</td>
<td>5</td>
<td>A systematic approach is developed and deployment is greater than 50% in all areas.</td>
</tr>
<tr>
<td></td>
<td>High</td>
<td>6</td>
<td>A systematic approach is developed and deployment is greater than 90% in all areas.</td>
</tr>
<tr>
<td>Results</td>
<td>Low</td>
<td>7</td>
<td>Deployment of the approach has produced some relevant improvement in the “quality of event” and/or the product design and/or value to the customer—minimum quality requirement.</td>
</tr>
<tr>
<td></td>
<td>Medium</td>
<td>8</td>
<td>Deployment of the approach has produced moderate (50%) relevant results improvement in the “quality of event” and the product design and/or value to the customer.</td>
</tr>
<tr>
<td></td>
<td>High</td>
<td>9</td>
<td>Deployment of the approach has produced substantial (80%) relevant results improvement in the “quality of event” and the product design and/or value to the customer.</td>
</tr>
<tr>
<td></td>
<td>Outstanding</td>
<td>10</td>
<td>The organization is best-in-class and able to demonstrate significant innovation in new approaches. Excellent relevant results are available over a sustained period.</td>
</tr>
</tbody>
</table>
proper. This is a review process of the results of an FMEA whereas the FMEA criteria are evaluations of risk. The peer review process provides for assessment and scoring of an engineering organization (or individual) by another engineering organization (or individual). The peer review should include coaching and learning from one peer to another. It is recommended that the initial review by the peer be kept confidential. Subsequent reviews should be published to provide an indication of strengths and weakness and to show continual improvement.

Whereas Table 16.2 shows an overview of the guidelines, these are still not functional. To have useful guidelines the criteria must be measurable and at least somewhat specific. The rest of the chapter will present such guidelines on a per-stage basis. We begin with the definition product and process requirements.

The objective here is to establish or prioritize customer wants, needs, delights, and so on. Therefore, the requirements are to identify customers and establish or prioritize these wants, needs, delights, real world usage profiles, and demographics. To do that, points are developed for each question and weighted against each other, as well as to the other subcategories (see Table 16.3). The actual numerical scheme is not as important as the differentiation and understanding of the questions asked. In our example each question is given 10 points for a total of 100 subsection points.

The second subsection of the definition stage is the derivation of customer-driven specification—a pure engineering task. The requirements here are to translate customer, corporate, and regulatory functionalities, make appropriate trade-offs, and establish product or process specifications (requirements) and engineering test plans. The specific questions are shown in Table 16.4. Notice that each question is again weighted on a 10 points per question for a total of 100 points for this subsection. Just like before, the actual numerical values are not that significant. What is significant is the rationale and weighing process for differentiation. One may use any numerical scheme, as long as the outcome satisfies the objective.

The third subsection of the definition stage is the definition system architecture and function. Again this subsection is a pure engineering task. The requirements here are to define system architecture, inputs/outputs, and ideal function for each of the system elements and identify interfaces. Interfaces turn out to be very critical in the ultimate design since they present challenges from interaction. The classical interface opportunities are due to the physical proximity of different items, information transfer, different material compatibility, and energy transfer. The specific questions are shown in Table 16.5. Notice that each question is again weighted on a 10 points per question for a total of 50 points for this subsection. As before, the actual numerical values are not significant. What is significant is the rationale and weighing process for
differentiation. One may use any numerical scheme, as long as the outcome satisfies the objective.

The second stage in the product development process is to design the product and process. The evaluation here is based on a total of 500 points and is divided into several subsections. Each subsection carries its own requirements and its own weight of points.

The first subsection is the selection of product or process concept. The requirements are to create or establish alternative product design and manufacturing process concepts and derive best alternatives for development. There are six questions (10 points per question) that will facilitate the decision and the process. The questions (see Table 16.6) are designed to promote an open discussion about newness. That means that the discussion should be

<table>
<thead>
<tr>
<th>Item #</th>
<th>Criteria</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The target customers for the product family are defined.</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>A study of all available information about the relevant customer usage, wants, needs, and delights has been completed.</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Areas for potential target customer market research are identified and research was performed.</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Performance requirements and lessons learned have been reviewed for both corporate, its subsidiaries, and relevant competition.</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Customer engagement activities for design engineers, manufacturing engineers, managers, and all other team members have been planned and implemented.</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Customer environmental conditions, usage and operating conditions, demographics and profiles, and performance evaluations are documented.</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Competition (features, performance, and craftsmanship) has been benchmarked.</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Innovative ideas, delights, and new wants have been identified.</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>New features and technological wants have been prioritized for further development.</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Definitions of customer wants and needs have been established.</td>
<td></td>
</tr>
</tbody>
</table>

Section subtotal (100 points possible)
open, without fear of intimidation or retaliation. As before, the numerical scheme is not the important characteristic of the process. What is important, is the ability to differentiate the differences in a manner that is appropriate to the customer, organization at large, and the regulatory bodies.

In the spirit of selecting the new concept for either product or process or both, the engineer must also consider concurrent product and process design. It is an imperative that in our modern world that concurrent engineering must take place and this stage of product development should address it. The requirements are indeed very simple but very hard to implement. Specifically, we are interested in design and model products and

<table>
<thead>
<tr>
<th>Item #</th>
<th>Criteria</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Customer wants, needs, and delights; corporate and regulatory requirements are translated into functional requirements at appropriate system levels.</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Performance based on customer usage profiles have been translated into key life verification tests as appropriate.</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Manufacturing/assembly/usage/environmental/deterioration sources of variation are anticipated (robustness) in the specification tests and incorporated into the design verification plan (DVP).</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Functional attributes (including cost, weight and craftsmanship) and reliability targets are established.</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Targets are established for high mileage functional degradation.</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Functional/reliability targets are verified with customers and strategic suppliers.</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Engineering specifications (system, subsystem, and component) developed to adequately cover customer (low and high performance), corporate and regulatory requirements.</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>An effective, efficient engineering program is planned, based upon actions for optimal development of customer-driven engineering characteristics.</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Timing for program actions is established and verified with customers and suppliers.</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Resources are allocated for plan implementation.</td>
<td></td>
</tr>
</tbody>
</table>

Section subtotal (100 points possible)
Table 16.5 Requirements and criteria for system architecture definition.

<table>
<thead>
<tr>
<th>Item #</th>
<th>Criteria</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>System architecture has been partitioned to minimize/simplify function and organization interfaces.</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Ideal functions defined and specified for each functional element.</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Metrics are established for ideal function assessment.</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Strategy to manage functional boundary interfaces implemented.</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Requirements and targets have been allocated and cascaded to subsystems and components.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Section subtotal (50 points possible)</td>
<td></td>
</tr>
</tbody>
</table>

Table 16.6 Requirements and criteria for selection of the product or process concept.

<table>
<thead>
<tr>
<th>Item #</th>
<th>Criteria</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Best-in-class components are evaluated for craftsmanship, cost, weight, material, quality, serviceability &amp; variation, and method of manufacture; and competitor’s components are accessible (boarded if possible) for reference.</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Applicable advanced technology concepts have been researched, evaluated, and included (where applicable).</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Robustness implications of the advance technology concepts have been considered; concepts are prioritized by their potential for robustness.</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>New product and process concepts have been evaluated against customer-driven criteria.</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>A better concept has been systematically derived by combining the best features of available product and process concepts.</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Design conflicts/contradictions and manufacturing feasibility issues have been identified and addressed.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Section subtotal (60 points possible)</td>
<td></td>
</tr>
</tbody>
</table>
processes concurrently using low-cost tolerances and inexpensive materials. We can do that with parameter and tolerance design as part of the development, with the sole purpose of designing robust designs. That is why in design for Six Sigma we must focus on $Y = f(x,n)$ rather than the traditional $Y = f(x)$.

There are 14 basic questions (10 points per question) that will facilitate the decision and the process. The questions (see Table 16.7) are designed to promote an understanding of concurrent engineering and the application ramification in the design process. This is the stage where much engineering discussion is geared for alternative analysis and optimization of testing possibilities. As before, the numerical scheme is not the important characteristic of the process. What is important, is the ability to differentiate the differences in a manner that is appropriate to the customer, organization at large, and the regulatory bodies. The basis for this analysis is focused (as appropriate) on trade-off and many other tools and methodologies.

The third subsection in evaluating the design product and process is the approach (methodology or process) which allows the engineer to identify and prevent failure. The requirement here is to improve product and process through reduction of potential failure modes and functional variability (see Table 16.8). In this category usually there are four core questions (10 points each) which will guide the evaluation process. As before, the numerical scheme is not important. What is important, is to be able to see and discuss potential failures and eliminate them from the design. The questions, hopefully, will facilitate the process and will focus the discussion to priority items.

The fourth component of the design product and process is the optimization function in the presence of noise. In the design for Six Sigma this is the most important characteristic. Whereas in the DMAIC model we focus on problem fixing, in the design for Six Sigma we must focus on prevention and robustness. It turns out that the robustness is indeed the focal point of design if we are really serious about improvement. The traditional model of $Y = f(x)$ is not appropriate any more. We must focus on the $Y = f(x,n)$, which means that the customer functionality ($Y$) has to be satisfied with engineering requirements ($x$), but in the presence of noise ($n$).

Therefore, the requirement in this stage is to optimize product and manufacturing/assembly process functions by testing in the presence of anticipated sources of variation (noise). There are six questions (10 points each) and just as before they are not the only questions (see Table 16.9). They are to serve as the springboard of ideas for sound evaluation.

The fifth component of designing product and process is the issue of tolerance design. Perhaps one of the most misunderstood concept in any design endeavor. Tolerance design is not the same as tolerancing. Major differences exist between the two. The first is modern thinking and it forces the engineer to think in Systems thinking—holistic top to bottom approach,
Table 16.7 Requirements and criteria for concurrent product and process design.

<table>
<thead>
<tr>
<th>Item #</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The manufacturing, assembly, inspection (GD&amp;T), and serviceability processes are developed simultaneously with the product design.</td>
</tr>
<tr>
<td>2</td>
<td>Initial design for product and process includes product reusability (components, tools, fasteners, and fixtures) and craftsmanship.</td>
</tr>
<tr>
<td>3</td>
<td>The initial design uses low-cost materials and maximum manufacturing/assembly tolerances with the goal of obtaining high quality/reliability at low cost.</td>
</tr>
<tr>
<td>4</td>
<td>Engineering calculations (for example, physics stress/strength and thermal expansion) have been analyzed for product/process initial design.</td>
</tr>
<tr>
<td>5</td>
<td>Initial product and process design embodies the appropriate “design fors” (design for assembly, design for dis-assembly, design for manufacturing, design for service, design for reliability, design for reusability, and so on).</td>
</tr>
<tr>
<td>6</td>
<td>Verify that the design meets all worldwide design requirements/regulatory/safety/campaign prevention requirements and relevant critical characteristics have been identified and communicated to manufacturing/assembly and suppliers.</td>
</tr>
<tr>
<td>7</td>
<td>Simultaneously update design verification testing while developing design.</td>
</tr>
<tr>
<td>8</td>
<td>Where appropriate, analytical models (CAE) have been utilized to identify and improve physical and functional performance over time.</td>
</tr>
<tr>
<td>9</td>
<td>Reliability/quality targets have been estimated and actions taken to improve the product/system performance over time.</td>
</tr>
<tr>
<td>10</td>
<td>Mistake-proofing techniques are utilized as appropriate.</td>
</tr>
<tr>
<td>11</td>
<td>Tests for discovery have been conducted to verify assumptions and confirm engineering theory.</td>
</tr>
<tr>
<td>12</td>
<td>Assessment of function/cost weight/reliability has been conducted for current organizational requirements, its subsidiaries, and competitive designs. Design opportunities have been implemented to provide increased value (VA/VE).</td>
</tr>
<tr>
<td>13</td>
<td>Manufacturing/assembly feasibility has been assessed and issues resolved.</td>
</tr>
<tr>
<td>14</td>
<td>A series of constructive peer, expert design reviews have been conducted to improve the product and process.</td>
</tr>
<tr>
<td></td>
<td>Section subtotal (140 points possible)</td>
</tr>
</tbody>
</table>

where tolerancing is the traditional specification orientation at all costs—bottom to top approach.
The requirement for tolerance design is to selectively adjust product/process tolerances and materials to achieve desired performance (with cost/benefit trade-offs) and to identify key characteristics for manufacturing control and continued variability reduction. There are four questions that deal with this subsection (10 points each). See Table 16.10.

### Table 16.8 Requirements and criteria for preventing failure modes and decrease variability.

<table>
<thead>
<tr>
<th>Item #</th>
<th>Criteria</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Historical failure modes (warranty, TGW, lessons learned, including campaign prevention, and so on) were reviewed and initial design and process failure modes identified by a cross-functional team.</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Design and process improvements identified and implemented to reduce occurrence/severity (DFMEA/PFMEA) of functional variability.</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Cost and quality effect of reduced functional variability determined.</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>DVP includes analysis/tests for priority potential failure modes.</td>
<td></td>
</tr>
</tbody>
</table>

Section subtotal (40 points possible)

### Table 16.9 Requirements and criteria for optimizing function in the presence of noise.

<table>
<thead>
<tr>
<th>Item #</th>
<th>Criteria</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Product/process experimentation strategy are concurrently developed within (and between) each of the system’s functional boundaries.</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>For each function, the system signal, control, noise factors, and response have been identified.</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Strategy developed for anticipating effects of major sources of noise during experimentation for each of the system’s functional elements.</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>A series of product and process experiments have been conducted to optimize functional performance in the presence of noise.</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>DVP includes important noises for priority functions.</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Assumptions used in the analysis have been verified and functional/cost performance improvements (for both product and process) are documented.</td>
<td></td>
</tr>
</tbody>
</table>

Section subtotal (60 points possible)
The sixth subsection of designing the product or process deals with finalizing process/control plans. The requirement here is to concur with process tooling, gages, and control plans. There are nine questions that should guide the evaluation process, 10 points each. See Table 16.11.

The seventh subsection of designing the product or process is design verification. The requirement for this substage is to integrate and verify design and manufacturing process functions with production-like hardware/software. There are seven questions (10 points each) that may facilitate the understanding and decision making. See Table 16.12.

The third stage in the product development process is to verify product and process. The evaluation here is based on a total of 100 points and is divided into two subsections. Each subsection carries its own requirements and its own weight of points.

The first subsection deals with design/manufacturing confirmation. The requirement here is to confirm manufacturing and assembly process capability to achieve design intent. Remember that the intent is always driven by the customer’s functionality. Therefore, if the intent is not met, functionality is not met and as a consequence the customer is not satisfied. There are six questions that focus on this intent (10 points each). See Table 16.13.

The second subsection of verifying product and process deals with launch and mass production confirmation. Obviously, if an organization does not deal with this, it is not appropriate for evaluating purposes. If this subsection is relevant to an organization, remember that the requirement here is

---

**Table 16.10 Requirements and criteria for tolerance design.**

<table>
<thead>
<tr>
<th>Item #</th>
<th>Criteria</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Cause and effect relationships between material/tolerance choices and functional performance have been systematically studied, using designed experiments, and understood.</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Design has been modified to selectively adjust product and process tolerances and materials to meet functional targets.</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Tolerance studies (root mean square, worst case stack-up, GD&amp;T, and so on) are finalized for fit and finish to mating components.</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Potential significant characteristics have been identified and communicated to manufacturing/assembly where further variance reduction (within the tolerance range) will improve functional performance and customer satisfaction.</td>
<td></td>
</tr>
</tbody>
</table>

Section subtotal (40 points possible)
Table 16.11  Requirements and criteria for finalizing process/control plans.

<table>
<thead>
<tr>
<th>Item #</th>
<th>Criteria</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Key product and process characteristics translated to process control plans.</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Key measurement processes are identified, specified, and reviewed.</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>All DFMEA/PFMEA high risk failure modes have mistake-proof methods designed into the respective product and/or process.</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Manufacturing process sheets, operator instruction sheets, and job aids have been reviewed. (This is very important for Assembly Plants &amp; Suppliers.)</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Training plans for engineers, operators, and skilled trades are reviewed.</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Preventative, predictive, and general assembly/manufacturing/supplier repair/rework plans and procedures reviewed.</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Process and gage control plans are reviewed (including recalibration schedules and reaction plans for out-of-control).</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Supplier FMEAs and control plans have been reviewed by the appropriate engineering activities.</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Linkage between DFMEA, PFMEA, DVP, and process control plans is evident.</td>
<td></td>
</tr>
</tbody>
</table>

Section subtotal (90 points possible)

Table 16.12  Requirements and criteria for design verification.

<table>
<thead>
<tr>
<th>Item #</th>
<th>Criteria</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Prototypes are manufactured by the production source with production-like content and manufacturing/assembly processes.</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Initiate DVP tests and verify optimized product and process functional performance has met reliability targets under laboratory and/or field conditions.</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Review dunnage, packaging, shipping, and delivery systems together with testing of dunnage.</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Verify service requirements and repair procedures/time studies.</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Review manufacturing process and machine capacity/capability verification from vendor sites.</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Supplier DVP reports have been reviewed by the appropriate engineering activity.</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Concern resolution process is in place and all relevant activities identified and tracked.</td>
<td></td>
</tr>
</tbody>
</table>

Section subtotal (70 points possible)
to launch the product, ramp up, and confirm that mass production delivers function, cost, quality, and performance objectives. To facilitate this, there are four questions (10 points each). See Table 16.14.

The fourth and final stage in the product development process is to manage the program. The evaluation here is based on a total of 150 points and is divided into three subsections. Each subsection carries its own requirements and its own weight of points.

The first subsection is to form a team. The requirement is to establish and maintain a highly effective team (for both product and process) that has a shared vision. Without this shared vision everyone will pull their own way. The result will be failure. There are nine questions (10 points each) that focus on the team effort and are shown in Table 16.15.

The second subsection of the fourth stage deals with establishing a program information center. The requirement is to maintain and use a program information center to understand global program—if applicable, social, and institutional knowledge. How sad that even major corporations keep repeating the same steps to a repetitive problem, all the time because no one has taken the time to document appropriately the information. In this subsection we focus on four questions (10 points each). See Table 16.16.

The third subsection of managing the program is related to the last subsection. It deals with updating your corporate memory. We all talk about things learned but unfortunately very few, if any, systematically documents

### Table 16.13 Requirements and criteria for design/manufacturing confirmation.

<table>
<thead>
<tr>
<th>Item #</th>
<th>Criteria</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Product engineering supports all pre-job #1 builds and launch with representatives who are knowledgeable about the program and the build/launch procedures.</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Review measurement capability and process capability for each significant/critical characteristic using data from manufacturing operations/suppliers.</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Review process potential capability/capacity trial data for part submission warrant samples.</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Performance to functional specifications verified through fresh eyes launch readiness reviews, and quantified through validation testing.</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Degradation data are used to improve analytical model correlation/test correlation to field performance.</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Areas requiring concern resolution are identified, reviewed and updated. PV sign-off is completed.</td>
<td></td>
</tr>
</tbody>
</table>

Section subtotal (60 points possible)
### Table 16.14 Requirements and criteria for launch/mass production confirmation.

<table>
<thead>
<tr>
<th>Item #</th>
<th>Criteria</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Concur with supplier launch support plans.</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Support manufacturing, marketing, service, and production launch teams.</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Review changes in measurement capability, process capability, fit/finish, and functional performance resulting from increased volume production.</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Strategy developed/refined to produce continual improvement/reduction of product and process variability.</td>
<td></td>
</tr>
</tbody>
</table>

Section subtotal (40 points possible)

### Table 16.15 Requirements and criteria for forming a team.

<table>
<thead>
<tr>
<th>Item #</th>
<th>Criteria</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Each multidisciplinary team has established roles and responsibilities.</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Team meets on a regular basis, and maintains a record of open issues and actions.</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Team is fully staffed on time and includes manufacturing, assembly, product engineering, suppliers, customers, and so on, with the necessary know-how.</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Team member capabilities (skills) have been assessed by team leader. The team has people who are qualified to do the job.</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Team member training is provided on a just-in-time basis.</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Shared vision/mission statement is fully understood, documented, and has the commitment of every team member.</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Management fosters team building events/workshops.</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Attributes of a high-performance team are evident (passion for customer, knowledge about the program and corporate requirements, freedom to act without fear, willingness to participate in peer reviews, and so on).</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Mechanisms for a learning environment (that is, dialogue, left-hand column, and so on) are active.</td>
<td></td>
</tr>
</tbody>
</table>

Section subtotal (90 points possible)
these learned things to the point where they are used again directly or as a surrogate data for other problems.

The requirement here is to update the corporate knowledge database with technical, institutional, and social lessons learned. To do that the focus is on two basic questions, 10 points each. See Table 16.17.

Finally, for the convenience of the practicing engineer, Table 16.18 presents a summary score sheet that may be used to log the design review process, along with some typical working documents (checklist of sorts—not an exhaustive one), to remind them what has to be done, the focus and the results of the review in a typical FMEA process.

### Table 16.16 Requirements and criteria for establishing a program information center.

<table>
<thead>
<tr>
<th>Item #</th>
<th>Criteria</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Point-of-need library-like facilities (designated team room/learning center) are established and used.</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Program knowledge for product and process (including benchmark competitive information, relevant field data, reliability data, and so on) has been gathered and organized.</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Daily operation and management procedures (staff) established.</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Corporate lessons learned and best practices have been disseminated.</td>
<td></td>
</tr>
</tbody>
</table>

Section subtotal (40 points possible)

### Table 16.17 Requirements and criteria for establishing corporate knowledge.

<table>
<thead>
<tr>
<th>Item #</th>
<th>Criteria</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Robustness of product and process improved by application of database information.</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Corporate memory system updated with new information/lessons learned resulting from application of appropriate timing activities.</td>
<td></td>
</tr>
</tbody>
</table>

Section subtotal (20 points possible)
Table 1618  A summary score sheet with some typical working documents.

<table>
<thead>
<tr>
<th>Scoring summary sheet</th>
<th>Program:</th>
<th>PMT No:</th>
<th>Leader: Phone:</th>
<th>Relevant milestone</th>
<th>Functional area</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>QSA-PD section</td>
<td></td>
<td>Total # of criteria</td>
<td>Maximum available points</td>
<td>Actual average team score</td>
<td>Comments</td>
<td>Typical working documents</td>
</tr>
<tr>
<td>I. Define product and process</td>
<td>250</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A. Establish/prioritize customer wants, needs, delights</td>
<td>10</td>
<td>Benchmarking studies</td>
<td>Customer focused reports</td>
<td>Inspection reports</td>
<td>Focus group reports</td>
<td>Kano/QFD studies</td>
</tr>
<tr>
<td>B. Derive customer-driven specifications</td>
<td>10</td>
<td>True quality characteristics</td>
<td>QFD</td>
<td>Historic quality database</td>
<td>Key life tests</td>
<td>Established targets</td>
</tr>
</tbody>
</table>

(Continued)
Table 16.18  A summary score sheet with some typical working documents. (Continued)

<table>
<thead>
<tr>
<th>II. Define product and process</th>
<th>500</th>
<th></th>
</tr>
</thead>
</table>
| A. Select product and process concept | 10 | Competitive benchmarking  
Review past/current technology  
Parameter attribute analysis/concepts matrix  
TRIZ studies  
Preliminary manufacturing feasibility |
| B. Concurrent product and process design | 14 | CAE/FEA reports  
Peer design reviews  
Craftsmanship guidelines  
DVP  
“Design for” studies  
Test for discovery  
VA/VE reports  
Manufacturing feasibility report  
Reliability target documentation  
GD&T study or example  
Analytical calculations  
Critical characteristics  
Poka Yoke techniques |
| C. Prevent failure modes and decrease variability | 4 | Functional block diagrams  
Fault tree analysis  
Process decision program chart  
Previous and or surrogate  
DFMEA/PFMA with cost and quality effect of actions  
DVP  
Analysis of historic failures  
Campaign prevent documents  
FMAs |
### Table 16.18  
A summary score sheet with some typical working documents.  
(Continued)

<table>
<thead>
<tr>
<th>Section Description</th>
<th>Score</th>
<th>Details</th>
</tr>
</thead>
</table>
| D. Optimize function in the presence of noise             | 6     | P-diagrams  
  Identify signal, noise and control factors  
  Identification of responses  
  Correlation analysis  
  DVP  
  Design of experiments  
  Control factor orthogonal array  
  Regression analysis  
  Confirmation experiments |
| E. Tolerance design                                        | 4     | Interrelationship diagrams  
  Tolerance design studies  
  Cause and effect diagrams  
  SC identification evidence  
  DOE results showing significant tolerances  
  Drawing showing SCs  
  Revised engineering specification  
  Percentage contribution to variation in function |
| F. Finalize product and process plans                     | 9     | Process control plan  
  Process sheets  
  Example of illustration sheets/job aids  
  Operator/skilled training plan  
  Process gage control plans  
  Maintenance procedures  
  Updated DFMEA/PFMEAs with mistake proofing  
  Repair/rework procedures |
| Design/verifcation | 7 | Updated DVP and reports  
| Test parts list  
| Engineering test plan  
| Dunnage, packaging, shipping report  
| Report on supplier readiness for build  
| Program risk assessment  
| Service procedures/ time studies  
| Prototype supplier list  
| Maching capacity and capability studies |
|---|---|---|
| III. Verify product and process | 100 | APQP documentation  
| Process capability data from PSW parts  
| PSW documentation  
| Work plan of suppliers visits  
| Validation test results  
| Degradation analysis  
| Updated PMT risk assessment  
| SC and CC capability  
| Launch readiness assessment |
| Design/manufacturing confirmation | 6 | Launch team member list  
| Launch team member skills matrix  
| Process decision program chart  
| Launch support plan  
| Concern reaction plan  
| Supplier capability confirmation  
| Continual improvement plan |
| Launch/mass production confirmation | 4 |
### Table 16.18  A summary score sheet with some typical working documents. (Continued)

<table>
<thead>
<tr>
<th>IV. Manage program</th>
<th>150</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Form a team</td>
<td>9</td>
<td>PMT meeting minutes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Team member roles and responsibilities</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PMT roster</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Skills matrix for team members</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Training plan matrix for team members</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Copy of program vision statement</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Team building activities</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Program organization chart</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Defined PMT goals</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Evidence of learning organizational tools and methods</td>
</tr>
<tr>
<td>Establish a program</td>
<td>4</td>
<td>Program information center location</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Web site address</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Verbal testimony of &quot;how to use&quot;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Evidence of use of prior lessons learned</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Roles and responsibilities list for updating knowledge base</td>
</tr>
<tr>
<td>Update corporate memory</td>
<td>2</td>
<td>Update engineering documents</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Update lessons learned database</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Global problem-solving results in corporate memory</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Robustness studies put into corporate data information base</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Update timing documentation as a result of team direction</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Update design handbook</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Generic FMEA templates updated</td>
</tr>
</tbody>
</table>

Total average score
REFERENCES

——— 2003. Design for Six Sigma (DFSS) and reliability. In In vehicle networks, safety critical systems, accelerated testing and reliability. SAE. Warrendale, PA. (Also, SAE paper 2003-01-1374.)
This chapter focuses on the concept of robustness as it relates to the FMEA. Specifically, we will address the issue of $P$-diagram, functional diagram, boundary diagram, interface diagram, and the characteristic matrix.

Robustness is the latest buzz word in the preparation of an FMEA. Its focus is on three things: (1) reduce development problems, (2) increase corporate image, and (3) increase customer satisfaction through reduction in warranty costs. To optimize these three items we must apply the robustness principle early in the design process in order to increase the design’s insensitivity to noise. How do we do that? By starting our analysis with a functional diagram, following it with the boundary diagram and interface diagram, and evaluating the ideal function through the $P$-diagram. Table 17.1 summarizes some of the key issues of what robustness is all about.

Table 17.1  Summary of robustness.
The rules for integrating robustness in any design are the following:

1. Concentrate on ideal function, and establish a way to measure it. Do not use symptoms of poor quality.

2. Identify sources of the five types of noises and expected magnitudes. (Remember Noise 5—internal environment.)

3. Concentrate on the effects of the noises; maybe one noise can be used to represent others.

4. Understand how error states and noise factors cross system interfaces and boundaries. Establish contracts with neighboring teams.

5. Develop a noise factor management strategy. Removing the noise might be easier than becoming robust to it. The laws of physics are strict.

6. Work out how to include remaining noise factors in all tests in the PVP.

7. Plan a robustness assessment of current design to compare against ideal performance.

8. Where robustness improvement strategy is obvious from knowledge of physics, do it!

9. Where robustness improvement is not obvious, plan parameter design studies to discover the improvement.

**Functional Diagram:** Generally, advanced development begins with the technical baseline for the system and proceeds through the translation of established system level requirements into detail qualitative and quantitative design requirements. This process is facilitated with what is known as the system functional analysis or simply functional analysis.

It takes its name from the fact that a function constitutes a specific or discrete action required to achieve a given objective. However, that objective must be met in relationship to the entire system at hand. Therefore, the functional approach helps to assure:

1. That all facets of system development, operation, and support are covered. This includes design, production/construction, test, deployment, transportation, training, operation, and maintenance.

2. That all elements of the system (prime equipment, test and support equipment, facilities, personnel, data, software, and so on) are fully recognized and defined.

3. That a means of relating equipment packaging concepts and support requirements to given functions is provided. This identifies
the relationship between the need and the resources required to support that need.

4. That the proper sequences and design relationships are established, along with critical design interfaces.

Functional analysis is a logical and systematic approach to system design and development. It constitutes the process of translating system operational and support requirements into specific qualitative and quantitative design requirements. This process is iterative, and is accomplished through the development of functional flow block diagrams.

Functional flow block diagrams are developed for the primary purpose of structuring system requirements into functional terms. They are developed to indicate basic system organization and to identify functional interfaces. Functional blocks are concerned with what is to be accomplished, versus the realization of how something should be done. It is relatively easy to evolve prematurely into equipment block diagrams without having first established functional requirements. The decision concerning which functions should be performed by a piece of equipment, or by an element of software, or by a human being, or by a combination of each, should not be made until the complete scope of functional requirements has been clearly defined. In other words, not one piece of equipment should be defined or acquired without first justifying its need through the functional requirements definition process.

The functional analysis (and the generation of functional flow diagrams) is intended to facilitate the design, development, and system definition process in a complete and logical manner. The functional analysis is based on the definition of system operational requirements and the system maintenance concept, and is subsequently used as the basis for detail design. There are a number of interrelated detail design tools which must track the top-level functional analysis (for example, operational and maintenance functional block diagrams). Some of the ultimate objectives are to (1) identify system/subsystem functions; (2) identify the method for accomplishing the various functions—manually, automatically, or a combination thereof; and (3) identify the resources required to accomplish the function. Both the operational and maintenance support aspects, as related to anticipated system life-cycle use in the consumer environment, must be addressed.

The translation of system operational and maintenance concepts into specific qualitative and quantitative design requirements commences with the identification of the major functions that the system is to perform, followed by the development of functional flow diagrams. Functional flow diagrams are employed as a mechanism for portraying system design requirements in a pictorial manner, illustrating series-parallel relationships, the hierarchy of system functions, and functional interfaces. Functional
flow diagrams are designated as top level, first level, second level, and so on. The top level shows gross operational functions. The first level and second level diagrams represent progressive expansions of the individual functions of the preceding level. Functional flow diagrams are prepared down to the level necessary to establish the needs (hardware, software, facilities, personnel, data) of the system. The indenture relationships of functions by level are shown as:

Need—System requirements
Top level functions—A, B, C
   Second level functions—A1, B1, C1
      Third level functions—A1a, B1b, C1c

It is very important for each functional diagram to contain a reference to its next higher functional diagram through the use of a reference block. For example, function A1 should be shown as a reference block in the case where the functions A1a... A1 and so on, are being used to expand function A1. Reference blocks should also be used to indicate interfacing functions as appropriate.

Furthermore, each function block on a functional diagram should be presented in a single box enclosed by a solid line. Blocks used for reference to other flows should be indicated as partially enclosed boxes labeled “Ref.” Each function may be as gross or detailed as required by the level of functional diagram.

**Boundary Diagrams:** (Block diagrams. The reader should notice that boundary and block diagrams are the same. The difference is that in the automotive industry the boundary diagram is preferred.)

Once the functional diagram is completed, the focus is on the scope of the FMEA. The scope is defined using a boundary diagram illustrating its subsystems/components. Furthermore, to insure that all sources of failure mode causes and effects are considered, it also illustrates elements outside the FMEA. In essence then the boundary diagram is a tool that qualifies and clarifies the relationships between systems.

Boundary diagrams are mandatory, breaking the FMEA into manageable levels. It does this by graphically illustrating the relationships between the subsystems, assemblies, subassemblies, and system components. When correctly constructed it provides detailed information to the interface matrix, P-diagram, and the FMEA. It is important to note that when completed or revised, the boundary diagram must be attached to the FMEA.

Although boundary diagrams can be constructed to any level of detail, it is important to identify the major elements, understand how they interact with each other, and how they may interact with outside systems. Furthermore,
early in the design program, a boundary diagram may be no more than a few blocks representing major functions and their interrelationships at the system level. Then, as the design matures, boundary diagrams may be revised, or additional ones developed to illustrate lower levels of detail, all the way down to the component level.

In both the concept and design FMEAs the scope is the boundary or extent of the analysis and defines what is included and excluded. Setting the correct boundaries prior to doing an FMEA analysis will focus the FMEA and avoid expanding the FMEA analysis into areas not being revised or created. This will prevent setting the incorrect scope, lengthening or missing the analysis, and establishing the wrong team membership. A typical boundary diagram is shown in Figure 17.1. The arrows indicate interaction, the boxes are the actual functions, and the dotted box indicates the boundary (scope) of the FMEA.

**Interface Diagram:** The interface matrix is a recommended robustness tool that acts as an input to design FMEA. The interface matrix identifies and quantifies the strength of system interactions. It is important to note that not addressing interactions at this point can lead to potential warranty and recall issues. Therefore, the interface matrix should always be used, especially on new designs. The interface matrix is also an input to the potential causes/mechanisms failure column of the DFMEA, the boundary diagram, and the $P$-diagram’s noise section. The interface matrix is also used to check the validity of the completed causes. When completed or revised, attach the interface matrix to the FMEA. A typical interface matrix

![Figure 17.1](image)

*Figure 17.1*  A typical boundary structure.
(see Figure 17.2, and Appendix I on the CD) identifies and quantifies the strength of system interactions by:

- Showing whether the relationship is necessary or adverse
- Identifying the four basic types of relationship (energy transfer, material exchange, information exchange, and physically touching)

The relationships are identified in a square format (Figure 17.2) with each corner of the square identifying via a numerical value the strength of the relationship, in terms of no relationship, positive or negative. In addition, every interaction, both positive and negative, should be verified. Then, negative values are analyzed for corrective action recommendations. Figure 17.2 identifies the matrix with A, B, C, and D as the main items to be evaluated. The a, b, c, and d in each of the square boxes address the relationship of the items in terms of the numerical strength for each of the four types. This evaluation is conducted by assigning numbers in each of the intersection boxes of the matrix in each corner. For example:

0 = no effect; 1 = interaction is beneficial, but not necessary for functionality

−1 = energy transfer which causes negative effects, but does not prevent functionality

+2 = there is a physical contact between systems and is necessary for function

−2 = interaction must be prevented to achieve functionality

<table>
<thead>
<tr>
<th></th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td></td>
<td>a b</td>
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<td></td>
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<td>B</td>
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<td></td>
<td>c d</td>
<td>c d</td>
<td>c d</td>
<td></td>
</tr>
</tbody>
</table>

**Figure 17.2** A typical interface matrix.
The numerical values may be project depended, however, make sure that there is enough discrimination between them to make the analysis worthwhile.

**P-Diagram:** *P*-diagram is a structured tool recommended to identify intended inputs (signals) and outputs (functions) for the subject under investigation. Once these inputs and outputs are identified for a specific function, error states are identified. After the error states are identified, the noise factors that could lead to the error states are listed (according to the five basic sources of noise):

- Piece to piece variation
- Changes in dimension over time or mileage (wear, fatigue, and so on)
- Customer usage
- External conditions of usage (road, climate, and so on)
- Internal conditions of usage (that is, system interactions)

Control factors are identified and means for the noise factor management settled to compensate for the noise factors as identified. Depending on the level of detail contained in the *P*-diagram, this information will input to various FMEA columns. When completed or revised, attach the *P*-diagram to the FMEA. The *P*-diagram (see Figure 17.3):

- Describes noise factors, control factors, ideal function, and error states
- Assists in the identification of:
  - Potential causes for failure (system interactions, piece to piece variation, external climatic and road conditions, and customer usage)
  - Failure modes (degradation)
  - Potential effects of failure (error states)

![Image](image-url)

**Figure 17.3** A typical P-diagram format.
– Current controls (control factors)
– Recommended actions (control factors)

A control factor is a list of the factors already incorporated in the design that tend to reduce the likelihood of the error states existing. Control factors are the means to make the items function more robust.

An error state can be classified into two categories:

1. Deviation of intended function (deviation of intended function is equal to potential failure modes in the FMEA. Degrees of potential failure modes are: no function, partial function (including degraded function over time), intermittent function, and over function).

2. Unintended system output.

Noise factors are unintended interfaces, or conditions and interactions that may lead to failure of the function.

Responses are ideal, intended functional output.

Signal factors are what the inputs, which trigger the function being analyzed.

Characteristic Matrix: This matrix is recommended as an aid in developing product-to-process and product-to-product linkage. When compiling this matrix, identify all of the process steps that can compromise the part characteristics identified in the DFMEA. That is: on the top identify all the functions (tasks) from the process flow diagram; and the vertical column identify all the product characteristics from the DFMEA. When completed or revised, attach the product characteristic matrix to the FMEA. A typical characteristic matrix is shown in Figure 17.4.

<table>
<thead>
<tr>
<th>Product characteristics</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>Legend (possible items of concern)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ST</td>
<td></td>
<td>A</td>
<td></td>
<td>X - Characteristic is created or changed</td>
</tr>
<tr>
<td>SS</td>
<td></td>
<td>X</td>
<td></td>
<td>C - Characteristic is used for clamping</td>
</tr>
<tr>
<td>YZ</td>
<td></td>
<td>A</td>
<td></td>
<td>L - Characteristic is used for locating</td>
</tr>
<tr>
<td>STS</td>
<td></td>
<td>X</td>
<td></td>
<td>T - Common tool creates more than one characteristic</td>
</tr>
<tr>
<td>TTT</td>
<td></td>
<td>X</td>
<td></td>
<td>M - Characteristic is automatically monitored</td>
</tr>
<tr>
<td>VU</td>
<td></td>
<td>X</td>
<td></td>
<td>A - One finished product characteristic has a strong effect on another</td>
</tr>
<tr>
<td>SVT</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figure 17.4 A typical characteristic matrix.
A part characteristic is a feature about the part, which when compromised, generates a failure mode. It may be a dimension, such as a hole’s inside diameter; or it may be a specification, such as material content or sulfur in a metal.

Any time a potential critical/significant failure is identified when doing a design FMEA, the failure mode must be reviewed to determine if any part characteristics, which if compromised, causes the failure mode. An effective way to do this is to go to the cause column on the FMEA form. Then, look at each cause and determine if there is an associated part characteristic, which when compromised, initiates the cause. Sometimes there may not be one. Other times there may only be one. However, on some occasions there may be more than one.

Once all of the failure mode’s associated part characteristics are identified, they must be summarized and communicated to the corresponding process FMEA team. These characteristics are then placed on a characteristic matrix, aligning them individually with each of the process steps where they can potentially be compromised. It is important to understand that any time one of these part characteristics is compromised, the associated design FMEA failure mode is reintroduced along with its effects. Therefore, the part characteristic is the link between the design and process FMEA. (The compromise may be justified on a cost-benefit analysis or any other quantifiable reason.)

**Linkages:** It is imperative for the reader to understand that in generating any FMEA there has to be inputs and outputs. These linkages, therefore, determine the inputs and the outputs as well as their interrelationships with the elements of the FMEA as they are identified in the discussion and or the form. In a sense, they are the process output that summarizes error states, noise factors and the associated design controls. It is also an input into the design verification plan. These linkages are summarized for concept, design, and process FMEAs, as follows:

**Design Concept Input**

- Corporate requirements
- Regulatory requirements
- Customer requirements
- Benchmarking techniques
- Historical performance information
• Product specific needs, wants and expectations (results of a QFD) ranked by customer’s importance
• Generic SDSs
• Pre-product/development targets for system performance
• SDSs for the system

Process Concept Input

• Customer requirements
• Regulatory requirements
• Historical performance information
• Benchmarking techniques

Design Concept Output

• Program target values or recommendations
• Recommendations for new generic testing now required DVP input
• Specific system/subsystem or component design specification (specific SDSs; GDT information; validation criteria, including engineering specifications, reliability targets, and robustness needs)

Process Concept Output

• Program target values or recommendations
• Recommendations for new generic testing now required DVP input

Design Input

• Concept FMEA → recommendations for new generic testing now required DVP input → DVS and methods and schedule
• P-diagram
• Boundary diagram
• Historical design performance
• Information including reliability
• Interface matrix
• Specific system/subsystem or component design specifications (specific SDSs; GDT information; validation criteria, including: engineering specifications, reliability targets, and robustness needs)

**Design Output**

• Potential criteria and or significant characteristics → prototype control plans
• Design information related to potential strategies
• Reliability and checklist
• New DVS
• Test methods or revisions based on FMEA analysis
• Other recommended actions for product robustness → target performance review and validation
• Other recommended actions for future products or programs → target performance review and validation

**Process Inputs**

• Design FMEA → potential critical and/or significant characteristics → prototype control plans
• Design FMEA → design information related to potential strategies
• Design FMEA → reliability and robustness checklist
• Design Concept FMEA → program target values or recommendations
• Process Concept FMEA → program target values or recommendations
• Process Concept FMEA → recommendation to new generic process controls
• Historical controls; control plan information
• Gaging information specified using GDT
• Problem solving and FMEA data
• Characteristic matrix
• Process flow and specification information
• P-diagram
• Engineering specification
• Historical manufacturing performance information

Process Output

• Safety sign-off
• Confirmed critical and significant characteristics → D and R sign-off and pre-launch control plans
• Pre-launch Control plans → production control plans → D and R sign-off
• Recommended manufacturing actions for product robustness
• Other recommended actions for future products or programs

Machinery Output

• Operator safety sign-off
• Production control plan
• Design information related to potential strategies
• New design/equipment methods or revisions based on FMEA analysis
• Other recommended actions for equipment specifications → target performance review and validation
• Other recommended actions for future equipment → target performance review and validation

REFERENCES


An Overview of Some Typical Tools Used in FMEA

This chapter provides the reader with a quick reference of some typical and most often used tools in the problem-solving process and especially in the FMEA. The most basic of all problem-solving methodologies we believe is the eight-stage process, which of course is a derivative of the scientific approach. The individual stages are:

1. Identify 5. Implement
2. Scope 6. Evaluate
3. Define 7. Follow-up
4. Analyze 8. Continually improve

**TOOLS/METHODOLOGIES**

**Affinity Diagram.** A number of small cards (1" X 3") each inscribed with an idea or solution. The affinity diagram is based on brainstorming and a cause-and-effect diagram.

*What it does:* Tool that is useful when (1) facts/thoughts are in chaos, (2) a breakthrough in traditional concepts is needed, (3) support for justifying a proposed implementation is needed.

*When to use it:* Stage 1: Identify
Stage 3: Define
Stage 4: Analyze
**Box and Whisker Plot.** Alternative to a histogram. Has appearance of a rectangle (the box) with a horizontal and a vertical line passing through its center and extending outside the box (the whisker).

*What it does:* Displays the main features of a data set and permits simple comparisons of several data sets.

*When to use it:* Stage 4: Analyze  
Stage 5: Implement  
Stage 6: Evaluate

**Brainstorming.** An idea-generating technique that relies on team participation and interaction. All ideas are noted before any less practical ones are discarded.

*What it does:* Enables a team to create as many ideas as possible in as short a time as possible.

*When to use it:* Stage 1: Identify  
Stage 5: Implement

**Cause-and-Effect Diagram.** Simple means for finding the causes of an effect (problem) by an individual or a team. Also known as the fishbone diagram because of its shape.

*What it does:* Graphically shows the relationship of causes and sub-causes to an identified effect. Helps reveal potential root causes.

*When to use it:* Stage 4: Analyze  
Stage 6: Evaluate

**Computer Simulation.** Computer-based technique probably requiring the assistance of operations research to prepare the programs.

*What it does:* A pictorial representation of an area layout showing the movement of items within that area. A means of solving what-if questions and examining the effects of various related data over long- and short-term periods.

*When to use it:* Stage 4: Analyze  
Stage 6: Evaluate  
Stage 7: Follow-up  
Stage 8: Continually improve

**Control Chart—c.** Standard control chart for the total number of nonconformities, based on a constant sample size.

*What it does:* Graphically displays stability of process. (For example, total number of errors in a batch of 100 forms rather than just the number of faulty forms.)

*When to use it:* Stage 4: Analyze  
Stage 5: Implement  
Stage 6: Evaluate
**Control Chart—Median and R.** Standard chart that is an alternative to the $X$-bar and $R$ chart for the control of processes. It is less sensitive to trends, however, and under some circumstances is considered to be more difficult to construct.

*What it does:* Graphically displays stability of a process. Yields similar information to $X$-bar and $R$ charts, but has several advantages: (1) easier to use—daily calculations are not required; (2) individual values and medians are plotted, median chart shows spread of process output and gives an ongoing view of process variation; (3) shows where nonconformities are scattered through a more or less continuous flow of a function; (4) shows where nonconformities from different areas may be evident.

*When to use it:* Stage 4: Analyze
Stage 5: Implement
Stage 6: Evaluate

**Control Chart—np.** Standard control chart similar to the $c$ chart, but must be used if the sample sizes vary.

*What it does:* Graphically displays stability of process. Measures actual number of nonconforming items rather than total number of faults. (For example, total number of faulty forms in a batch irrespective of faults in any one form.)

*When to use it:* Stage 4: Analyze
Stage 5: Implement
Stage 6: Evaluate

**Control Chart—p.** Standard control chart requiring a constant sample size. Charts either conforming or nonconforming items.

*What it does:* Graphically displays stability of process. Measures actual number of conforming and nonconforming items rather than total number of faults. Expresses numbers in either fractional or percentile terms (whether conforming or nonconforming items are used) of total sample. (For example, total number of faulty forms in a batch irrespective of number of faults in any one form.)

*When to use it:* Stage 4: Analyze
Stage 5: Implement
Stage 6: Evaluate

**Control Chart—u.** Standard control chart that is similar to the $c$ chart, but must be used if the sample sizes vary.

*What it does:* Graphically displays stability of process. (For example, total number of errors in a batch of 100 forms rather than just the number of faulty forms.)
When to use it: Stage 4: Analyze  
Stage 5: Implement  
Stage 6: Evaluate

Control Chart X-bar and R. Standard control chart; the most used chart. Requires a number of consecutive units be taken \( n \) times per work period and analyzed for specific criteria.

What it does: Graphically displays process stability. Shows data in terms of spread (piece-to-piece variability) and its location (process average). \( X \)-bar covers averages of values in small subgroups (sample taken); known as measure of location. \( R \) chart deals with range of values within each sample (highest minus lowest); known as measure of spread.

When to use it: Stage 4: Analyze  
Stage 5: Implement  
Stage 6: Evaluate

Control Chart X-bar and S. Standard control chart similar to \( X \)-bar and \( R \) chart, however the \( S \) part of chart considers standard deviation and is more complicated to calculate.

What it does: Graphically displays stability of process \( S \) factor; is more accurate indicator of process variability—especially with larger sample sizes. This chart is less sensitive in detecting special causes of variation that produce only one value in a subgroup as unusual.

When to use it: Stage 4: Analyze  
Stage 5: Implement  
Stage 6: Evaluate

Cross-functional Process Map. Shown as a series of columns representing departments across which the flow of a process is mapped.

What it does: Allows a map of the process to be shown, its order of precedence, and which departments it is routed through.

When to use it: Stage 4: Analyze  
Stage 5: Implement  
Stage 6: Evaluate

Design of Experiments (DOE). Several methods available of which the following are examples: (1) Taguchi method, including \( S/N \) ratios, (2) accelerated testing methods, (3) factorial and fractional factorial designs.

What it does: Factors common cause variation into its components in order to optimize process/product variables and reduce variation.

When to use it: Stage 3: Define  
Stage 4: Analyze  
Stage 5: Implement  
Stage 6: Evaluate
**Dot Plots.** A display somewhat similar to a histogram, but the axis is divided into many more divisions.

*What it does:* Usually used when there are insufficient criteria to construct a histogram or a box and whisker plot. Used for comparison purposes.

*When to use it:* Stage 4: Analyze  
Stage 5: Implement  
Stage 6: Evaluate  
Stage 7: Follow-up

**Failure Mode and Effect Analysis (FMEA).** A what-if approach to evaluating design weaknesses that starts at the component level and proceeds through the complete system.

*What it does:* Bottom-up approach that identifies potential product/process weaknesses. Begins with study of known failure modes for each component of product or process. By using physical analysis or mathematical models, a determination is made of the effect of failure on a component, subsystem, or complete system.

*When to use it:* Stage 3: Define  
Stage 4: Analyze  
Stage 6: Evaluate  
Stage 7: Follow-up  
Stage 8: Continually improve

**Fault-tree Analysis.** Graphical display similar to the shape of a tree.

*What it does:* Begins with the definition of an undesirable event and traces that event through the system to identify basic causes—a top-down appraisal.

*When to use it:* Stage 3: Define  
Stage 4: Analyze  
Stage 6: Evaluate  
Stage 7: Follow-up  
Stage 8: Continually improve

**Gauge Repeatability and Reproducibility (Gauge R and R).** A measurement of the repeatability and reproducibility of a gauge and the operator, respectively.

*What it does:* Measures variations in gauges and test equipment to ascertain: (1) bias in accuracy due to improper calibration, (2) variation in precision due to operation of the device, (3) variation in reproducibility when different people use the equipment, (4) variations in stability due to changes in environment, power fluctuations, and so on.

*When to use it:* Stage 4: Analyze
Graphs—Bar Charts. An X-Y type of graph that uses narrow rectangular bars to signify frequencies of occurrence.

*What it does:* Compares discrete data from a number of sources (for example, absenteeism on specific days in several offices).

*When to use it:* Stage 4: Analyze
Stage 6: Evaluate

Graphs—Gantt Charts. An X-Y type of graph that uses narrow rectangles or lines, usually parallel to the X axis, to represent periods of time on a specific task or tasks.

*What it does:* Displays, to scale, time to perform a unit of work that occurs at a given point in the process. Allows a comparison of its position in the process with other units of work and how they relate. Useful tool to use with a process flowchart to highlight and quantify information in both pre- and post-investigation situations.

*When to use it:* Stage 4: Analyze
Stage 6: Evaluate
Stage 7: Follow-up

Graphs—Pie Charts. Circle divided into sectors, each of which represents a factor and its area is a proportion of the whole-expressed as a percentage.

*What it does:* Shows all the criteria involved in a process/survey and individual percentages of the total. Area of the circle can be used to demonstrate a change/compare circumstances (for example, a chart showing car market by year and a specific company’s share of that market).

*When to use it:* Stage 4: Analyze
Stage 6: Evaluate

Histogram. An X-Y graph that uses narrow rectangles to display frequencies of occurrence of a specific set of data.

*What it does:* Gives a picture of the frequency of occurrence for a range of specific data and demonstrates its normalcy or lack of it. In other words, if the center point of the top of each column of recorded frequencies were joined by a continuous line (normal distribution curve), the shape produced would be that of a bell, more or less distributed around the median (central point).

*When to use it:* Stage 4: Analyze
Stage 6: Evaluate
Stage 7: Follow-up
**Operational Definitions.** Terms necessary for the common understanding of a process.

*What it does:* Contains three elements: (1) a set of criteria; (2) a test by which criteria are applied; (3) a yes/no result from the test. The result must be accepted by all who use it.

*When to use it:* Stage 1: Identify
Stage 2: Scope
Stage 3: Define
Stage 4: Analyze
Stage 5: Implement
Stage 6: Evaluate
Stage 7: Follow-up
Stage 8: Continually improve

**Pareto Diagrams.** X-Y bar chart with the bars prioritized in descending order (from left to right) and distinguished by a cumulative percentage line. It is based on the 80/20 rule which states that about 80 percent of improvement in an effect can be achieved by acting on 20 percent of the causes.

*What it does:* The prioritization of the inputs (causes) indicates those that should be considered first (in other words, those on the left of the chart).

*When to use it:* Stage 1: Identify
Stage 4: Analyze
Stage 6: Evaluate
Stage 8: Continually improve

**Program Evaluation and Review Technique (PERT) or Critical Path Analysis.** Road map of interdependent elements within a process and containing criteria indicating critical routes through the elements.

*What it does:* Illustrates elements within a process and indicates earliest and latest event timing against each element. Clarifies order of sequential priority within process and allows a critical path through the process to be identified.

*When to use it:* Stage 4: Analyze
Stage 6: Evaluate
Stage 7: Follow-up

**Process Flow Chart.** A road map of the process from supplier(s) to customer(s).

*What it does:* Illustrates/clarifies events in a process and the events between them. Assists in highlighting: (1) present situation, (2) differences between what should/is thought to be happening and actual situation, (3) proposed situation, and (4) potential problem areas (gaps, and so on).

*When to use it:* Stage 1: Identify
Stage 2: Scope
Stage 3: Define  
Stage 4: Analyze  
Stage 6: Evaluate

Program Decision Process Chart (PDPC). A tree-type chart.  

*What it does:* Maps conceivable events/contingencies that occur when moving from problem to statement to possible solutions. Used to plan possible chains of events that need to occur when problem/goal is unfamiliar.  

*When to use it:* Stage 4: Analyze  
Stage 6: Evaluate

Pugh Technique. A chart that shows alternatives on the X axis and base criteria on the Y axis.  

*What it does:* Technique that allows comparisons between current concept/design, criteria required, and a number of alternative solutions. Each alternative is compared with current situation, requirement by requirement, and summarized in form of total +/- points, which indicate the alternative to use.  

*When to use it:* Stage 4: Analyze  
Stage 6: Evaluate

Quality Function Deployment (QFD). An array which enables a comparison of customer requirements against a number of design elements. Also allows areas of conflict to be plotted.  

*What it does:* Broad management system that assists in translating the voice of the customer into operational definitions that can be used to produce and deliver product/service desired by the customer. Highlights conflicting customer requirements so they can be reconciled in an optimum manner.  

*When to use it:* Stage 1: Identify  
Stage 2: Scope  
Stage 3: Define  
Stage 4: Analyze  
Stage 5: Implement  
Stage 6: Evaluate  
Stage 7: Follow-up  
Stage 8: Continually improve

Regression Analysis. A procedure for fitting a mathematical model (expressed in terms of equations with variables and coefficients; for example, \( y = Mx + b \)) to a set of data.  

*What it does:* Used to explore factors in a given set of data (for example, barometric and humidity effects on production of CO production from combustion). Also used in instrument calibration, design, and process analysis.
When to use it: Stage 3: Define
Stage 4: Analyze
Stage 6: Evaluate

Reliability Analysis. A series of statistical formulae, tables, and graphs based on probability.

What it does: Broad area of study that is concerned with random occurrences of undesirable events/failures, during the life of a physical system.

When to use it: Stage 4: Analyze
Stage 6: Evaluate

Run Charts. An X-Y type of graph that compares a measurement (%, $, and so on) on the Y axis with time or sequence (days, order, and so on) on the X axis.

What it does: Used to monitor a process to assess whether or not the long-range average is changing. If it is changing is it improving or deteriorating?

When to use it: Stage 4: Analyze
Stage 5: Implement
Stage 6: Evaluate
Stage 7: Follow-up

Scatter Diagrams. An X-Y graph that examines the possibility of a relationship between two variables.

What it does: Checks for possible cause-and-effect relationships. Cannot prove one variable causes another, but makes clear whether or not a relationship exists and strength of relationship.

When to use it: Stage 4: Analyze
Stage 6: Evaluate

Shared and Interlocking Objectives Matrix. Chart that lists various departments on both the X and Y axis.

What it does: Enables department heads to specify their requirements from each of the other departments in order to achieve a certain goal (in other words, each customer can specify his or her requirements from each supplier).

When to use it: Stage 2: Scope

Stem and Leaf Plots. A vertical line with data to the left of the line being known as the stem and individual criteria as stem ends. Criteria to right of line is known as the leaf. An alternative to the histogram.

What it does: Quicker to produce than histograms and allows data used to be viewed in traditional column format.

When to use it: Stage 4: Analyze
Stage 6: Evaluate
Surveys. Investigative questioning technique.

*What it does:* Through a programmed questioning of supplier and customer a picture is formed of: (1) problems encountered, (2) customer desires, and (3) shape of the process, and so on.

*When to use it:* Stage 1: Identify  
Stage 2: Scope  
Stage 7: Follow-up  
Stage 8: Continually improve

**Time Series Forecasting.** Series of statistical formulae, tables, and graphs.

*What it does:* Broad area of study that takes data measured at discrete, equispaced time intervals. Constructs mathematical models for forecasting over a given period of time (lead time).

*When to use it:* Stage 4: Analyze  
Stage 6: Evaluate  
Stage 7: Follow-up  
Stage 8: Continually improve

**FORECASTING RULES OF THUMB**

In any FMEA the practitioner will be asked—sooner or later—to project old or current data to the future. When that happens forecasting occurs. Forecasting, even though it is not an exact science it can come very close to the expected outcome of your expectation if one knows the rules and obeys them. This section will attempt to summarize some of these generic rules. As such, here are a number of *dos* and *don’ts* which practitioners generally agree should be considered while forecasting:

1. **Avoid Falling Victim to the Law of the Instrument**

   - The Law of the Instrument states: “Give a small boy a hammer and everything he encounters needs pounding.” Some forecasters seem to suffer from familiarity of a specialized forecasting technique and seem to use it on every occasion. However, there is no such thing as the ideal method. The *right* forecasting technique depends on a number of conditions.
   - Purpose of market potential? Sales forecast?
   - What is the forecasting horizon?
• What is the accuracy required? The acceptable range of the forecast? Does it have to be exact because the firm has to make a number of costly, fixed decisions based on the forecast? Or, does the firm have a number of outs should the forecast be in error?

• How much time is there to do the forecast? Is there time for a survey of buyers’ intentions? Or, will the company have to settle for secondary data that’s readily available?

• What about the personnel doing the survey? What is their level of expertise and how much time do they have to spend on the forecast?

• What kind of budget is the company working with? Can it hire, for example, outside experts?

• What kind of data is available? In some industries there are a number of syndicated services available. Take the housing industry, for example: here regression analysis is a possibility. In other industries, especially new industries, there may be little historical data. Here qualitative techniques may be the only ones which can be used. On the other hand, in some industries, especially for product development, both qualitative and quantitative methodologies are common.

• What are management’s inclinations? Do they want a highly scientific forecast? If so, and if other conditions are right, the company may wish to subscribe to the syndicated services of a firm such as Data Resources Institute. Or hire them to make an *econometric* forecast. Or do regression analysis. On the other hand, if management is suspicious of such techniques, it may wish to use more simple techniques such as trend line analysis and sales force composite.

The techniques any particular company uses will depend upon whether it is in industrial or consumer marketing. There are differences: (1) Industrial markets are usually highly concentrated geographically (only a few customers make up the bulk of the demand) and their purchases are planned. For these reasons, a survey of buyers’ intentions tends to be more feasible than for the consumer market. (2) Since industrial demand is a derived demand, it’s more volatile than consumer demand. Because of this, industrial forecasting is more concerned with general economic and business conditions. (3) Group buying is more prevalent in industrial than in consumer markets. (4) Industrial market forecasts are mainly concerned with market size and potential estimation. Unlike consumer marketing, there is
little attention given to psychological market segmentation. (5) The industrial marketing manager has less money and time to spend on each product category. Thus he or she usually does not use consultants and has to rely more heavily upon secondary data, executive opinion, and sales force composite.

**Use Multi-methods**

Max Gunther made a study of lucky people. He reported his findings in *The Luck Factor*. One of his findings was that lucky people seemed to base their actions on forecasts derived from both hard and soft data (Corollary 2 of *The Hunching Skill*—collect soft facts along with the hard). In forecasting, it’s a good idea to follow Gunther’s Corollary 2. Use a collage of techniques, some quantitative and some qualitative. This approach helps the forecast to stand the test of common sense. Too often forecasters get so enamored with a technique that they accept the results without question. This danger is perhaps especially prevalent when using esoteric quantitative techniques. (In manufacturing this is very dangerous. When one evaluates the process controls for the failures. We do have a tendency to repeat past control even though they may have worked marginally or not at all, just because we have become comfortable.)

One of the techniques one should always use—even though the results may not be incorporated in its findings—is a trend line. Do this because others in the company will always make a forecast from the trend line (even though it may be a very crude trend line). If the forecast should deviate from the trend line, make sure that it is known by how much and the reason why. Then too, following this approach also helps the forecast stand the test of common sense. For example, one manager had this to say about a process engineer who had been hired, “He (the engineer) came up with a very precise forecast using regression analysis. The forecast was considerably different from the industry trend. His explanation of why the forecasts differed was very weak. I asked him if he had drawn a trend line, and he replied that he hadn’t.” The engineer is no longer working for this company.

**2. Be Wary of Transition Periods**

There are certain stages of the product/service life cycle curve when forecasting is most difficult. When the product/service is changing from one stage to another (that is, from introduction to growth) or when it is undergoing rapid growth or decline and/or when structural changes are taking place. If statistical techniques are used during these periods, make sure that the coefficients/formulae are adjusted with qualitative judgments.
3. Search for Causal Relationships

There is the story about a person lying down with his ear pressed to the ground. A cowboy rode up, saw the person and asked, “What is it?” The person replied, “Half hour from here. Wagon. Four wheels. Pulled by two horses. One beige. One roan. Driven by man in black suit. Black hat. Person riding next—” The cowboy cut him off. “Why that’s tremendous. To be able to hear all that.” The person replied, “Not hear—see. Wagon run over me one-half hour ago!”

Sometimes things aren’t what they seem. One should make sure to understand the correct causal relationships; if it hasn’t been done already, put together a demand formula (transformation function; multiple regression) for the specific product and or process (sometimes even for the industry). The company may not have all the data necessary to run the formulae, but the mere attempt of formulation will help to better understand the causal relationships within the company or even the industry.

4. Consider Potential Competitive Actions

Rudyard Kipling describes perhaps a typical battle between a mongoose and a cobra. The two are almost equally matched: the mongoose with its lightening speed and the cobra with its deadly, swift strike. Yet the mongoose almost invariably wins because of its competitive strategy.

The two meet—the mongoose feints an attack. The cobra strikes, fully extending itself. And thus begins the dance of death. But the mongoose, perhaps smarter, has a strategy. After each successive feint attack, the mongoose shortens its feint. The cobra however, continues to fully extend itself trying to bite the mongoose. Soon, however, the mongoose’s feint attack is nothing more than a movement of the head; the cobra’s strike however, leaves the cobra fully extended. While the cobra is thus extended and its mobility is greatly reduced, the mongoose attacks, crushing the cobra’s head with its jaws.

Too many forecasts just do not take into account potential competitive actions. Such forecasts usually are based on the assumption that competitors will be benign—they will continue to do the same thing that they have been doing in the past. Short shrift is given to the prospect that competitors may design their product better, come out with new models, improve their productivity in an effort to increase their market share, lower price, and perhaps by so doing, increase the industry’s price sensitivity. Always ask, “Have I considered how industry conditions, and subsequently, industry demand might be changed by competitive actions?” (Here be very careful of benchmarking studies. Many companies try to emulate their competitors—not the
best in class—assuming that their improvement will be good enough for the market. What they fail to recognize is that the benchmarking company is moving as well.

5. Get Management Involvement

The market forecast is the basis for all company activity. Consequently, management must believe in the forecast if it is to be used. Forecasts will always be questionable because of different motives of management personnel. For example:

- Manufacturing tends to want a narrow product line and long production runs to keep production costs low. It also tends to want to keep raw materials inventory at maximum; it doesn’t want to run out of materials which would, later on, cause overtime. On the other hand, it wants to keep finished goods inventory at a minimum to keep down inventory carrying costs.

- Marketing tends to want a large variety of products to provide choice to customers, and wants a large finished goods inventory so it can provide quick delivery.

- Finance tends to want to keep all inventories at a minimum in order to reduce cash requirements.

The forecast will be especially suspect if it is not surprise free. That is, if it differs from what management expects to happen—conventional wisdom. Forecast believability will be highly questionable if the forecast differs from the past trend or the firm is operating in a high change environment where structural stability is under stress. Thus, the less the forecast is surprise free, the greater the need for involvement. If management is to be convinced of the plausibility of the forecast, they should be involved at the outset of the forecasting process rather than at its conclusion. Precisely because management has been involved at the outset, there tends to be less difficulty in selling the final forecast.

One staff executive, in setting up long-range forecasting methodology for his company, visited a number of firms. Of one company’s procedure he said, “I was convinced that their process was likely to end up in failure because of the way the planning department allocated its time. They spend 80 percent developing their scenarios and 20 percent involving and influencing top management. I thought this was the wrong mix. It should be the other way around.” He went on to say that this company had difficulties in trying to gain acceptance of its forecasts after the fact. In his words, “That’s the wrong time to do it. You should be trying to gain acceptance as you go
along. In fact, my principle, is, ‘let the people who will be using them have some level of feeling that they developed them.’"

When in close and constant communication with top management, it can be effective to get top management’s input informally. For instance, in an industrial and farm equipment manufacturer the informal approach works well, because, as explained by one manager of planning, “The lines of communication in our company are very short. The total corporate staff are all located within 100 feet of each other. It’s very easy for people to communicate and share. The officers of the company are very accessible to people doing this kind of work. Typically, getting inputs is informal, as opposed to, ‘Here’s a questionnaire we want you to fill out’.”

For many firms, however, formal meetings seem to be a better way of getting top management’s input. Even firms that prefer the informal approach may find meetings necessary when there is a wide divergence of opinion among top management. In some companies, all it will take to provoke discussion is a brief, initial discussion, perhaps an industry forecast by an outside expert.

Of course, there are costs in managerial involvement. First, it’s time consuming. So make sure that the procedure used for involving management is considered productive. Then, make sure that management is informed of general economic and industry trends prior to direct involvement. This can be done by sending short, timely, condensed economic and industry bulletins. Remember, a group of uninformed executives assisting in developing the forecast will not improve its quality. The Law of Two Head Fallacy states, “Two heads are only better than one if the probability is better than chance that both heads would arrive at the correct decision independently.”

6. Avoid the Dowser-rod Syndrome

Some people claim that people who witch for water are using the dowser rod as an excuse for drilling a well in a location where they would like the well to be. In forecasting, make sure that you do not arrive at a forecast which will give an excuse for pursuing a course of action already chosen. Make sure that the forecast is more than a methodological excuse. Avoid wishful thinking coloring the forecast.

We do not see the world as it actually exists, but rather we see a distorted picture of that world. Our minds discard much that reaches them through an unconscious process of selective perception. Studies have shown that a person tends to selectively perceive (intake) the environment that supports her or his beliefs. On the other hand, a person tends to selectively perceive the environment in order to keep her or his beliefs secure from attack. We all are suspect
to selective perception. We tend to avoid conflicting data, especially if we have attitudes that are strongly centrally held—the nucleus of values and beliefs; related to our view of ourselves relative to others; and/or associated with deeply-seated needs. The intensity of our selective perception will vary with the degree to which these values are felt to be insecure or under attack.

A way to minimize selective perception is to consciously gather information which does not conform to present beliefs. In the forecast section of the plan, have a sheet of paper titled “Disquieting Information.” Here record those concepts and ideas about future market conditions that do not conform to commonly held beliefs. Study them carefully. Refer back to them on occasion. This may well lead to revising the forecast.

7. Be Careful of Intuition

Be careful of intuition, especially in areas about which little is known. Occasionally one may run into a person who has a sixth sense—able to predict what is going to happen just by sixth sense. But one will only find these people rarely. The last person I heard of who could do this was, unfortunately, crucified over 2,000 years ago. More common is the type of situation where a person knows an industry so thoroughly that he or she develops what they think is an intuitive sense. But what he does is subconscious, he draws trend lines and adjusts them for seasonal and competitive behavior, and the like. Many times this is quite accurate. But then, the so-called intuitive forecasting can get one into trouble—especially where a person believes they have a sixth sense, but actually has been good at forecasting because of his or her intimate knowledge of a particular type of business. When someone believes they have a sixth sense and starts shooting from the hip, trouble may ensue.

A very successful travel agent had established his business from scratch. He was proud of his accomplishment, and rightfully so. While basking in his success, a client offered him a real deal. The client had planned to set up a retail shop selling African art, jewelry, floor coverings (zebra skins), and the like, but the client’s partner backed out at the last minute. The client, however, offered to sell the travel agent this inventory at a considerable bargain. The travel agent, believing his retailing experience to be universal, snapped up the deal. He found a location. Two months later he opened the store. Then, two months later, the store was closed, a dismal failure.

But one might say, “Of course that would happen to a small businessperson, but in a large corporation you have checks and balances.” Well, let’s see. A number of years ago a director of marketing of a billion-dollar bank hired a consultant to do a market research study to see if there was any
future for a medical/dental billing service the bank was offering. It seems that they had been offering this service for over four years. Projections were that it would take over 800 accounts for the bank to break even. Currently they had 14 accounts on line. Was the low (nil) market penetration due to poor marketing or was the service itself not a viable product? A quick market survey revealed that the service was not one wanted by the medical profession. So the question is: How did the bank happen to offer this service? It seems that an executive vice president (who had been most successful in commercial lending) was sitting in a dental chair one morning and the idea came to him. After the appointment he rushed to his bank to explain this great idea. “And one doesn’t question his ideas,” the director of marketing lamely added.

But you might say that such an error in judgment might happen with a product/service line, but it wouldn’t happen with major investments, such as acquisitions or in product development in an automotive corporation. Don’t be too sure.

The CEO of one company related this incident. His firm—which he had started in a booth of a restaurant—had been extremely successful. Its sales had reached over $75 million, with practically no debt and profits exceeding 10 percent after tax. He, along with his management team, decided they should diversify. Within two years, the firm was almost bankrupt. As one might expect, this caused the CEO to do a lot of soul searching. He explained that he realized where they had made their mistake. Because they had been so successful in their basic business, they believed the reason for their success was because they were just good managers and that they could manage anything. “But,” as he explained, “that was not the reason for our success. We had grown up in our industry. We knew it inside and out. We were continually making adjustments, subconsciously, for competition, buyer demands, production capabilities, inventory levels, and the like. Although those actions were never formalized—put in writing—they were based on a keen sense of the industry. And our beliefs were changing with the industry. However, when we moved into different industries, we had no background. It was as if we understood German IV and now we had moved into Chinese IV without having taken Chinese, I, II and III.”

Be careful of intuition.

8. Seek Out (But Scrutinize) Secondary Data

Much has been written. Unfortunately, it’s hard to find. Although there are a number of sources, here are some of the major ones that shouldn’t be overlooked:
• Industry association. It may be that the trade association has a library. Why not keep in constant contact with the librarian? Or if it doesn’t (and this is probably a good idea even if it does have a librarian), make sure to be on good terms with the executive vice president of the association and that he or she knows the type of information that is being sought. In manufacturing, especially, make sure to utilize the corporate knowledge including, warranty information.

• Libraries. Get to know several librarians.

• Syndicated data sources, such as Mead Data Control. Spend noon hours talking with reps.

• Make sure, however, to check the authenticity of the secondary data. First, what is the timeliness of the data? Then, what was the character of the known agency that wrote the article/conducted the research? Did they have a vested interest in the point of view that they were trying to make?

Then, if the data were based on a survey, examine these three levels:

• Level 1: Was it the right universe?

• Level 2: Was the sample representative of that universe?

• Level 3: What about the survey instrument and execution itself? Did they seem appropriate? Or were they likely to create bias?

9. Watch Out for Target Fixation

Sometimes one gets so involved in trying to find a certain bit of information on a particular customer and or product or service that they spend a disproportionate amount of time in the search. One of the dangers of low-level fighter strafing is that pilots tend to become so involved in destroying a truck, tank, and so on that they lose their senses of closure. “That truck, I’ve hit it a number of times. Why doesn’t it blow up? Just a few more cannon bursts and I’ll have him...” And so on. But unfortunately, the pilot gets so wrapped up that he gets too close to the ground. By the time he comes to his senses...

Avoid target fixation by planning and budgeting the forecasting process. This is just common, managerial sense. But a short review won’t hurt. Understand (or determine):

• The accuracy required. What is the magnitude of the decision resting on this forecast?
• What is the acceptable range of the forecast accuracy in terms of dollars and/or units?

• When must the forecast be completed?

• What kind of budget is there to work with in terms of personnel time and money?

Then, lay out the steps that will have to be completed in order to finish the forecast. Why not use an arrow diagram to help organize your thinking? On each activity specify the time and resources required. This will help avoid spending excessive time on non-critical areas.

When you’re having someone else do the forecast, make sure that he or she knows, in specific terms, what to accomplish (see above). Avoid such loose terms as determine potential. Rather, let him or her know the accuracy required, how his or her tasks fits into the forecasting process, and what actions will be taken as a result of the forecast. It might not be a bad idea to also have him or her lay out their planned procedure on an arrow diagram.

10. Don’t Wait for All the Facts

Here’s an excerpt from Lee Iacocca’s book, Iacocca (New York: Bantam Books, 1984, pp. 50–52). Although he’s referring specifically to decision making, the general theme applies to putting the forecast to bed. “If I had to sum up in one word the qualities that make a good manager, I’d say that it all comes down to decisiveness. You can use the fanciest computers in the world and you can gather all the charts and numbers, but in the end you have to bring all your information together, set up a timetable, and act.

“And I don’t mean act rashly. In the press, I’m sometimes described as a flamboyant leader and a hip-shooter, a kind of fly-by-the-seat-of-the-pants operator. I may occasionally give that impression, but if that image were really true, I could never have been successful in this business.

“Actually, my management style has always been pretty conservative. Whenever I’ve taken risks, it’s been after satisfying myself that the research and the market studies supported my instincts. I may act on my intuition—but only if my hunches are supported by the facts.

“Too many managers let themselves get weighted down in their decision making, especially those with too much education. I once said to Philip Caldwell, who became the top man at Ford after I left: “The trouble with you, Phil, is that you went to Harvard, where they taught you not to take any action until you’ve got all the facts. You’ve got ninety-five percent of them, but it’s going to take you another six months to get that last five percent. And by the time you do, your facts will be out of date because the market has moved on you. That’s what life is all about—timing.”
“A good business leader can’t operate that way. It’s perfectly natural to want all the facts and to hold out for the research that guarantees a particular program will work. After all, if you’re about to spend $300 million on a new product, you want to be absolutely sure you’re on the right track.

“That’s fine in theory, but real life just doesn’t work that way. Obviously, you’re responsible for gathering as many relevant facts and projections as you possibly can. But at some point you’ve got to take that leap of faith. First, because even the right decision is wrong if it’s made too late.

“Second, because in most cases there’s no such thing as certainty. There are times when even the best manager is like the little boy with the big dog waiting to see where the dog wants to go so he can take him there.

“What constitutes enough information for the decision-maker? It’s impossible to put a number on it, but clearly when you move ahead with only 50 percent of the facts, the odds are stacked against you. If that’s the case, you had better be very lucky—or else come up with some terrific hunches. There are times when that kind of gamble is called for, but it’s certainly no way to run a railroad. At the same time, you’ll never know 100 percent of what you need. Like many industries these days, the car business is constantly changing. For us in Detroit, the great challenge is always to figure out what’s going to appeal to customers three years down the road, I’m writing these words in 1984, and we’re already planning our models for 1987 and 1988. Somehow I have to try to predict what’s going to sell three and four years from now, even though I can’t say with any certainty what the public will want next month.

“When you don’t have all the facts, you sometimes have to draw on your experience. Whenever I read in a newspaper that Lee Iacocca likes to shoot from the hip, I say to myself: ‘Well, maybe he’s been shooting for so long that by this time he has a pretty good idea of how to hit the target.’

“To a certain extent, I’ve always operated by gut feeling. I like to be in the trenches. I was never one of those guys who could just sit around and strategize endlessly.

“But there’s a new breed of businessmen, mostly people with M.B.A.s, who are wary of intuitive decisions. In part, they’re right. Normally, intuition is not a good enough basis for making a move. But many of these guys go to the opposite extreme. They seem to think that every business problem can be structured and reduced to a case study. That may be true in school, but in business there has to be somebody around who will say: ‘Okay, folks, it’s time. Be ready to go in one hour.’ When I read historical accounts of World War II and D-Day, I’m always struck by the same thought: Eisenhower almost blew it because he kept vacillating. But finally he said: ‘No matter what the weather looks like, we have to go ahead now. Waiting any longer could be even more dangerous. So let’s move it!’"
“The same lesson applies to corporate life. There will always be those who will want to take an extra month or two to do further research on the shape of the roof on a new car. While that research may be helpful, it can wreak havoc on your production plans. After a certain point, when most of the relevant facts are in, you find yourself at the mercy of the law of diminishing returns. That’s why a certain amount of risk-taking is essential. I realize it’s not for everybody. There are some people who won’t leave home in the morning without an umbrella even if the sun is shining. Unfortunately, the world doesn’t always wait for you while you try to anticipate your losses. Sometimes you just have to take a chance and correct your mistakes as you go along.

“Back in the 1960s and through most of the 1970s, these things didn’t matter as much as they do now. In those days the car industry was like a golden goose. We were making money almost without trying. But today, few businesses can afford the luxury of slow decision-making, whether it involves a guy who’s in the wrong job or the planning of a whole new line of cars five years down the road.

“Despite what the textbooks say, most important decisions in corporate life are made by individuals, not by committees. My policy has always been to be democratic all the way to the point of decision. Then I become the ruthless commander. ‘Okay, I’ve heard everybody,’ I say, ‘Now here’s what we’re going to do.’ You always need committees, because that’s where people share their knowledge and intentions. But when committees replace individuals—and Ford these days has more committees than General Motors—then productivity begins to decline.

“To sum up: nothing stands still in this world. I like to go duck hunting, where constant movement and change are facts of life. You can aim at a duck and get it in your sights, but the duck is always moving. In order to hit the duck, you have to move your gun. But a committee faced with a major decision can’t always move as quickly as the events it’s trying to respond to. By the time the committee is ready to shoot, the duck has flown away.”
I

In any endeavor, more than one person is responsible for carrying the task to completion. The efforts resulting in this book are no exception. Many people have contributed to the production of this book, either directly or indirectly.

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To my wonderful wife Carla Jeanne, daughter Christine, and sons Cary, Stephen, and Timothy
Epilogue*

The FMEA can be a legal document. As such, the engineer, the entire organization, and everyone involved with producing or using FMEAs must be familiar with the ramifications of the FMEA content.

It is hoped that by having an FMEA as part of the total records in the organization’s system, design, process, and/or service the courts will take a favorable view of the liability or negligence at hand. It is important to note that the liability or negligence of the product or service (either because of deficiencies in design or safety considerations) is not negated in any way, shape, or form—it always stays with the product and the organization.

Conversely, punitive damages may be proved to be one area where the FMEA can contribute infinitely. Punitive damages may be minimized and/or eliminated, if it can be proven that a proper FMEA was conducted and the appropriate risks were identified and acted upon with state-of-the-art tools.

As it was addressed in the section covering liability, the courts recognize that a perfect system, design, process, and/or service is not attainable. Therefore, a business and the engineer must prove that the risks taken for the system, design, process, and/or service are accounted for, analyzed, and the appropriate actions are in place to either minimize or eliminate them.

The FMEA does all that plus it contributes to the efficiency, manufacturability, maintainability, and integrity of the product and/organization. In addition, the FMEA can contribute to minimizing liability through other documentation in the organization.

* Portions of this chapter were adapted from the following source with permission: Bass, L. 1993. Cumulative supplement to Products Liability: Design and Manufacturing Defects. Colorado Springs, CO: Shepard’s/McGraw-Hill.
One of the primary supplemental contributions the FMEA can make in
minimizing product liability exposure involves marketing and advertising
claims. The information must be technically correct. Specifically, sales
agreements should be carefully reviewed in order not to expose the com-
pany to unnecessary product liability claims. Many product liability loss
prevention programs are compromised because the company has accepted
unnecessary product liability from its suppliers or distributors. The com-
pany should make conscious choices as to whether to give hold-harmless
agreements to the suppliers, distributors, or customers.

All sales personnel and distributors of a company’s products should be
made aware of their role in product liability prevention and risk reduction.
The representations by the sales force as they relate to durability, perfor-
ance, compatibility, safety, and recommended uses carry great weight in
a court of law. The FMEA is the perfect tool to contribute to the knowledge
base of such activity. Some guidelines for the sales forces follow.

1. Do not make unrealistic statements regarding the performance of
products. The capability of a company’s products to meet
standards and other performance criteria is the result of
engineering analysis and testing. These are the groups that know
best the performance limitations of the product. The engineering
department should be consulted in the event of any questions as
to whether products can meet the performance criteria of a
particular user.

2. Do not get involved in any unnecessary discussions regarding
product failures or defects with people outside the company.
Sales personnel should promptly notify the product review
board of any information relating to product failures or defects.
Without the advice of company management or legal counsel,
no further discussions should be held.

3. Do not suggest or approve the use of any product for a specific
purpose which is not explained in the product literature. A great
deal of time and effort has gone into the development of the
product literature. This has been with a view toward both the
ability of the products to perform successfully and of potential
product liability exposure. Recommending a product for a
purpose that has not been approved by engineering or the product
safety review board may be offering a customer a warranty that
the company cannot fulfill. Statements of this nature will increase
the product liability exposure of the company.
4. Do not use adjectives and superlatives to describe the performance and use of products unless they accurately reflect the capability of the product. Representatives of product performance and use should be carefully worded to be sure that they are accurate and of the proper degree. With the use of superlatives, a salesperson may unintentionally expose the company to a high product liability risk.

5. Do not inform a customer that a product conforms to the specifications of a given code or standard unless this information is contained in the product literature.

6. Do not get involved in discussions regarding the legal interpretation of warranties or contracts. Discussions relating to warranties or contracts are best left to legal counsel. When in doubt, refer the question back to management for clarification.

7. Do not recommend or suggest the use of replacement parts manufactured by others unless they are equivalent to original manufacturing company’s parts.

8. Do not make specific recommendations to customers regarding how a product should be assembled or installed except in accordance with applicable service bulletins and manuals.


10. Report all instances or alleged instances regarding product failure, product defects, property damage, or bodily injury.

11. Make realistic oral and written statements regarding the performance of products.

12. Discard old and/or obsolete advertising or sales literature.

13. Do not assume that labels and warnings on the product are sufficient to prevent liability. They may not be adequate.

Creation and Retention of Documentation

The questions always seem to be “What is appropriate documentation?” and “What is the retention period for such documentation?” All documentation begins with an identification of the types of records that are significant to the design, manufacturing, and distribution of the product. These records fall into the following categories:
1. Research and development records indicating how and why a product design was approved for manufacture. These documents include records of alternative designs which were analyzed, tested, and rejected. In addition they may include analyses and tests that document compliance with industry and/or government standards and other design criteria.

2. Production records documenting the purchase of component parts and raw materials; production steps and processes; and product blueprints defining the materials, surface finishes, and tolerances allowed during manufacturing.

3. Quality control and inspection records describing general quality control procedures, as well as acceptance or rejection criteria for the product.

4. Quality assurance records describing procedures and/or rejection criteria for the product.

5. Sales and marketing records, including brochures, promotional literature, product specifications, product models or samples, and instructional materials which accompanied or preceded introduction of the product into the marketplaces. Marketing records also include the results of market research relating to the functions and potential market for a new product. Sales records include the names, location, and sales of distributors, and the names or description of purchasers of the product.

6. Product service and performance records, including reports of failures of the product and injuries caused by the product. Service records also include warranty returns, repairs, requests for spare parts, and the service history of the product. Of particular importance in this category are any documents that might establish that the manufacturer knew or should have known that a defect or problem existed in the design of the product.

**Practices to Minimize the Risk of Harmful Documents**

Documents are created during the development, production, sale, and use of a product in order to run the company effectively. (The actual length of the documentation will depend on the scope and definition of the project, the requirements of the organization itself, and/or its customers, and/or the government regulations.) The problem of creating damaging documents must be dealt with at all levels of the company. For many products, safety decisions
are made by middle and lower management. Most documents are created at that level, or at the engineering, manufacturing, or sales level. The company needs honest, accurate documentation of test and inspection results. This includes failure analysis of products that have not performed satisfactorily in service or are the subject of a consumer complaint. These documents should be prepared in a way that will not prove damaging to the company in the event it is required to defend itself from a product liability lawsuit.

For example, the quality assurance department should not use the legal term *defect*. They should substitute the term *nonconforming*, or *noncompliance* and describe the nonconformance or noncompliance. A company can use such practices to minimize the likelihood of creating damaging documents during the product’s life cycle. The tool for such document is the FMEA.

**Critical Documents Should Be Reviewed and Maintained by One Responsible Person**

Safety-critical and sensitive documents prepared during each stage of the product’s life cycle should be maintained under the direction of one designated person. Documents pertaining to that stage of the product’s life cycle should be reviewed by this person. A document control instead of copies should be used for especially sensitive documents. Any comments that personnel have regarding the document are made on attachments to the document. Answers or responses to these comments can be prepared and attached to the document package so that a complete history of comments and resolutions is maintained. If necessary, a revision of the FMEA could be considered, if appropriate.

**A Clear and Complete Product History File Should Be Maintained**

The manufacturer should establish a product history file which documents why certain design alternatives, warnings, or instructions were chosen. The records should also show why other possible design and warning alternatives were rejected. The same type of documentation should be established for the manufacturing, quality control, marketing, sales, use, and disposal phases of the product’s life cycle. The perfect document for such documentation is the FMEA.

**Unfavorable Reports or Test Results Should Be Evaluated**

Unfavorable test results, reports, or complaints regarding the product or service must be evaluated for potential corrective action. The organization
cannot ignore information relating to a potential safety problem. Not responding to unfavorable results or comments may provide the basis for both general and punitive damages. Even a negligent response by a concerned manufacturer probably will eliminate the possibility of an award for punitive damages. Again, the FMEA is the perfect tool to help develop a trail or history of the problems and improvements to the product or service.
Glossary

TERMINOLOGY USED IN THE CONSTRUCTION OF AN FMEA

The vocabulary used in this appendix are abbreviated (and paraphrased) versions of some common words used in the FMEA based on the new ISO 9000 guidelines and the ASQ definitions. For the exact ISO definitions refer to the ANSI/ISO/ASG G9000:2000 American National Standard Series guidelines, and for the ASQ definitions, refer to ANSI/ASQ standard A3-1978.

**Actions taken**—The right-hand section of an FMEA form in which a description of the action and the effective date is recorded.

**Advanced statistical methods**—To analyze and understand the complex relationships between process variables (for example, design of experiments, correlation analyses, and so on).

**Assembly variation**—A normal distribution curve that shows the characteristic variation expected or measured during a manufacturing or assembly operation.

**Attachments**—A feature (if the FMEA is computerized) that allows storage of notes and files directly in the FMEA. If manual hardcopy, these attachments stay with the FMEA, but do not appear on the standard FMEA printout. (Typical attachments may be: the boundary diagram, P-diagram, characteristic matrix, process flow diagram and interface diagram.)
Attributes—Output characteristics classified into two categories which indicate OK and not OK (for example, characteristics such as the presence of a required label and installation of all required fasteners). Other examples include characteristics that are inherently measurable, but have results recorded in a simple yes/no fashion. For these examples, $p$, $np$, and $c$ charts are used instead of $X$-bar and $R$ charts.

Average—A central tendency. The sum of values divided by the number (sample size) of values. The average is designated by a bar over the symbol for the values being averaged or a tilde-bar over the symbol of subgroup medians.

Awareness—Personal understanding of the interrelationship of quality and productivity, directing attention to requirement for management commitment and statistical thinking to achieve continuous improvement.

Basic statistical methods—Applies methods of collection and organization of sample data through use of statistical process control; includes control chart construction and interpretation (for both variables and attributes data) and capability analysis.

Bimodal distribution—A distribution that has two identifiable curves within it with different averages. Indicates a mixing of two populations, such as different shifts, machines, workers, and the like.

Binomial distribution—A discrete probability distribution for attributes data that applies to conforming and nonconforming units and underlies the $p$ and $np$ charts.

Black box—An assembly purchased by the customer. The supplier is responsible for the design of the components, but the customer’s product engineering is responsible for providing design or material specifications. All aspects of the assembly’s function are directed by the customer’s engineering specification.

Block diagram—Now known as boundary diagram. See definition under boundary diagram.

Boundary diagram—Formerly known as a block diagram. It is an illustration that represents the scope of the FMEA, including interfaces. It is usually used in a design FMEA.
Box—A schematic showing many of the factors that affect a process: the customer, outputs of the process, inputs of the process, and associated tasks.

Brainstorming—An intentionally uninhibited technique for generating the greatest number of possible solutions to a problem, for later evaluation and development using group dynamics.

Breakthrough—An improvement in process performance that has never previously been attained. The improvement must be a result of human effort, not a result of chance.

Capability—(Can be determined only after the process is in statistical control.) A process is capable when process average plus and minus the 3-sigma spread of the distribution of individuals ($X \pm 3\sigma$) is contained within specification tolerance (variables data), or when at least 99.73 percent of individuals are within specification (attributes data). Efforts to improve capability must continue, however, consistent with the company’s philosophy of continuous improvement in quality.

Capability index—Ratios that show the ability of a process to produce products that conform to a given specification. These indices provide a convenient way to refer to the capabilities of a process after the process has been verified to be in a state of statistical control. Typical indices are: $C_p = \frac{X}{3\sigma}$ the ratio of the part specification tolerance to the Six-Sigma process spread without regard to the location of the data. It is calculated after verifying that the process is in a state of statistical control; $C_{pk} = \frac{X}{3\sigma}$ It is a capability index that considers both the process spread and the proximity of the process spread to specification limits. It is calculated after verifying that the process is in a state of statistical control. The $C_{pk}$ index is used to quantify process capability; $P_p = \frac{X}{3\sigma}$ This is an index similar to $C_p$ but based on data from early, short-term studies of new processes. $P_p$ can be calculated only when the data from the study indicate that process stability has been achieved. ($P_p = \text{Process Capability}$); and $P_{pk} = \frac{X}{3\sigma}$ It is an index similar to $C_{pk}$ but based on data from early, short-term studies of new processes. Data from at least 20 subgroups are required for preliminary assessments. $P_{pk}$ can be calculated only when the data from the studies indicate that stability has been achieved. ($P_{pk} = \text{Preliminary Process Capability}$.)

Cause—The how or why that leads to the failure mode. In a design FMEA and concept design FMEA, cause is a description of the factor(s) contributing to the failure mode. These include design defi-
ciencies that prevent performance to specification, create incorrect inputs, or result in adverse interactions between elements in a system. It is the manifestation of a design weakness, the consequence(s) of which is a failure mode. On the other hand, in a process FMEA and concept process FMEA, cause is a manufacturing or assembly deficit that impacts the functionality of the item or the process and results in an unacceptable condition.

**Cause-and-effect diagram**—A technique developed to represent the relationship between some effect and all the possible causes influencing it. In the FMEA, it is used to show cause-effect relationships between a single undesired event (failure) and the various contributing causes.

**Central line**—Line on a control chart that represents average or median value of items being plotted.

**Characteristic**—Distinguishing feature of a process or its output on which variables or attributes data can be collected.

**Common cause**—Source of variation that is always present; part of random variation inherent in the process itself. Origin usually can be traced to an element of the system that only management can correct. Employees, however, can contribute to identification of causal factors and corrections needed.

**Competitive benchmarking**—A technique that measures products, services, and business practices against the competition and/or excellent companies to identify opportunities for process improvements. In addition, competitive benchmarking promotes a learning experience to adapt and build upon the practices of excellent companies to enhance process improvement efforts.

**Consecutive**—Units of output produced in succession; a basis for selecting subgroup samples.

**Continuous improvement in quality and productivity**—Operational philosophy that makes best use of talent within a company to produce products of increasing quality for customers in an increasingly efficient way that protects return on investment to stockholders. A dynamic strategy designed to enhance the strength of the company in
face of present and future market conditions. It contrasts with any static strategy that accepts (explicitly or implicitly) some particular level of outgoing defects as inevitable.

**Control chart**—Graphic representation of a characteristic of a process, showing plotted values of some statistic gathered from that characteristic a central line and one or two control limits. Has two basic uses: a judgment to determine if a process was in control, and an aid in achieving and maintaining statistical control.

**Control factors**—A list of the factors already incorporated in the design that tends to reduce the likelihood of the *error states* existing. They are generated from the *P*-diagram.

**Control limit**—Line(s) on a control chart used as a basis for judging significance of variation from subgroup to subgroup. Variation beyond a control limit is evidence that special causes are affecting process. Control limits are calculated from process data and are not to be confused with engineering specifications.

**Critical characteristic**—A product requirement (dimension, specification, test) or process parameter that can affect compliance with government regulations or safe product function. Requires special actions for manufacturing, assembly, shipping, or monitoring. Critical characteristics must be included in control plans. When all producers require special controls, they are identified on customer’s drawings and specifications with the appropriate symbol designation. The potential for a critical characteristic is determined in a DFMEA. The critical characteristic is confirmed in the PFMEA.

**Criticality**—A relative measure of the combined influence of the consequences of a failure mode (severity or S) and its frequency (occurrence or O). It is a product of severity times occurrence. Criticality is used in the automotive industry.

**Current controls**—Refers to those controls associated with standard commercial practice and includes the normal and customary methods, practices, techniques, and tests used by a producer for a given product. These controls would typically be found on historic DVP&Rs for a DFMEA and on historic control plans for a PFMEA.
**Customer**—Any person, section, department, plant, or operation, whether internal or external, that receives or purchases services or goods.

**Design classification**—A symbol that reflects special characteristics identified against a potential cause.

**Design controls**—A description of the engineering tools, methods, calculations, reviews, tests, and so on, intended to detect the identified potential failure modes prior to engineering release. These methods can include DV tests. (See **Design Verification**)

**Design failure mode**—The failure of a function to meet design intent completely and correctly. There are five thought-starter failure mode categories that can be evaluated. They are: no function; degradation over time, partial, intermittent, and surprise.

**Design FMEA (DFMEA)**—An FMEA used to analyze a product at the system, subsystem, or component level before it is released for production.

**Design for assembly (DFA)**—When comprehensively applied, this discipline seeks to reduce assembly variability and assembly costs while improving product quality. The intended outcome is improvement in the design to reduce assembly difficulties or potential defects. For example, analysis of attaching and fastening schemes may lead to a redesign to eliminate some fasteners. DFA might be seen in the controls column of a design FMEA. If DFA is not performed or well performed, the remaining issues will often appear in the **Cause** column FMEA as **Second Assumption of Causes** type issues.

**Design for manufacturing (DFM)**—When comprehensively applied, this discipline seeks to reduce manufacturing variability and manufacturing costs while improving product quality. The intended outcome is improvement in the design to reduce manufacturing difficulties or potential defects. For example, analysis of fixturing and holding schemes may lead to a redesign to improve a clamping detail to improve machining operations. DFM might be seen in the controls column of a design FMEA. If DFM is not performed or not well performed, the remaining issues will often appear in the **Cause** column FMEA as **Second Assumption of Causes** type issues.
**Design for recycling (DFR)**—When comprehensively applied, this discipline seeks to improve recycling and reusability for the customer’s products. Sometimes this is also called *Design for the Environment*.

**Design for service (DFS)**—When comprehensively applied, this discipline seeks to reduce service-related issues. The intended outcome is improvement in the design to reduce service costs, frequency, or time for the ultimate customer or eliminate the need for special tools for the service customer. DFS might be seen in the controls column of a design FMEA, most often as a *service sign-off* or as a *customer specification review*.

**Design intent**—A description of what a given component/subsystem/system is expected to do or not to do.

**Design life**—The period for which the design is intended to perform its requirements. (The durability target of the item.) After the target period, the item is expected to be discarded because it ceases to function, or the item becomes too expensive to repair. Design life can be expressed in terms of a variety of measurements such as: kilometers, time (months or years), cycles, combination of these, and many more.

**Design of experiments**—An efficient method of experimentation that identifies factors affecting the design of experiments mean and variation with minimum testing.

**Design validation/verification**—A program intended to assure that the design meets its requirements.

**Design verification plan and report (DVP&R)**—The formalized testing performed on a product to assure the product’s compliance with all requirements. On successful completion the design is signed off and released. Alternately deviations are secured and the design is released. The elements of the DVP&R are found in the *Current Control* column of a DFMEA and in the *Recommended Actions* that modify that plan. Also known as *Design Verification Plan, Sign Off Report*.

**Design verification tests (DV)**—A description of the tests that are used to detect identified potential failure modes prior to engineering release.
Design weakness—A design deficiency such as wrong geometry, incorrect material, sensitivity to the environment, design life less than service life, apparent part symmetry where correct orientation is required, and so on. In an FMEA, these are typically the causes of failure.

Detection (D)—Design FMEA: a rating of the ability of the proposed design control to detect a potential failure mode or cause before engineering release. Process FMEA: a rating of the ability of the current process control(s) to detect a failure mode or cause before the item leaves the manufacturing or assembly facility.

Detection—or inspection—Past-oriented strategy that attempts to identify and separate unacceptable output after it has been produced. (See Prevention)

Distribution—Statistical pattern into which observed values fall. This is based on the concept of natural variation that states that anything measured repeatedly in a stable process will arrive at different results. A bell-shaped curve (normal distribution) is an example of a distribution in which the greatest number of observations fall in the center with fewer and fewer observations falling evenly on either side of the average. A process has distribution only if it is stable. (See Stability)

Dynamic control planning (DCP)—A process that links quality tools to build robust control plans. It strategically uses elements like flowcharts, FMEAs, and control plans together with the in-depth knowledge of process experts to seek to indirectly control many product and process characteristics by linking and directly controlling a few characteristics.

Effect—A description of the impact of a failure mode on the operation, function, or status of the part, assembly, subsystem, system, product, customer, manufacturing operations, manufacturing operators, manufacturing tooling and equipment, or government regulations.

Element—A general term used to refer to a subset of a system, subsystem, assembly, or subassembly. A part or group of parts comprising a system.

Error state—What may happen when the ideal function does not happen. An outcome of the P-diagram analysis.
Facilitator—Ideally an expert with no vested interest in the process under investigation, but with knowledge and ability to guide the project leader and the team through the various process improvement steps. The facilitator will work with the sponsor to identify the opportunity, develop a structure for the project, contract for the boundaries of the project and timing issues. He or she should be aware of sources for information, expert advice, and practical assistance.

Failure mechanism—(1) The process that results in failure. These processes can include chemical, electrical, physical, thermal, and informational. (2) The process of degradation, or a chain of events leading to and resulting in a particular failure mode.

Failure mode—A design failure is the manner in which a system, subsystem, or part fails to meet its intended purpose or function. A process failure is the manner in which a process fails to meet its intended purpose.

Failure mode analysis (FMA)—A disciplined approach to identify the failure modes, failure rates, and root causes of known failures.

Failure rate—The number of failures of an item within the population per unit measure of life such as cycles, time, transactions, computer runs, or some other stressful usage. Or the number of times a piece, or population of a design or process, is likely to fail in a given time period.

Fault tree analysis (FTA)—A deductive analytical technique that uses a graphical tree.

Feature—A product characteristic (for instance, radius, hardness) or a process characteristic (for instance, insertion force, temperature).

Fishbone diagram—A deductive analytical technique. It is used to brainstorm causes of failure. The failure mode would typically be entered into the “head” of the fish, and the “bones” would be used to list the causes. Also known as an Ishikawa diagram.

FMEA review—A feature that generates an on-screen analysis of simple deficiencies like blank FMEA header and data fields or missing Recommended Actions under conditions that require one, and so forth. This report can be printed using the icon at the top of its panel.
Frequency distribution—Statistical table that graphically presents a large amount of data arranged in order of magnitude and occurrence in such a way that the central tendency (mean, median, mode) and distribution are clearly displayed.

Function—The intended purpose or characteristic action of a system, subsystem, or part. A primary function is the specific purpose or action for which a product is designed. There may be more than one primary function. A secondary function is another function the product performs that is subordinate to, but supports, the primary function.

Gap—Used to describe differences between what the customer needs and what the process provides. Objective of process improvement is to define and measure that gap and provide the tools to close it.

Graphics—Drawings, diagrams, and so on, created or revised in an FMEA session to assure that all the interfaces have been considered.

Gray box—An assembly purchased by the customer, for which the supplier has design, development, and engineering drawing responsibility. Customer’s product engineering has responsibility to provide design or material specifications. All aspects of the assembly’s function are specified by the customer’s engineering specification.

Hardware—A term used to describe a physical part, assembly, or system.

High impact (HI)—A designation in the PFMEA that denotes a characteristic to be controlled in the process because of its importance to an operation. This designation may be given to potential critical and significant items identified in the DFMEA. It does not require special controls but is still deemed operationally important to the process and will be listed on the control plan.

Individual—Single unit or measurement of a characteristic.

Interaction—The effect of one part, element, subsystem, or system on another.

Interface—The common boundary between the system, subsystem, and/or parts being analyzed. This information should be displayed as part of the boundary diagram created in DFMEA pre-work. The boundary diagram should be included in the FMEA as a note/attachment.
**Interface matrix**—A robustness tool that identifies and quantifies the strength of system interactions. It shows whether the relationship is necessary or adverse. It also identifies the type of relationship (for example, energy transfer, physical proximity, material compatibility, and information exchange).

**Item**—A generic term used to designate a system, subsystem, assembly, part, or component, which is the scope of the analysis of the FMEA.

**Location**—General concept for denoting placement of typical values or central tendency of a distribution measured by a mean or median.

**Loss of function**—Degraded performance or operation outside the design specification limits. Loss of function is usually the anti-function or the no function type of failure mode.

**Manufacturing variation**—Process variation represented by a normal distribution curve that shows the characteristic variation expected or measured during a manufacturing or assembly operation.

**Mean**—The average of values in a group of measurements.

**Median**—Middle value in a group of measurements, when arranged from lowest to highest. Conventionally if the number of values is even, the average of the middle two values is used as the median. Subgroup medians form basis for simple control charts for process location. Medians are designated by a tilde (˜) over the symbol for individual values: \( \bar{X} \) is the median of a subgroup.

**Mode**—Point in a frequency distribution where the greatest number of observations lie.

**Noise factors**—A term from robustness which references the five elements often overlooked in designs which eventually impact customer satisfaction: systems interactions, customer usage/duty cycle, environment, degradation/deterioration over time, and manufacturing variation (piece-to-piece).

**Nonconforming units**—Units that do not conform to a specification or other inspection standard; sometimes called discrepant or defective units. \( P \) and \( np \) control charts are used to analyze systems producing nonconforming units.
Nonconformities—Specific occurrences of a condition that does not conform to specifications or other inspection standards; sometimes called discrepancies or defects. An individual nonconforming unit can have the potential for more than one nonconformity (for example, a door could have several dents; a functional check of a carburetor could reveal any number of discrepancies). \( C \) and \( u \) charts are used to analyze systems producing nonconformities.

Normal controls—Refers to those controls associated with standard commercial practice and includes the normal and customary methods, practices, techniques, and tests used by a producer for a given product. These controls would typically be found on historic DVP&R’s for a DFMEA and on historic control plans for a PFMEA.

Normal distribution—The continuous, symmetrical, bell-shaped frequency distribution for variables data that underlies control charts for variables. When measurements have a normal distribution, about 68.26 percent of all individuals lie within ± one standard deviation unit of the mean, about 95.44 percent lie within ± two standard deviation units of the mean, and about 99 to 73 percent lie within ± three standard deviation units of the mean. These percentages are the basis for control limits and control chart analysis (since subgroup averages tend to be normally distributed even if the output as a whole is not), and for many capability decisions (since output of many industrial processes follows the normal distribution).

Occurrence (O)—Design FMEA and concept-design FMEA: a rating corresponding to the cumulative number of failures that could occur for a given cause over the design life of a system or part. Process FMEA and concept-process FMEA: a rating corresponding to the estimated number of cumulative failures that could occur for a given cause over a given quantity of elements produced with the current controls.

Operational definition—Means of clearly communicating quality expectations and performance; consists of (1) a criterion to be applied to an object or a group, (2) a test of the object of the group, (3) a decision: yes or no—object or group did not meet criterion.

Operator safety (OS)—The designation for operator safety items in a PFMEA. These are failure modes with a severity rating of 9 or 10, and
affect the process only. This designation is a major concern in the
machinery FMEA.

**Pareto**—A simple tool for problem solving that involves ranking all
potential problem areas.

**Pareto chart**—A bar chart with problems prioritized in descending
order of importance. The prioritizing helps direct attention and
resources to the important problems.

**Part**—Any physical hardware of the product that is considered a sin-
gle replaceable piece with respect to field service. The least subdivi-
sion before assembly into a subsystem or system (for example, a
shock absorber, a switch, or a radio). An end item.

**P-diagram**—A robustness tool that identifies and describes noise
and control factors and error states. It assists in the identification of
potential causes of failure (for instance, system interactions) and fail-
ure modes for instance, degradation).

**Poisson distribution**—Discrete probability distribution for attributes
data that applies to nonconformities and underlies the $c$ and $u$ control
charts.

**Population**—The set of all possible observations about a specific
characteristic of interest.

**Potential critical characteristics**—A symbol generated in a
DFMEA classification that may become a designated critical charac-
teristic after a PFMEA is completed. Severity ranking is 9 or 10.

**Prevention**—Future-oriented strategy that improves quality by
directing analysis and action toward correcting the production
process. Prevention is consistent with a philosophy of continuous
improvement.

**Problem solving**—Process of moving from symptoms to causes
(special or common) to actions that improve performance. Among
techniques that can be used are Pareto charts, cause-and-effect dia-
grams, and statistical process control techniques.
**Process average**—Location of the distribution of measured values of a particular process characteristic, usually designated as an overall average \( X \)-bar or \( X \) double bar.

**Process capability**—Measured, built-in reproducibility (consistency) of product turned out by the process. Such a determination is made using statistical methods, not wishful thinking. The statistically determined pattern/distribution can only then be compared to specification limits to determine if a process can consistently deliver product within those parameters. This process capability can be measured by a \( C_{pk} \), \( C_p \) and/or \( C_r \).

**Process change**—A change in a process that could alter the capability of the process to meet the design requirements or durability of the product.

**Process characteristic**—Measurable characteristics of process inputs and their interactions that affect the process output. Examples of process parameters include speeds, feeds, temperatures, chemical concentrations, pressures, and voltages.

**Process failure mode**—The failure of a manufacturing or assembly process to meet the requirements of the intended process function.

**Process flow diagram**—An illustration created or revised in an FMEA session to assure that all interface and incoming variations are considered.

**Process FMEA (PFMEA)**—An FMEA used to analyze manufacturing and assembly processes and output control plans.

**Process improvement**—A process that identifies work in the form of interrelated processes and then (utilizing improvement techniques) ensures that those processes are meeting customer needs and wants, and eliminates negative value operations.

**Process map**—A visual display of various stages of the process and a demonstration of the flow of product or service over time. Shows how a process operates and focuses on what is done, not only on what is produced.
**Process spread**—Extent to which distribution of individual values of process characteristic vary about the mean; often shown as the process average ± some number of standard deviations.

**Process variation**—Represented by a normal distribution curve that shows the characteristic variation expected or measured during a manufacturing or assembly operation.

**Process**—Combination of people, machines/equipment, raw materials, methods, and environment that produces a given product or service.

**Product**—A general term that refers to a component, part, assembly, subsystem, or system.

**Product characteristic**—Quantifiable/measurable features such as dimension, size, form, location, orientation, texture, hardness, tensile strength, coating, reflectivity, finish, color, or chemistry.

**Project leader**—Person responsible to process sponsor for leading the investigation, selling solution(s), and implementing the revised/new process. The leader also can act as the facilitator. (See **Facilitator**.)

**Project scope**—Used to decide study limits, provide a vehicle for stakeholders to understand their involvement, identify team members, and provide a framework for them to work within.

**Quality function deployment (QFD)**—A structured method in which customer requirements are translated into appropriate technical requirements for each stage of product development and production.

**Quality**—Defined by customers; customers want products and services that, throughout their lives, meet customers’ needs and expectations at a cost that represents value.

**Randomness**—Condition in which individual values are not predictable, although they may come from a definable distribution.

**Range**—Measure of variation in a set of data. It is calculated by subtracting the lowest value in the data set from the highest value in that same set.
Response—Ideal, intended functional output. An outcome of the P-diagram.

Revised detection (RD)—A value entered in the RD field when the recommended action is completed and the action has improved the detection of the failure mode or cause.

Revised occurrence (RO)—A value entered in the RO field when the recommended action is completed and the action has reduced the likelihood that this cause will occur and generate the failure mode.

Revised RPN (RRPN)—The generated product of the RS rating times the RO rating times the RD rating (RS \times RO \times RD). It is a value from 1 to 1000. However, it is expected to be less than the original RPN. If not, then the recommended and actions taken were not appropriate and the cycle must begin all over again.

Revised severity (RS)—A value entered in the RS field when the recommended action is completed and the action had reduced the severity of the failure mode. This can only occur when there is a change in design.

Risk priority number (RPN)—The product of the severity, occurrence, and detection ratings.

Robust design—A producer’s capability to manufacture and/or assemble with a low sensitivity to manufacturing and/or assembly process variation. A robust design assumes there are no design weaknesses. If a design is not robust, sensitivity to process variation is high and this implies special process controls may be necessary.

Robustness/reliability matrix—Summarizes key robustness attributes and design controls. It is an input into the design verification plan. Also a key element for review in the design review process.

Root cause—The primary singular event that results in a failure mode. In a component-level design FMEA (DFMEA) this will be a part characteristic.

Run chart—Simple graphic representation of a characteristic of a process, showing plotted values of some statistic gathered from the
process (often individual values) and a central line (often the median of the values), which can be analyzed for runs.

**Runs**—Patterns in a run/control chart within which a number of points line up on only one side of the central line. Beyond a certain number of consecutive points (statistically based) the pattern becomes unnatural and worthy of attention.

**Sample**—One or more individual events/measurements selected from the output of a process for purposes of identifying characteristics and performance of the whole.

**Scope**—Boundary or extent of the analysis. Defines what is included and excluded in an FMEA.

**Secondary function**—A function the product performs that is secondary to, but supports, the primary function.

**Severity (S)**—In a design FMEA: a rating of the seriousness of the effect of a failure mode on the next assembly, system, product, customer, or government regulation. In a process FMEA: a rating of the seriousness of the effect of a failure mode on a downstream operation, the equipment and tooling of the process operation, operator safety or next assembly, system, product, customer, or government regulation. Severity applies to the most serious effect of a failure mode.

**Sigma (σ)**—The Greek letter used to designate the standard deviation of the distribution of individual values for a process parameter or a product characteristic.

**Signal factor**—What the input which triggers the function being analyzed is. It is the input to the $P$-diagram.

**Significant characteristic (SC)**—Product, process, and test requirements important for customer satisfaction and for which quality planning actions must be summarized on a control plan.

**Special cause**—Source of variation that is intermittent, unpredictable, unexpected, and signalled by a point beyond the control limits.

**Specification**—The engineering requirement for judging acceptability of a particular characteristic. Chosen with respect to functional or
customer requirements for the product, a specification may or may not be consistent with the demonstrated capability of the process (if it is not, out-of-specification parts are certain to be made). A specification should never be confused with a control limit.

**Sponsor**—Manager who has accepted the responsibility (possibly on behalf of a number of stakeholders) for taking the necessary steps to cause an improvement in a process.

**Spread**—General concept for extent by which values in a distribution differ from one another; dispersion.

**Stability**—Absence of special causes of variation; property of being in statistical control; predictable.

**Stable process**—A process in which variation in outcomes arise only from common causes. A process in statistical control.

**Stakeholder**—Manager who has a direct interest/responsibility in a process under investigation and would probably assign one (or more) of the staff to the process improvement team.

**Standard deviation**—Measure of spread of the process output or spread of a sampling statistic from the process (for example, of subgroup averages); denoted by Greek letter $\sigma$ (sigma).

**Statistical control**—Condition describing a process from which all special causes have been removed, shown on control charts by absence of points beyond control limits and by lack of nonrandom patterns/trends within control limits.

**Statistical process control (SPQ)**—Use of statistical techniques (such as control charts) to analyze a process or its output in order to take appropriate actions to achieve and maintain a state of statistical control and to improve the capability of the process.

**Statistic**—Value calculated from or based upon sample data (for example, subgroup average or range); used to make inferences about the process that produced the output from which sample came.

**Subgroup**—One or more events or measurements used to analyze the performance of a process. Rational subgroups usually are chosen
so that variation represented within each subgroup is as small as feasible for the process representing the variation from common causes, and so that any changes in process performance (in other words, special causes) will appear as differences between subgroups. Rational subgroups typically are made up of consecutive pieces, although random samples are sometimes used.

**Subsystem**—A set of interdependent elements or parts organized to achieve a defined objective by performing a specified function(s).

**Supplier**—Any person, section, department, plant, or operation, (internal or external) that gives or sells services or goods. This giving is based on a win-win relationship between supplier and customer as opposed to win-lose relationship which is the main characteristic of a vendor.

**System**—A set of interdependent subsystems or parts organized and linked in a coherent way to each other and to the whole.

**System design specification (SDS)**—Regulatory and other requirements that systems, subsystems, and components must meet. Testing requirements are often included in SDSs.

**Trends**—Patterns in a run chart or control chart that feature continued rise or fall of a series of points. Similar to runs, attention should be paid to such patterns when they exceed the seven points. The difference between a run and a trend is that the run is one or the other side of the average line, where the trend always crosses the average line in either an upward or a downward direction. In either case, a change in the process has occurred.

**Trigger**—The event or input that starts the process. It may be a document of some sort (invoice, request form, or a vehicle order) that helps define that which starts the process, and therefore, the input boundaries.

**Type I** (~H9251~) **error**—Ascribe a variation or mistake to a special cause, when the cause actually belongs to the system; overcontrol. It is usually referred as the producer’s error.

**Type II** (~H9252~) **error**—Ascribe a variation or mistake to the system when the cause actually was special; undercontrol. It is usually referred to as the customer’s error.
Value Analysis (VA)—Performed after tooling and utilizes the formula, Value = Function/Cost. Functions are inclusive in these methodologies and include primary functions and secondary functions.

Value Engineering (VE)—Performed before production tooling is committed and utilizes the formula, Value = Function/Cost. Functions are inclusive in these methodologies and include primary functions and secondary functions.

Variables—Characteristics of a part that can be measured (for example, length in millimeters, resistance in ohms, closing effort of a door in kilograms, and the torque of a nut in foot pounds). (See also Attributes)

Variation—The inevitable difference among individual outputs of a process; the sources of variation can be grouped into two major classes: common causes and special causes.

Voice of the customer—Feedback obtained on customers’ needs, wants, and expectations.

Voice of the process—Feedback obtained from performance indicators generated within the process (for example, measures of process performance).

Wants list—A list that describes the purposes, objectives, or functions of a particular system or part from the customer’s viewpoint. Wants are generally determined from Kano/QFD studies and/or marketing studies.
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Appendix A

Formulae

This appendix provides some of the advanced equations used in the electronic industry for failure identification, as well as miscellaneous information about block diagrams, how and when to use the appropriate reliability calculations, and so on. Specifically, the following items are covered:

- The Arrhenius equation and the Eyring Type model
- The Eyring and Reich-Hakim model
- Equations for accelerated factors
- Reliability block diagrams
- Development of block diagrams from system to units
- Equations for the calculation of the MTBF in series
- Equations for the calculation of the MTTF in parallel
- Equations for the reliability and mean life of complex systems with cyclical units
- Conversion factors for failure rate measurement units
\section*{THE ARRHENIUS EQUATION}

\begin{equation}
R(T) = C e^{-\frac{E_a}{kT}}
\end{equation}

where $C$ is a constant, $E_a$ is activation energy in eV, $T$ is temperature in $^0K$, $K$ is Boltzman’s constant $8.625 \times 10^{-5}$ eV/$^0K$

Acceleration equation:

\begin{equation}
\frac{r_1}{r_2} = e^{\frac{E_a}{K}} \left( \frac{1}{T_2} - \frac{1}{T_1} \right)
\end{equation}

where $r_1/r_2$ is the acceleration factor.

Activation energy equation:

\begin{equation}
E_a = e^{\frac{K}{ln} \left( \frac{r_1}{r_2} \right)}
\end{equation}

Standard deviation equation:

\begin{equation}
\sigma = ln \left( \frac{t_{50}}{t_{16}} \right)
\end{equation}

where $t_{50}$ is the median life or time to 50 percent failure and $t_{16}$ is the time to 16 percent failure.

\section*{THE EYRING TYPE MODEL}

\begin{equation}
t_{50} = A e^\frac{\Phi}{K} \times e^{\frac{1}{T}} \times e^{\frac{B}{RH}} \times e^{-\frac{E_a}{CA}}
\end{equation}

Where $A$ and $B$ are constants
\( \Phi \) is the activation energy in eV
$T$ is the temperate in $^0K$
$K$ is the Boltzmann constant in $eV/0K$

$RH$ is relative humidity in %

$E_{CA}$ is the electric field in the corrosion area

**THE EYRING AND REICH-HAKIM MODEL**

$$t_{s0} = A \left( \frac{\Phi}{e^K e^T e^{Be^{RH}}} \right) E_{CA}^{-1}$$

$$= G \left( \frac{T^{RH}}{e^{[RH]}} \right) E_{CA}^{-1}$$

where $G$ is a factor combining all the constants $A, \frac{\Phi}{e^K}, e^B$

**EQUATIONS FOR ACCELERATED FACTORS**

The equations for acceleration factors associated with temperature and voltage accelerated burn-ins use the following. The Arrhenius equation is:

$$\text{Accel. factor} = \exp \frac{\Theta}{K} \times \frac{1}{T_d} - \frac{1}{T_s}$$

where:

$K = $ Boltzmann’s Constant, $8.662E - 5eV/0K$

$\Theta$ activation energy, $eV$

$T_s =$ stress temperature, $0K$

$T_d/$operating temperature, $0K$

The voltage acceleration equation is:

$$\text{Accel. factor} = \exp \frac{C}{T_{ox}} \times (VS - VD)$$

where:

$C =$ electric field constant

$T_{ox} =$ thickness of gate oxide, A

$VS =$ stress voltage, $V$

$VD =$ dynamic life operating voltage, $V$
The purpose of burn-in is to create accelerated temperature and voltage stress conditions to screen out early life failures, especially those related to MOS oxide defects.

**FAILURE RATE CONVERSION**

Example: If you know that the failure rate is 10 fr/106 hr, you can find the failure rate in % fr/1,000 hr if you multiply 10 by $10^{-1}$, or $10 \times 10^{-1} = 1$; consequently, the failure rate is 1% fr/1,000 hr. [1 FIT = 1 fr/10⁹ hr.; 1 BIT = 1 fr/10¹⁰ hr.]. The reader may benefit from the following conversion factors for failure rate measurement units found abundantly in the literature.
<table>
<thead>
<tr>
<th>When you know</th>
<th>You can find</th>
<th>If you multiply by:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Failures per million hours, fr/106 hr</td>
<td>Failures per hour, fr/hr</td>
<td>(10^6)</td>
</tr>
<tr>
<td></td>
<td>(%/1,000)</td>
<td>(10^{-1})</td>
</tr>
<tr>
<td></td>
<td>(% \text{ fr}/1,000 \text{ hr})</td>
<td>(10^{-1})</td>
</tr>
<tr>
<td>Percent failures per 1,000 hours</td>
<td>FITS</td>
<td>(10^3)</td>
</tr>
<tr>
<td></td>
<td>BITS</td>
<td>(10^4)</td>
</tr>
<tr>
<td>PPM hours, parts failing per million device-hours</td>
<td></td>
<td>(1)</td>
</tr>
<tr>
<td>(%/1,000)</td>
<td>fr/ 106 hr</td>
<td>(10)</td>
</tr>
<tr>
<td></td>
<td>fr/hr</td>
<td>(10^{-5})</td>
</tr>
<tr>
<td></td>
<td>FITS</td>
<td>(10^4)</td>
</tr>
<tr>
<td></td>
<td>BITS</td>
<td>(10^5)</td>
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<tr>
<td></td>
<td>PPM hours</td>
<td>(10)</td>
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<tr>
<td>FITS</td>
<td>fr/106 hr</td>
<td>(10^{-3})</td>
</tr>
<tr>
<td></td>
<td>(%/1,000 \text{ hr})</td>
<td>(10^{-4})</td>
</tr>
<tr>
<td>BITS</td>
<td>fr/106 hr</td>
<td>(10^{-4})</td>
</tr>
<tr>
<td></td>
<td>(%/1,000 \text{ hr})</td>
<td>(10^{-5})</td>
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</table>
Figure A.2  Development of block diagrams from system to units.
### Table A.1 Equations for the calculation of the MTBF in series.

<table>
<thead>
<tr>
<th>Case number</th>
<th>System structure</th>
<th>MTTF</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td><img src="image" alt="Single, constant failure rate unit" /></td>
<td>$\frac{1}{\lambda}$</td>
<td>Single, constant failure rate unit</td>
</tr>
<tr>
<td>2</td>
<td>$\lambda(T) = kT$</td>
<td>$\left(\frac{\pi}{2k}\right)^{\frac{3}{2}}$</td>
<td>Single, linearly increasing, failure rate unit. In the Rayleigh pdf $k = \frac{2}{\eta}$. In the Weibull pdf $\beta = 2$, $k = \frac{2}{\eta^2}$, and $\gamma = 0$.</td>
</tr>
<tr>
<td>3</td>
<td>$\lambda(T) = \frac{\beta}{\eta} \left(\frac{T - \gamma}{\eta}\right)^{\beta - 1}$</td>
<td>$\gamma = \eta \Gamma \left(\frac{1}{\beta} + 1\right)$ [\Gamma(n) = \int_0^\infty e^{-x}x^{n-1}dx] is the gamma function.</td>
<td>Single, Weibull failure rate unit.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Case number</th>
<th>System structure</th>
<th>MTTF</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>$\lambda_1(T) = \frac{\beta_1}{\eta_1} \left( \frac{T - \gamma_1}{\eta_1} \right)^{\beta_1-1}$ $\lambda_2(T) = \frac{\beta_2}{\eta_2} \left( \frac{T - \gamma_2}{\eta_2} \right)^{\beta_2-1}$ $\gamma_2 &lt; \gamma_1$</td>
<td>$\gamma_2 + \frac{\eta_2}{\beta_2} \int \left[ \left( \frac{T - \gamma_1}{\eta_1} \right)^{\beta_1} + \left( \frac{T - \gamma_2}{\eta_2} \right)^{\beta_2} \right] dT$, where $G(n, z) = \int_0^z e^{-x^m} dx$ is the incomplete gamma function. If $\gamma_1 = \gamma_2 = \gamma$ and $\beta_1 = \beta_2 = \beta$, then the MTTF becomes $\gamma + \Gamma \left( \frac{1}{\beta} + 1 \right) \left[ \left( \frac{1}{\eta_1} \right)^{\beta} + \left( \frac{1}{\eta_2} \right)^{\beta} \right] \frac{1}{\beta}$ where $\Gamma(n) = \text{gamma function.}$</td>
<td>Two series, Weibull failure rate units.</td>
</tr>
<tr>
<td>5</td>
<td>$\lambda_1(T) = \lambda_1$, $\lambda_2(T) = \lambda_2$, . . . $\lambda_n(T) = \lambda_n$, $\lambda_1$, $\lambda_2$, . . . $\lambda_n$.</td>
<td>$\frac{1}{\sum_{i=1}^{n} \lambda_i}$</td>
<td>$n$ series, constant failure rate units.</td>
</tr>
</tbody>
</table>
### Table A.1  Equations for the calculation of the MTBF in series.

<table>
<thead>
<tr>
<th>Case number</th>
<th>System structure</th>
<th>MTTF</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>$\lambda_1(T) = \frac{\beta_1}{\eta_1} (T - \gamma_1) \beta^{-1}$, $\lambda_2(T) = \frac{\beta_2}{\eta_2} (T - \gamma_2) \beta^{-1}$, \ldots, $\lambda_n(T) = \frac{\beta_n}{\eta_n} (T - \gamma_n) \beta^{-1}$</td>
<td>$\gamma + \Gamma \left( \frac{1}{\beta} + 1 \right) \sum_{i=1}^{n} \left( \frac{1}{\eta} \right)^{\frac{1}{\beta}}$</td>
<td>$n$ series Weibull failure rate units, all with the same shape parameter $\beta$ and location parameter $\gamma$.</td>
</tr>
<tr>
<td>7</td>
<td>$\lambda_1(T) = \lambda_1$, $\lambda_2(T) = \lambda_2$, \ldots, $\lambda_n(T) = \lambda_n$, $\lambda_{n+1}(T) = k_1 T$, $\lambda_{n+1}(T) = k_2 T_2$, \ldots, $\lambda_{n+r}(T) = k_r T_r$</td>
<td>$\left( \frac{\pi}{k} \right)^{\frac{1}{2}} e^{\frac{\lambda}{k}} \left( 1 - \Phi \left( \frac{\lambda}{\sqrt{k}} \right) \right)$</td>
<td>$n + r$ series units, $n$ with a constant failure rate and $r$ units with a linearly increasing failure rate.</td>
</tr>
</tbody>
</table>

**Notes**

- $\Gamma(n)$ is the gamma function.
- $\Phi(z) = \frac{1}{(2\pi)^{\frac{1}{2}}} \int_{-\infty}^{z} e^{-\frac{x^2}{2}} dx.$
Table A.2  Equations for the calculation of the MTTF in parallel.

<table>
<thead>
<tr>
<th>Case number</th>
<th>System structure</th>
<th>MTTF</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>( \lambda_1(T) = \lambda_1, \lambda_2(T) = \lambda_2 )</td>
<td>[ \frac{1}{\lambda_1} + \frac{1}{\lambda_2} - \frac{1}{\lambda_1 + \lambda_2} ]</td>
<td>Two parallel, constant failure rate units.</td>
</tr>
<tr>
<td>2</td>
<td>( \lambda_1(T) = \frac{\beta_1}{\eta_1} \left( \frac{T - \gamma_1}{\eta_1} \right)^{\beta_1 - 1} ), ( \lambda_2(T) = \frac{\beta_2}{\eta_2} \left( \frac{T - \gamma_2}{\eta_2} \right)^{\beta_2 - 1} ), ( \gamma_2 &lt; \gamma_1 )</td>
<td>[ \gamma + \eta_1 \Gamma\left( \frac{1}{\beta_1} + 1 + \frac{\eta_2}{\beta_2} \Gamma\left( \frac{1}{\beta_1} + 1 \right) \right) ] [ - \frac{\eta_2}{\beta_2} G \left[ \frac{1}{\beta_2}, \left( \frac{\gamma_1 - \gamma_2}{\eta_2} \right)^{\beta_2} \right] ] [ - \int_{\gamma_1}^{\infty} e^{-x} x^{\beta_2 - 1} dx, ]</td>
<td>Two parallel, constant failure rate units.</td>
</tr>
</tbody>
</table>

where \( \Gamma(n) \) = gamma function, and
\[ G(n, z) = \int_{\gamma_1}^{\infty} e^{-x} x^{n-1} dx, \]
is the incomplete gamma function. If \( \gamma_1 = \gamma_2 = \gamma \) and \( \beta_1 = \beta_2 = \beta \), then the MTTF becomes
\[ \gamma + \Gamma\left( \frac{1}{\beta} + 1 \right) \left\{ \eta_1 + \eta_2 - \frac{\frac{1}{\beta}}{\left( \frac{1}{\eta_1} + \frac{1}{\eta_2} \right)^{\beta}} \right\} \]
### Table A.2 Equations for the calculation of the MTTF in parallel. (Continued)

<table>
<thead>
<tr>
<th>Case number</th>
<th>System structure</th>
<th>MTTF</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>$\lambda_i(T) = \lambda_i, \quad i = 1, \ldots, n.$</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
\[ \frac{1}{\lambda_1} + \frac{1}{\lambda_2} + \cdots + \frac{1}{\lambda_n} = \frac{1}{\lambda_1 + \lambda_2 + \cdots + \lambda_n} \]  
\[ + \cdots + (-1)^{n+1} \frac{1}{\sum_{i=1}^{n} \lambda_i}, \] 
\[ \text{If } \lambda_i = \lambda, \quad i = 1, \ldots, n, \text{ then } \sum_{k=1}^{n} \frac{1}{k\lambda} \] | $n$ parallel, constant failure rate units. |
| 4 | $\lambda_i(T) = \frac{\beta}{\eta_i} \left( \frac{T - \gamma}{\eta_i} \right)^{\beta-1}, \quad i = i, \ldots, n$ | 
\[ \gamma + \Gamma \left( \frac{1}{\beta} + 1 \right) \left\{ \sum_{i=1}^{n} \frac{1}{\eta_i - \gamma} - \left[ \left( \frac{1}{\eta_1} \right) + \left( \frac{1}{\eta_2} \right) \right]^{\frac{1}{\beta}} \right. 
\[ \left. + \cdots + \left[ \left( \frac{1}{\eta_{n-1}} \right) + \left( \frac{1}{\eta_n} \right) \right]^{\frac{1}{\beta}} \right\} 
\[ + \cdots + (-1)^{n+1} \left[ \sum_{i=1}^{n} \left( \frac{1}{\eta_i} \right) \right]^{\frac{1}{\beta}} \] | $n$ parallel, Weibull units having the same shape parameter $\beta$ and location parameter $\gamma$. |

where $\Gamma(n)$ = gamma function
Table A.3  Equations for the reliability and mean life of a complex system with cyclical units.

<table>
<thead>
<tr>
<th>Case number</th>
<th>Circuit</th>
<th>Reliability of circuit</th>
<th>Mean life of circuit</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td><img src="image1" alt="Circuit Diagram 1" /></td>
<td>$r^2 + 2 \frac{\lambda_c}{\lambda} rq$</td>
<td>$(1.5 - \frac{\lambda_c}{\lambda}) m$</td>
</tr>
<tr>
<td>2</td>
<td><img src="image2" alt="Circuit Diagram 2" /></td>
<td>$r^2 + 2 \frac{\lambda_c}{\lambda} rq$</td>
<td>$(1.5 - \frac{\lambda_c}{\lambda}) m$</td>
</tr>
<tr>
<td>3</td>
<td><img src="image3" alt="Circuit Diagram 3" /></td>
<td>$r^3 + 3 \frac{\lambda_c}{\lambda} rq + 3 \left(\frac{\lambda_c}{\lambda}\right)^2 rq^2$</td>
<td>$\left[2 + 3 \frac{\lambda_c}{\lambda} + 6 \left(\frac{\lambda_c}{\lambda}\right)^2 \right] \frac{m}{6}$</td>
</tr>
<tr>
<td>4</td>
<td><img src="image4" alt="Circuit Diagram 4" /></td>
<td>$r^3 + 3 \frac{\lambda_c}{\lambda} rq + 3 \left(\frac{\lambda_c}{\lambda}\right)^2 rq^2$</td>
<td>$\left[2 + 3 \frac{\lambda_c}{\lambda} + 6 \left(\frac{\lambda_c}{\lambda}\right)^2 \right] \frac{m}{6}$</td>
</tr>
<tr>
<td>5</td>
<td><img src="image5" alt="Circuit Diagram 5" /></td>
<td>$r^3 + \left(2 + \frac{\lambda_o}{\lambda}\right) rq + \left[4 \frac{\lambda_o}{\lambda} - 3 \left(\frac{\lambda_o}{\lambda}\right)^2 \right] rq^2$</td>
<td>$\left[\frac{2}{3} + \frac{3}{2} \left(\frac{\lambda_o}{\lambda}\right) - \left(\frac{\lambda_o}{\lambda}\right)^2 \right] m$</td>
</tr>
<tr>
<td>6</td>
<td><img src="image6" alt="Circuit Diagram 6" /></td>
<td>$r^3 + \left(2 + \frac{\lambda_c}{\lambda}\right) rq + \left[4 \frac{\lambda_c}{\lambda} - 3 \left(\frac{\lambda_c}{\lambda}\right)^2 \right] rq^2$</td>
<td>$\left[\frac{2}{3} + \frac{3}{2} \left(\frac{\lambda_c}{\lambda}\right) - \left(\frac{\lambda_c}{\lambda}\right)^2 \right] m$</td>
</tr>
</tbody>
</table>
Table A.3  Equations for the reliability and mean life of a complex system with cyclical units.  

<table>
<thead>
<tr>
<th>Case number</th>
<th>Circuit</th>
<th>Reliability of circuit</th>
<th>Mean life of circuit</th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td><img src="image1.png" alt="Circuit 1" /></td>
<td>( r^4 + 4 \frac{\lambda_o}{\lambda} r^3 q + 6 \left( \frac{\lambda_o}{\lambda} \right)^2 r^2 q^2 + 4 \left( \frac{\lambda_o}{\lambda} \right)^3 q r^3 )</td>
<td>( \left[ \frac{1}{4} + \frac{1}{3} \left( \frac{\lambda_o}{\lambda} \right) + \frac{1}{2} \left( \frac{\lambda_o}{\lambda} \right)^2 + \left( \frac{\lambda_o}{\lambda} \right)^3 \right] m )</td>
</tr>
<tr>
<td>8</td>
<td><img src="image2.png" alt="Circuit 2" /></td>
<td>( r^4 + 4 \frac{\lambda_c}{\lambda} r^3 q + 6 \left( \frac{\lambda_c}{\lambda} \right)^2 r^2 q^2 + 4 \left( \frac{\lambda_c}{\lambda} \right)^3 q r^3 )</td>
<td>( \left[ \frac{1}{4} + \frac{1}{3} \left( \frac{\lambda_c}{\lambda} \right) + \frac{1}{2} \left( \frac{\lambda_c}{\lambda} \right)^2 + \left( \frac{\lambda_c}{\lambda} \right)^3 \right] m )</td>
</tr>
<tr>
<td>9</td>
<td><img src="image3.png" alt="Circuit 3" /></td>
<td>( r^4 + 4r^3 q + \left[ 2 + 8 \frac{\lambda_o}{\lambda} - 6 \left( \frac{\lambda_o}{\lambda} \right)^2 \right] r^2 q^2 + 4 \left[ \frac{\lambda_o}{\lambda} - \left( \frac{\lambda_o}{\lambda} \right)^3 \right] q r^3 )</td>
<td>( \left[ \frac{3}{4} + \frac{5}{3} \left( \frac{\lambda_o}{\lambda} \right) - \frac{1}{2} \left( \frac{\lambda_o}{\lambda} \right)^2 - \left( \frac{\lambda_o}{\lambda} \right)^3 \right] m )</td>
</tr>
<tr>
<td>10</td>
<td><img src="image4.png" alt="Circuit 4" /></td>
<td>( r^4 + 4r^3 q + \left[ 2 + 8 \frac{\lambda_c}{\lambda} - 6 \left( \frac{\lambda_c}{\lambda} \right)^2 \right] r^2 q^2 + 4 \left[ \frac{\lambda_c}{\lambda} - \left( \frac{\lambda_c}{\lambda} \right)^3 \right] q r^3 )</td>
<td>( \left[ \frac{3}{4} + \frac{5}{3} \left( \frac{\lambda_c}{\lambda} \right) - \frac{1}{2} \left( \frac{\lambda_c}{\lambda} \right)^2 - \left( \frac{\lambda_c}{\lambda} \right)^3 \right] m )</td>
</tr>
<tr>
<td>11</td>
<td><img src="image5.png" alt="Circuit 5" /></td>
<td>( r^4 + \left( 3 + \frac{\lambda_o}{\lambda} \right) r^3 q + 3 \left[ 1 + \frac{\lambda_o}{\lambda} - \left( \frac{\lambda_o}{\lambda} \right)^2 \right] r^2 q^2 + 6 \frac{\lambda_o}{\lambda} - 9 \left( \frac{\lambda_o}{\lambda} \right)^2 + 4 \left( \frac{\lambda_o}{\lambda} \right)^3 )</td>
<td>( \left[ \frac{3}{4} + \frac{11}{6} \left( \frac{\lambda_o}{\lambda} \right) - \frac{5}{2} \left( \frac{\lambda_o}{\lambda} \right)^2 + \left( \frac{\lambda_o}{\lambda} \right)^3 \right] m )</td>
</tr>
</tbody>
</table>
### Table A.3 Equations for the reliability and mean life of a complex system with cyclical units. (Continued)

<table>
<thead>
<tr>
<th>Case number</th>
<th>Circuit</th>
<th>Reliability of circuit</th>
<th>Mean life of circuit</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td><img src="image" alt="Circuit 12" /></td>
<td>( r^4 + \left(3 + \frac{\lambda_c}{\lambda}\right)r^3q + 3\left[1 + \frac{\lambda_c}{\lambda} - \left(\frac{\lambda_c}{\lambda}\right)^2\right]r^2q^2 + 6\left(\frac{\lambda_c}{\lambda}\right)^2 - 9\left(\frac{\lambda_c}{\lambda}\right)^2 + 4\left(\frac{\lambda_c}{\lambda}\right)^2 \right) r q^3 )</td>
<td>( \left[\frac{3}{4} + \frac{11}{6}\left(\frac{\lambda_c}{\lambda}\right) - \frac{5}{2}\left(\frac{\lambda_c}{\lambda}\right)^2 + \left(\frac{\lambda_c}{\lambda}\right)^3\right] m )</td>
</tr>
<tr>
<td>13</td>
<td><img src="image" alt="Circuit 13" /></td>
<td>( r^4 + \left(2 + 2\frac{\lambda_o}{\lambda}\right)r^3q + 6\frac{\lambda_o}{\lambda}r^2q^2 + \left[6\left(\frac{\lambda_o}{\lambda}\right)^2 - 4\left(\frac{\lambda_o}{\lambda}\right)^2\right] r q^3 )</td>
<td>( \left[\frac{5}{12} + \frac{2}{3}\left(\frac{\lambda_o}{\lambda}\right) + \frac{3}{2}\left(\frac{\lambda_o}{\lambda}\right)^2 - \left(\frac{\lambda_o}{\lambda}\right)^3\right] m )</td>
</tr>
<tr>
<td>14</td>
<td><img src="image" alt="Circuit 14" /></td>
<td>( r^4 + \left(2 + 2\frac{\lambda_c}{\lambda}\right)r^3q + 6\frac{\lambda_c}{\lambda}r^2q^2 + \left[6\left(\frac{\lambda_c}{\lambda}\right)^2 - 4\left(\frac{\lambda_c}{\lambda}\right)^2\right] r q^3 )</td>
<td>( \left[\frac{5}{12} + \frac{2}{3}\left(\frac{\lambda_c}{\lambda}\right) + \frac{3}{2}\left(\frac{\lambda_c}{\lambda}\right)^2 - \left(\frac{\lambda_c}{\lambda}\right)^3\right] m )</td>
</tr>
</tbody>
</table>

\( r = \) reliability of each unit,  
\( m = \int_0^\infty r \, dt = \frac{1}{\lambda}, \) mean life of each unit  
\( \lambda = \lambda_o + \lambda_c, \) the total failure rate of each unit  
\( \lambda_o = \) failure rate in the failing open mode  
\( \lambda_c = \) failure rate in the failing close mode
Appendix B

Sample Checklist for Design Review

This appendix provides the reader with a very detailed checklist and miscellaneous information about the FMEA. The intent of the checklist is to provide the reader with a structured tool that facilitates the questions regarding the system, design, process, and/or service. Obviously the checklist is not exhaustive. The miscellaneous information will guide the team with the flow of the FMEA, as well as the interrelationships of the FMEA with other tools in the development process. Specifically, the following information is provided:

• Sample checklists for design review
• System development process
• Considerations for a new product design
• Design FMEA procedure
• Process FMEA interrelationships
• Sequence of FMECA activities and responsibilities
• Design review schedule in relationship to program phases
• Reliability growth in terms of contract milestones
• Critical characteristics
Checklist

Portions of this checklist are adapted from questions and concerns from several Ford Motor Company publications and Logistics Engineering and Management by B. Blanchard (1986) with their permission. These questions will help teams identify missing information and problem areas. Read each question and answer it “Yes” or “No.” If necessary, write comments in the space provided below each question. Comments should indicate areas or items that are not complete and need additional information or work.

Engineering Drawings

1. Have all characteristics that affect fit, function, and durability been identified?
   Yes No
   Comments:

2. Are tolerances compatible with accepted manufacturing standards?
   Yes No
   Comments:

3. Are enough control points and datum lines identified to design functional gauges?
   Yes No
   Comments:

4. Are features dimensioned to prevent unnecessary loss of tolerance during normal processing?
   Yes No
   Comments:
5. Have all critical/significant characteristics been identified?
   Yes  No
   Comments:

6. Have feasibility meetings been held to establish the feasibility of the design?
   Yes  No
   Comments:

7. Have prints been drawn using geometric dimensioning and tolerancing principles with control points and datum lines identified for the design of gauges and test equipment? Will the gauges facilitate gathering variable data?
   Yes  No
   Comments:

8. Are there any requirements that must be inspected that cannot be evaluated using the known inspection techniques?
   Yes  No
   Comments:

9. Are tolerance stack-ups containable for assembly and function?
   Yes  No
   Comments:
10. Are all specified tests and requirements, including heat treat and metallurgical requirements, clearly defined and understood?
   Yes    No
   Comments:

11. Are required standards for color, grain, and so on available?
    Yes    No
    Comments:

12. Are there any requirements shown that cannot be evaluated using known inspection techniques?
    Yes    No
    Comments:

13. Are tolerance stack-ups containable?
    Yes    No
    Comments:

**Engineering Specifications**

14. Is test loading sufficient to provide all conditions (in other words, production validation, ongoing and annual recertification)?
    Yes    No
    Comments:
15. Have dimensional or material characteristics that affect ES durability testing results been included in the control plan?
Yes No
Comments:

16. Are all specified tests and requirements clearly defined and understood?
Yes No
Comments:

Materials Specifications

17. Are the intended material suppliers on the approved source list?
Yes No
Comments:

18. Will material suppliers be required to provide certification with each shipment?
Yes No
Comments:

19. Are specified materials, heat treat, and surface treatments suitable for the intended environment?
Yes No
Comments:
Design FMEA

20. Have operations that affect high-risk failure modes been identified?
   Yes         No
   Comments:

21. Have previous manufacturing experiences shown that high risk operations are not capable?
   Yes         No
   Comments:

22. Will new/untried processing techniques be employed that will affect high-risk operations?
   Yes         No
   Comments:

23. Have operations for capability studies been identified?
   Yes         No
   Comments:

24. Have design FMEAs been conducted? (A design FMEA is required on all parts having critical characteristics and recommended for all new parts.)
   Yes         No
   Comments:
25. Will a process FMEA be conducted?
   Yes  No
   Comments:

26. Is a process flow diagram available that shows the sequence of production and inspection stations?
   Yes  No
   Comments:

27. Was the process FMEA used as an aid to develop the process flow?
   Yes  No
   Comments:

28. Have provisions been made to send repaired material to an inspection station before being used?
   Yes  No
   Comments:

29. Has a list of possible quality problems been identified for off-line operations such as repair and salvage stations?
   Yes  No
   Comments:
30. Should a design of experiments analysis be used to improve capability?
   Yes    No
   Comments:
   __________________________________________________________
   __________________________________________________________

31. Are statistical control points identified?
   Yes    No
   Comments:
   __________________________________________________________
   __________________________________________________________

**Process FMEA**

32. Have all operations affecting fit, function, and durability been identified and listed in order?
   Yes    No
   Comments:
   __________________________________________________________
   __________________________________________________________

33. Have required corrective actions been planned or taken for high-risk operations?
   Yes    No
   Comments:
   __________________________________________________________
   __________________________________________________________

34. Were historical warranty and consuming plant problems used as aids in developing the process FMEA?
   Yes    No
   Comments:
   __________________________________________________________
   __________________________________________________________
35. Have provisions been made to conduct process potential studies on high-risk operations where the possibility of occurrence is the major factor?
   Yes    No
   Comments:

36. On operations where the FMEA shows detection as the major factor, have provisions been made in the quality plan to control the cause before the operation in question?
   Yes    No
   Comments:

37. Should a cause-and-effect analysis (fishbone diagram) be used to identify additional causes?
   Yes    No
   Comments:

38. Have high-risk failure modes and operations that affect them been identified?
   Yes    No
   Comments:

39. Have previous manufacturing experiences shown any high risk operations that are not capable?
   Yes    No
   Comments:
40. Will new/untried processing techniques be employed that will affect high-risk operations?
   Yes  No
   Comments:____________________________________________________________________

41. Have operations for capability studies been identified?
   Yes  No
   Comments:____________________________________________________________________

42. Has a process FMEA been conducted? (A process FMEA is required on all parts that have critical/significant characteristics and is recommended for all processes.)
   Yes  No
   Comments:____________________________________________________________________

43. Was a check of historical warranty and consuming plant problems used as an aid in developing the process FMEA?
   Yes  No
   Comments:____________________________________________________________________

**Manufacturing Floor Plan Considerations**

44. Are process and quality control stations large enough, well lighted, and include all necessary equipment and files?
   Yes  No
   Comments:____________________________________________________________________
45. Are repair areas logically located to prevent accidental shipment of defective material?
   Yes  No
   Comments:

46. Have provisions been made to post visual aids for critical operations?
   Yes  No
   Comments:

47. Are controls adequate to prevent movement of rejected incoming material to storage or point of use?
   Yes  No
   Comments:

**New Equipment List**

48. Has the new equipment list been reviewed and, in your best judgment, is the equipment adequate?
   Yes  No
   Comments:

49. Has process potential been demonstrated on the new equipment?
   Yes  No
   Comments:
50. Have inspection gauges been identified to conduct capability studies?
   Yes  No
   Comments:

51. Has adequate test equipment been provided?
   Yes  No
   Comments:

52. Have requirements for special gauges been defined?
   Yes  No
   Comments:

53. Are test capacities sufficient to provide additional sampling when defectives are found? Is the data recorded?
   Yes  No
   Comments:

54. Was machine potential established on the equipment builder’s floor before delivery?
   Yes  No
   Comments:
Comments and Conditions

55. Have causes of field failure modes been identified?
   Yes  No
   Comments:

56. Have actual or possible causes of consuming plant quality problems been identified?
   Yes  No
   Comments:

57. Are design changes needed to make characteristics in question more workable?
   Yes  No
   Comments:

58. Have process changes been planned or taken to eliminate all quality concerns?
   Yes  No
   Comments:

59. Have control charts and capability studies been planned for characteristics and causes in question?
   Yes  No
   Comments:
60. Are enough personnel available to cover control plan requirements, layout, ES durability testing, and problem analysis?
Yes No
Comments:

61. Have provisions been made to certify and routinely calibrate new gauge and test equipment?
Yes No
Comments:

62. Is there a procedure for controlling incoming quality from subsuppliers, that requires documentation of rejects and follow-up?
Yes No
Comments:

63. Is there a procedure available for the installation, maintenance, and reaction plan for statistical control charts?
Yes No
Comments:

64. Are forms available for inspections/auditors to log/tally inspection results?
Yes No
Comments:
65. Are routine warehouse audits used to ensure integrity of ongoing controls?
   Yes No
   Comments: 
   
Sample Size

66. Are sample sizes sufficient to handle multistation equipment?
   Yes No
   Comments: 
   
67. Are sample sizes compatible with preset minimum requirements?
   Yes No
   Comments: 
   
68. Are all operators and inspectors provided with an inspection instruction that is keyed to the control plan? Do they have a complete set of instructions that show how to control the part?
   Yes No
   Comments: 
   
69. On operations where the FMEA shows the chance of detection as insufficient, have provisions been made in the quality plan to control the cause, (in other words, reduce the occurrence) during or before the operation in question?
   Yes No
   Comments: 
   
   Sample Checklist for Design Review  CD-29
70. Was a cause-and-effect analysis (fishbone diagram) used to identify additional causes?
   Yes  No
   Comments:

Reaction Plan
71. Has a reaction plan been documented?
   Yes  No
   Comments:

72. Does the reaction plan include responsibilities for production, process engineering, and quality control?
   Yes  No
   Comments:

Special Conditions
73. Have all measuring devices been calibrated?
   Yes  No
   Comments:

New Equipment List
74. Can variables data be generated from the gauge?
   Yes  No
   Comments:
75. Have provisions been made to certify and routinely calibrate new gauge and test equipment?
   Yes No
   Comments:

    

Incoming Material

76. Are intended material suppliers on the approved source list?
   Yes No
   Comments:

    

77. Will material suppliers be required to provide certification data with each shipment? A certification letter is not satisfactory. Data that show statistical evidence of stability and capability must be provided.
   Yes No
   Comments:

    

78. Is there a procedure for controlling incoming quality from subsuppliers?
   Yes No
   Comments:

    

Control Plan

79. Has a control plan been established and approved by SQA?
   Yes No
   Comments:

    

80. Have dimensional performance or material characteristics that affect ES durability testing results been included in the control plan?
Yes  No
Comments:

81. Are routine finished-product audits used to ensure integrity of ongoing controls? Is a feedback system in place?
Yes  No
Comments:

82. Were gauge repeatability and reproducibility (R&R) studies completed?
Yes  No
Comments:

83. Have unusual occurrences been recorded in a log?
Yes  No
Comments:

84. Has the goal that the measurement system variation does not consume more than one-tenth of the specification tolerance been met?
Yes  No
Comments:
Quality Improvement

85. Have necessary DOE analyses been used to improve capability?
   Yes  No
   Comments:

86. Are design changes needed to make characteristics in question more workable?
   Yes  No
   Comments:

87. Have process changes been planned or taken to eliminate all quality concerns?
   Yes  No
   Comments:

Note: This checklist is not exhaustive. It is offered as a starting point of questioning the system, design, and/or process with the intent of improvement.

The following questions are arranged by system and design. The focus is to show the level of complexity that a checklist may take. In no way does this list pretend to be complete. The format and level is based on B. Blanchard’s work. It is used here with permission.

System Design

General

1.0 System Operational Requirements

- Has the mission been defined? Mission scenarios?
- Have all basic system performance parameters been defined?
• Has the planned operational deployment been defined (quantity of systems per location)?
• Has the system life cycle been defined?
• Have system utilization requirements been defined? This includes hours of system/equipment operation or quantity of operational cycles per a given time period. Define an operational cycle if used.
• Has the operational environment been defined in terms of temperature extremes, humidity, shock and vibration, storage, transportation, and handling?

2.0 Effectiveness Factors

• Have system availability, dependability, readiness, or equivalent operational effectiveness factors been identified?
• Have quantitative reliability and maintainability factors been specified? This includes MTBF, MTBM, MDT, M, Mct, Mpt, Mmax, MMH/OH, Cost/OH, Cost/MA, and so on.

3.0 System Maintenance Concept

• Have the echelons or levels of maintenance been specified and defined?
• Have basic maintenance functions been identified for each level?
• Have quantitative parameters been established for turnaround time (TAT) at each level and logistics pipeline time between levels?
• Has the logistics pipeline time between levels been minimized to the extent feasible considering cost? The lack of adequate supply responsiveness has a major detrimental effect on total logistic support.
• Have level of repair policies been established? Repair versus discard? Repair at intermediate/depot level?
• Have the criteria for level of repair decisions been adequately defined?
• Has the level of maintenance (organizational, intermediate, depot, or supplier) been defined for each repairable item?
• Have criteria been established for test and support equipment at each level of maintenance? Software?
• Have criteria been established for personnel quantities and/or skills at each level of maintenance?

4.0 Functional Analysis and Allocation
• Have system operational and maintenance functions been defined?
• Have reliability and maintainability factors been allocated to the appropriate system elements (for example, unit, assembly, subassembly, and so on)
• Have cost factors been allocated to the appropriate system elements?
• Have logistic support factors been allocated where appropriate?

5.0 Logistic Support Analysis
• Have trade-off evaluations and analyses been accomplished to support all logistic support requirements?
• Are the responses to all questions in the analysis checklist positive? These questions cover life cycle cost analyses, maintenance analyses, and logistics modeling.
• Does the logistic support analysis data package justify system design for supportability?
• Have trade-off evaluations and analyses been adequately documented?

6.0 Logistic Support Operational Plan
• Has a plan been developed for the design, production, acquisition, deployment, and integration of the prime equipment and logistic support elements in the field? This includes a preliminary logistic support plan and an integrated logistic support plan (ILSP).
• Has a plan been developed for the handling of system modifications in the field?
• Has a plan been developed covering system/equipment phaseout?
Logistical Support Elements

1.0 Test and Support Equipment

- Have the test and support equipment requirements been defined for each level of maintenance?

- Have standard test and support equipment items been selected? Newly designed equipment should not be necessary unless standard equipment is unavailable.

- Are the selected test and support equipment items compatible with the prime equipment? Does the test equipment do the job?

- Are the test and support equipment requirements compatible with logistic support analysis?

- Have test and support equipment requirements (both in terms of variety and quantity) been minimized to the greatest extent possible?

- Are the reliability and maintainability features in the test and support equipment compatible with those equivalent features in the prime equipment? It is not practical to select an item of support equipment that is not as reliable as the item it supports.

- Have logistic support requirements for the selected test and support equipment been defined? This includes maintenance tasks, test equipment, spare/repair parts, personnel and training, data, and facilities.

- Is the test and support equipment selection process based on cost-effectiveness considerations (in other words, life cycle cost)?

- Have test and maintenance software requirements been adequately defined?

2.0 Supply Support (Spare/Repair Parts)

- Are the types and quantity of spare/repair parts compatible with the level of repair analysis?

- Are the types and quantity of spare/repair parts designated for a given location appropriate for the estimated demand at that location? Too many or too few parts can be costly.
• Are spare/repair part provisioning factors consistent with logistic support analysis?

• Are spare/repair part provisioning factors directly traceable to reliability and maintainability predictions?

• Are the specified logistics pipeline times compatible with effective supply support? Long pipeline times place a tremendous burden on logistic support.

• Have spare/repair parts been identified and provisioned for preoperational support activities (for example, interim supplier support, test programs, and so on)?

• Have spare/repair part requirements been minimized to the maximum extent possible?

• Have test and acceptance procedures been developed for spare/repair parts? These should be processed, produced, and accepted on a similar basis with their equivalent components in the prime equipment.

• Have the consequences (risks) of stock-out been defined in terms of effect on mission requirements and cost?

• Has an inventory safety stock level been defined?

• Has a provisioning or procurement cycle been defined (procurement or order frequency)?

• Has a supply availability requirement been established (the probability of having a spare available when required)?

3.0 Personnel and Training

• Have operational and maintenance personnel requirements (quantity and skill levels) been defined?

• Are operational and maintenance personnel requirements minimized to the greatest extent possible?

• Are operational and maintenance personnel requirements compatible with logistic support analysis and with human factors data?

• Are the planned personnel skills levels at each location compatible with the complexity of the operational and maintenance tasks specified?
• Has maximum consideration been given to the use of existing personnel skills for new equipment?

• Have personnel attrition rates been established?

• Have personnel effectiveness factors been determined (actual time that work is accomplished per the total time allowed for work accomplishment)?

• Have operational and maintenance training requirements been specified? This includes consideration of both initial training and replenishment training throughout the life cycle.

• Have specific training programs been planned? The type of training, frequency of training, duration of training, and student entry requirements should be identified.

• Are the planned training programs compatible with the personnel skill level requirements specified for the performance of operational and maintenance tasks?

• Have training equipment requirements been defined? Acquired?

• Have maintenance provisions for training equipment been planned?

• Have training data requirements been defined?

• Are the planned operating and maintenance procedures (designated for support of the system throughout its life cycle) utilized to the maximum extent possible in the training program?

4.0 Technical Data (Operating and Maintenance Procedures)

• Have operating and maintenance procedure requirements been defined? Have the necessary procedures been prepared?

• Are operating and maintenance procedures compatible with logistic support analysis data? This pertains particularly to the logic troubleshooting flow diagrams, task sequences, and support requirements defined in the maintenance analysis.

• Are operating and maintenance procedures as brief as possible without sacrificing necessary information?
• Are operating and maintenance procedures adequate from the standpoint of presenting simple step-by-step instructions; including appropriate use of illustrations and tables for presenting data?

• Are operating and maintenance procedures compatible with the level of activity performed at the location where the procedures are used? Depot maintenance instructions should not be included in manuals which are used at the intermediate level of maintenance. The maintenance procedures should be compatible with the level of repair analysis and the maintenance concept.

• Are operating and maintenance procedures written at the skill level of the individual accomplishing the functions covered by the procedures? Procedures should be written in a simple, clear, and concise manner for low-skilled personnel.

• Do the operating and maintenance procedures specify the correct test and support equipment, spare/repair parts, transportation and handling equipment, and facilities?

• Do the procedures include special warning notices in areas where safety is a concern?

• Are the designated operating and maintenance procedures used in system/equipment test programs?

5.0 Facilities and Storage

• Have facility requirements (space, volume, capital equipment, utilities, and so on) necessary for system operation been defined?

• Have facility requirements (space, volume, capital equipment, utilities, and so on) necessary for system maintenance at each level been defined?

• Have operational and maintenance facility requirements been minimized to the greatest extent possible?

• Have environmental system requirements (for example, temperature, humidity, and dust control) associated with operational and maintenance facilities been identified?

• Have storage or shelf-space requirements for spare/repair parts been defined?

• Have storage environments been defined?
• Are the designated facility and storage requirements compatible with the logistic support analysis and human factors data?

6.0 Transportation and Handling

• Are transportation and handling requirements for both operational and maintenance functions defined? This includes transportation of prime equipment, test and support equipment, spares, personnel, and data. National and international requirements should be identified.

• Are transportation and handling environments (temperature, shock and vibration, exposure to dust and salt spray, storage, and so on) defined?

• Are the modes (air, ground vehicle, rail, sea, or a combination) of transportation known? A profile or scenario, similar to that accomplished for mission definition, should be developed showing the various transportation and handling requirements.

• Are the requirements for reusable containers known? Design information should be developed on reusable containers.

• Are the requirements for packing known? This includes labor, material, preservation, storage limitations, and the processing of an item for shipment.

Design Features

1.0 Selection of Parts

• Have appropriate standards been consulted for the selection of components?

• Have all component parts and materials selected for the design been adequately evaluated prior to their procurement and application? Evaluation should consider performance parameters, reliability, maintainability, and human factors.

• Have supplier sources for component part procurement been established?
• Are the established supplier sources reliable in terms of quality level, ability to deliver on time, and willingness to accept part warranty provisions?

• Have the reliability, maintainability, and human factors engineers been consulted in the selection and application of parts? Reliability is concerned with part failure rates, stresses, tolerances, allowable temperature extremes, signal ratings, and so on. Maintainability and human factors are concerned with the part effects on maintenance times, mounting provisions, human interfaces, and so on.

2.0 Standardization

• Are standard equipment items and parts incorporated in the design to the maximum extent possible (except for items not compatible with effectiveness factors)? Maximum standardization is desirable.

• Are the same items and/or parts used in similar applications?

• Are the number of different part types used throughout the design minimized? In the interest of developing an efficient supply support capability, the number of different item spares should be held to a minimum.

• Are identifying equipment labels and nomenclature assignments standardized to the maximum extent possible?

• Are equipment control panel positions and layouts (from panel to panel) the same or similar when a number of panels are incorporated and provide comparable functions?

3.0 Test Provisions

• Have self-test provisions been incorporated where appropriate?

• Is the extent or depth of self-testing compatible with the level or repair analysis?

• Are self-test provisions automatic?

• Have direct fault indicators been provided (either a fault light, an audio signal, or a means of determining that a malfunction positively exists)? Are continuous performance monitoring provisions incorporated where appropriate?
• Are test points provided to enable checkout and fault isolation beyond the level of self-test? Test point for fault isolation within an assembly should not be incorporated if the assembly is to be discarded at failure. Test point provisions must be compatible with the level of repair analysis.

• Are test points accessible? Accessibility should be compatible with the extent of maintenance performed. Test points on the operator’s front panel are not required for a depot maintenance action.

• Are test points functionally and conveniently grouped to allow for sequential testing (following a signal flow), testing of similar functions, or frequency of use when access is limited?

• Are test points adequately provided for a direct test of all replaceable items?

• Are test points adequately labeled? Each test point should be identified with a unique number, and the proper signal or expected measured output should be specified on a label located adjacent to the test point.

• Are test points adequately illuminated to allow the technician to see the test point number and labeled signal value?

• Can every equipment malfunction (degradation beyond specification tolerance limits) which could possibly occur in the equipment be detected through a no-go indication at the system level? This is a measure of test thoroughness.

• Will the prescribed maintenance software provide adequate diagnostic information?

4.0 Packaging and Mounting

• Is functional packaging incorporated to the maximum extent possible? Interaction effects between modular packages should be minimized: It should be possible to limit maintenance to the removal of one module (the one containing the failed part) when a failure occurs and not require the removal of two, three, or four modules.

• Is the packaging design compatible with level of repair analysis decisions? Repairable items are designed to include maintenance provisions such as test points, accessibility, plug-in components, and so on. Items classified as discard at failure should be
encapsulated and relatively low in cost. Maintenance provisions within the disposable module are not required.

- Are disposable modules incorporated to the maximum extent practical? It is highly desirable to reduce overall support through a no-maintenance design concept as long as the items being discarded are relatively high in reliability and low in cost.

- Are plug-in modules and components utilized to the maximum extent possible (unless the use of plug-in components significantly degrades the equipment reliability)?

- Are accesses between modules adequate to allow for hand grasping? Are modules and components mounted such that the removal of any single item for maintenance will not require the removal of other items? Component stacking should be avoided where possible.

- In areas where module stacking is necessary because of limited space, are the modules mounted in such a way that access priority has been assigned in accordance with the predicted removal and replacement frequency? Items requiring frequent maintenance should be more accessible.

- Are modules and components, not of the plug-in variety, mounted with four fasteners or less? Modules should be securely mounted, but the number of fasteners should be held to a minimum.

- Are shock-mounting provisions incorporated where shock and vibration requirements are excessive?

- Are provisions incorporated to preclude installation of the wrong module?

- Are plug-in modules and components removable without the use of tools? If tools are required, they should be of the standard variety.

- Are guides (slides or pins) provided to facilitate module installation?

- Are modules and components labeled?

- Are modules and component labels located on top or immediately adjacent to the item and in plain sight?

- Are the labels permanently affixed and unlikely to come off during a maintenance action or as a result of environment? Is the
information on the label adequate? Disposable modules should be so labeled.

• In equipment racks, are the heavier items mounted at the bottom of the rack? Unit weight should decrease with the increase in installation height.

• Are operator panels optimally positioned? For personnel in the standing position, panels should be located between 40 and 70 inches above the floor. Critical or precise control should be between 48 and 64 inches above the floor. For personnel in the sitting position, panels should be located 30 inches above the floor. Refer to the latest reference on anthropometric data.

5.0 Interchangeability

• Are modules and components having similar functions electrically, functionally, and physically interchangeable?

• Are components with the same part number but provided by different suppliers completely interchangeable?

6.0 Accessibility

• Are access doors provided where appropriate? Are hinged doors utilized?

• Are access openings adequate in size and optimally located for the access required?

• Are access doors and openings labeled in terms of items that are accessible from within?

• Can access doors that are hinged be supported in the open position?

• Are access door fasteners minimized?

• Are access door fasteners of the quick-release variety?

• Can access be attained without the use of tools?

• If tools are required to gain access, are the number of tools held to a minimum? Are the tools the standard variety?

• Are accesses between modules and components adequate?
• Are access requirements compatible with the frequency of maintenance? Accessibility for items requiring frequent maintenance should be greater than that for items requiring it infrequently.

7.0 Handling

• For heavy items, are hoist lugs (lifting eyes) or base-lifting provisions for forklift-truck application incorporated? Hoist lugs should be provided on all items weighing more than 150 pounds.

• Are hoist and base-lifting points identified relative to lifting capacity? Are weight labels provided?

• Are packages, units, components, or other items weighing over 10 pounds provided with handles? Are the proper size handles used, and are they located in the right position? Are the handles optimally located from the weight-distribution standpoint? (Handles should be located over the center of gravity.)

• Are packages, units, or other items weighing more than 40 pounds provided with two handles (for two-person carrying capability)?

• Are containers, cases, or covers provided to protect equipment vulnerable areas from damage during handling?

8.0 Fasteners

• Are quick-release fasteners used on doors and access panels?

• Are the total number of fasteners minimized?

• Are the number of different types of fasteners held to a minimum? This relates to standardization.

• Have fasteners been selected based on the requirement for standard tools in lieu of special tools?

9.0 Panel Displays and Controls

• Are controls standardized?

• Are controls sequentially positioned?

• Is control spacing adequate?

• Is control labeling adequate?
• Have the proper control/display relationships been incorporated?
• Are the proper type of switches used?
• Is the control panel lighting adequate?
• Are the controls placed according to frequency of use?
• Has a human factor engineer been consulted relative to controls and panel design?

10.0 Adjustments and Alignments

• Are adjustment requirements and frequencies known?
• Have adjustment requirements been minimized?
• Are adjustment points accessible?
• Are adjustment-point locations compatible with the maintenance level at which the adjustment is made?
• Are adjustment interactions effects eliminated?
• Are factory adjustments specified?
• Are adjustment points adequately labeled?

11.0 Cables and Connectors

• Are cables fabricated in removable sections?
• Are cables routed to avoid sharp bends?
• Are cables routed to avoid pinching?
• Is cable labeling adequate?
• Is cable clamping adequate?
• Are connectors of the quick-disconnect variety?
• Are connectors that are mounted on surfaces far enough apart so that they can be firmly grasped for connecting and disconnecting?
• Are connectors and receptacles labeled?
• Are connectors and receptacles keyed?
• Are connectors standardized?
• Do the connectors incorporate provisions for moisture prevention?
12.0 Servicing and Lubrication

- Have servicing requirements been held to a minimum?
- When servicing is indicated, are the specific requirements identified? This includes frequency of servicing and the materials needed.
- Are procurement sources for servicing materials known?
- Are servicing points accessible?
- Have personnel and equipment requirements for servicing been identified? This includes handling equipment, vehicles, carts, and so on.
- Does the design include servicing indicators?

13.0 Calibration

- Have calibration requirements been held to minimum?
- Are calibration requirements known?
- Are calibration frequencies known?
- Are calibration tolerances known?
- Are standards available for calibration?
- Are calibration procedures prepared?
- Is traceability to the National Bureau of Standards possible?
- Have the facilities for calibration been identified?
- Are the calibration requirements compatible with the logistic support analysis and the maintenance concept?

14.0 Environment

- Has the equipment design considered the following: temperature, shock, vibration, humidity, pressure, wind, salt spray, sand and dust, rain, fungus, and radiation? Have the ranges and extreme conditions been specified and properly addressed in design?
- Have provisions been made to specify and control noise, illumination, humidity, and temperature in areas where personnel are required to perform operating and maintenance functions?
15.0 Storage

- Can the equipment and spare parts be stored for extended periods of time without excessive degradation (beyond specification limits)?
- Have scheduled maintenance requirements for stored equipment been defined?
- Have scheduled maintenance requirements for stored equipment been eliminated or minimized?
- Have the required maintenance resources necessary to service stored equipment been identified?
- Have storage environments been defined?
- Has the need for specialized environmentally controlled facilities been eliminated where possible?

16.0 Transportability

- Have transportation and handling requirements been defined?
- Have transportation requirements been considered in the equipment design? This includes consideration of temperature ranges, vibration and shock, humidity, and so on. Has the possibility of equipment degradation been minimized if transported by air, ground vehicle, ship, or rail?
- Can the equipment be easily disassembled, packed, transported from one location to another, reassembled, and operated with a minimum of performance and reliability degradation?
- Have container requirements been defined?
- Have the requirements for ground-handling equipment been defined?
- Was the selection of handling equipment based on cost effectiveness considerations?

17.0 Producibility

- Has the design been stabilized (minimum change)?
- Has the design been verified through prototype and qualification testing?
Is the design such that many models of the same item can be produced with identical results?

Are the production databases, drawings, and material lists adequate?

Are common materials used (in lieu of special materials)?

Can standard tooling and existing facilities be used for fabrication, assembly, and test operations?

Is the design such that rework requirements are minimized? Are spoilage factors held to a minimum?

Are standard fabrication, assembly, test, and inspection procedures applicable?

Is the design such that automated manufacturing processes (for example, robotics or numerical control techniques) can be applied for repetitive functions?

Is the design definition such that two or more suppliers can produce the equipment from a set of specifications and drawings with identical results?

18.0 Safety

Have fail-safe provisions been incorporated in the design?

Have protruding devices been eliminated or are they suitably protected?

Have provisions been incorporated for protection against high voltages? Are all external metal parts adequately grounded?

Are sharp metal edges, access openings, and corners protected with rubber, fillets, fiber, or plastic coating?

Are electrical circuit interlocks employed?

Are standoffs or handles provided to protect equipment from damage during the performance of bench maintenance?

Are tools that are used near high-voltage areas adequately insulated at the handle or at other parts of the tool which the maintenance person is likely to touch?
• Are the environments protected so that personnel safety is ensured? Are noise levels within a safe range? Is illumination adequate? Is the air relatively clean? Are the temperatures at a proper level?

• Has the proper protective clothing been identified for areas where the environment could be detrimental to human safety? Radiation, intense cold or heat, gas, and loud noise are examples.

• Are safety equipment requirements identified in areas where ordnance devices and the like are activated?

• Has a system hazard analysis been completed where required?

19.0 Reliability

• Has the system/equipment wear-out period been defined?

• Have failure modes and effects been identified?

• Are item failure rates known?

• Have parts with excessive failure rates been identified?

• Has mean life been determined?

• Have adequate derating factors been established and adhered to where appropriate?

• Has equipment design complexity been minimized?

• Is protection against secondary failures (resulting from primary failures) incorporated where possible?

• Has the use of adjustable components been minimized?

• Has the use of friction or pressure contacts in mechanical equipment been avoided?

• Have all critical, useful-life items been eliminated from the equipment design?

• Have cooling provisions been incorporated in design hot spot areas? Is cooling directed toward the most critical items?

• Have all reliability program requirements been met?
20.0 Software

- Have all system software requirements for maintenance activities been met?

- Is the maintenance software complete in terms of scope and depth of coverage?

- Is the software compatible relative to the equipment with which it interfaces? Is the maintenance software compatible with the operating software? With other elements of the system?

- Is the maintenance software language compatible with system language requirements in general?

- Has the software been adequately tested and verified for accuracy and reliability?
Figure B.2 Process flow diagram of typical considerations of a new product to be produced.
### Design FMEA Procedure

**Mode examples**
- Deformed
- Fractured
- Broken weld

**Effect examples**
- Inoperable
- False readings
- Bad sample
- Cannot assemble

**Cause examples**
- Overstressing
- Incorrect assembly spec.
- Incorrect material spec.
- Undercured

#### Figure B.3 Design FMEA procedure.
Sample Checklist for Design Review

**Feasibility analysis**
- Process/inspection flowchart
- Process FMEA
- Floor plan
- Historical warranty quality analysis
- New equipment list
- Previous statistical studies
- Design of experiments
- Cause-and-effect diagram

**SQA quality system**

Is the system approved by the customer?

Will SPC and quality procedures defined support the control plan?

Use the process FMEA to create the process sheets

**Manufacturing control plan**
- Quality system procedures
- Key process/product characteristics
- Sample size/frequency
- Inspection methods
- Reaction plan
- Statistical methods
- Problem-solving discipline

(1) Have key/critical characteristics been identified for SPC?

(2) Are control charts used for all key characteristics?

(3) Does the control plan have the customer's concurrence?

(4) Is 100 percent inspection a requirement for operations in the process?

(5) Is the process qualified for sign-off?

(6) Are the control plan requirements met in the process?

**Process potential study**
- Statistical training
- Implementation
- Results

**Process sign-off**
- Process sheets
- Inspection instructions
- Test equipment/gauges
- Initial samples
- Packaging

**Job #1**

Never-ending quality improvement

**Identify preventative actions**

**Monitor causes of concerns**

**Figure B.4** Process FMEA interrelationships.
Table B1  Sequence of FMECA activities and responsibilities.

<table>
<thead>
<tr>
<th>Component design engineer</th>
<th>System design engineer</th>
<th>Project reliability engineer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prepare analyses of all component failure modes and associated detection means. Submit analyses to system design engineer.</td>
<td>Determine effects of each components failure mode on subsystem. Identify those component failure modes that would result in subsystem failure.</td>
<td>Prepare failure mode analysis control log for components and subsystems. Distribute component failure modes analysis forms and subsystems failure modes analysis forms to responsible design groups.</td>
</tr>
<tr>
<td>Review critical items list and recommendations. Wherever feasible, incorporate design changes that will produce or reduce component criticality. Record action taken for every critical component. Prepare recommendations for those parts that remain critical. Submit action taken to reduce component criticality and recommendations for component design changes to project reliability engineer.</td>
<td>Conduct criticality analysis. Prepare order list of critical components. Prepare recommendations for criticality reduction. Submit critical components list and recommendations to system design engineer.</td>
<td>Revise critical components list in accordance with reduction in parts criticality through subsystem redesign. Delete those components that are no longer critical. Prepare additional recommendations for those components list and recommendations to component designers.</td>
</tr>
<tr>
<td>Wherever feasible, incorporate design changes that will reduce component criticality through use of part redundancy, part derating, redesign to fail-safe, etc. Submit action taken to reduce criticality of components to project reliability engineer.</td>
<td>Prepare final critical components list to identify those components that are still critical. Submit final critical component list to quality control for implementation of special control of critical components. Distribute copies of critical components list to responsible design groups. As design changes are made, the entire process is reiterated to insure that the critical components list is compatible with the latest design.</td>
<td></td>
</tr>
</tbody>
</table>

Table B.2  A typical design review schedule in relationship to process phases.

<table>
<thead>
<tr>
<th>Conceptual phase</th>
<th>Preliminary system design phase (validation)</th>
<th>Detail design and development phase (full-scale development)</th>
<th>Production and/or construction phase</th>
<th>System use and life cycle support phase (deployment)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feasibility studies, operational and maintenance concepts</td>
<td>System analysis optimization, synthesis, and definition</td>
<td>Detail equipment design, layouts, part lists, drawing, support data</td>
<td>Fabrication, assembly, test, inspect, and deploy operational system</td>
<td>Operate and maintain system in the field</td>
</tr>
</tbody>
</table>

Appendix C

Active Verbs and Nouns Used for Function

This appendix provides the reader with an example of verbs, nouns, and functions used in the construction of the FMEA. For obvious reasons, this is not an exhaustive list, but a sample of how the reader may go about starting the thinking process for the construction of an FMEA.
## Table C.1  Verbs and nouns for system/design FMEAs.

<table>
<thead>
<tr>
<th>Verbs</th>
<th>Nouns</th>
</tr>
</thead>
<tbody>
<tr>
<td>actuate</td>
<td>insulate</td>
</tr>
<tr>
<td>amplify</td>
<td>interrupt</td>
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<tr>
<td>apply</td>
<td>limit</td>
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<tr>
<td>change</td>
<td>locate</td>
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<tr>
<td>close</td>
<td>maintain</td>
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<tr>
<td>collect</td>
<td>module</td>
</tr>
<tr>
<td>conduct</td>
<td>mount</td>
</tr>
<tr>
<td>contain</td>
<td>move</td>
</tr>
<tr>
<td>control</td>
<td>prevent</td>
</tr>
<tr>
<td>create</td>
<td>protect</td>
</tr>
<tr>
<td>decrease</td>
<td>rectify</td>
</tr>
<tr>
<td>emit</td>
<td>reduce</td>
</tr>
<tr>
<td>establish</td>
<td>repel</td>
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<tr>
<td>fasten</td>
<td>rotate</td>
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<tr>
<td>filter</td>
<td>secure</td>
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<tr>
<td>hold</td>
<td>shield</td>
</tr>
<tr>
<td>ignite</td>
<td>shorten</td>
</tr>
<tr>
<td>impede</td>
<td>space</td>
</tr>
<tr>
<td>improve</td>
<td>support</td>
</tr>
<tr>
<td>increase</td>
<td>time (verb)</td>
</tr>
<tr>
<td>induce</td>
<td>transmit</td>
</tr>
</tbody>
</table>

appearance | light |
circuit | liquid |
contacts | noise |
contamination | oxidation |
convenience | paint |
current | panel |
damage | piston |
density | protection |
dust | radiation |
effect | repair |
energy | rust |
features | style |
flow | switch |
fluid | symmetry |
force | torque |
form | vibration |
friction | voltage |
heat | volume |
insulation | weight |

A partial list of verbs and nouns used in the construction of a system FMEA is provided.
<table>
<thead>
<tr>
<th>Verbs</th>
<th>Nouns</th>
</tr>
</thead>
<tbody>
<tr>
<td>allow</td>
<td>minimize</td>
</tr>
<tr>
<td>apply</td>
<td>modify</td>
</tr>
<tr>
<td>bake</td>
<td>move</td>
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<tr>
<td>band</td>
<td>produce</td>
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<tr>
<td>compress</td>
<td>receive</td>
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<tr>
<td>convey</td>
<td>reduce</td>
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<tr>
<td>decrease</td>
<td>remove</td>
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<tr>
<td>discard</td>
<td>resist</td>
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<tr>
<td>drive</td>
<td>restrict</td>
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<tr>
<td>dry</td>
<td>shape</td>
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<tr>
<td>eliminate</td>
<td>sort</td>
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<tr>
<td>friction</td>
<td>stake</td>
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<tr>
<td>finish</td>
<td>store</td>
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<tr>
<td>fire</td>
<td>support</td>
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<tr>
<td>form</td>
<td>transmit</td>
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<tr>
<td>generate</td>
<td>transport</td>
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<tr>
<td>improve</td>
<td>weigh</td>
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<tr>
<td>lift</td>
<td>wrap</td>
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<tr>
<td>load</td>
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</tr>
</tbody>
</table>

A partial list of verbs and nouns used in the construction of a process FMEA is provided.
Table C.3  Typical functions used in FMEA.

<table>
<thead>
<tr>
<th>Function</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>accept</td>
<td>reinforce</td>
</tr>
<tr>
<td>attach</td>
<td>remain instact</td>
</tr>
<tr>
<td>bearing surface</td>
<td>retain</td>
</tr>
<tr>
<td>conduct</td>
<td>return to normal position</td>
</tr>
<tr>
<td>connect</td>
<td>seal in</td>
</tr>
<tr>
<td>contain</td>
<td>seal out</td>
</tr>
<tr>
<td>damp</td>
<td>secure</td>
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<tr>
<td>indicate</td>
<td>sense</td>
</tr>
<tr>
<td>insulate</td>
<td>shield</td>
</tr>
<tr>
<td>isolate</td>
<td>store</td>
</tr>
<tr>
<td>locate</td>
<td>support</td>
</tr>
<tr>
<td>lubricate</td>
<td>transfer</td>
</tr>
<tr>
<td>position</td>
<td>transmit</td>
</tr>
<tr>
<td>protect</td>
<td>transport</td>
</tr>
<tr>
<td>provide pivot axis</td>
<td>vent</td>
</tr>
<tr>
<td>provide signal</td>
<td></td>
</tr>
</tbody>
</table>

Typical functions used in the construction of an FMEA.
Appendix D

FMEA Samples

This appendix provides samples as opposed to examples of FMEAs. The reason for this is because some of the FMEAs are quite lengthy and will detract from the purpose of providing the reader with a variety of examples in different stages.

System FMEAs
   Example 1: Sample of a Generic System FMEA
   Example 2: Fidd Quad LSD

Design FMEAs
   Example 3: Throttle Body Machine (Print, Flow Diagram, and Design FMEA)
   Example 4: Package/Layout
   Example 5: Armature

Product Design and Development FMEA
   Example 6: Cooling Fan Assembly

Process FMEAs
   Example 7: Nitride Etch
   Example 8: Slit Base Laminate
   Example 9: GDS Assembly
Service FMEA
  *Example 10*: Complaint Diagnosis

FTA Development
  *Example 11*: FTA Development of an Air Pumping System

Machine FMEA
  *Example 12*: Modular Oven
### Example 1
Sample of a generic system FMEA.

<table>
<thead>
<tr>
<th>Item Identification</th>
<th>Function</th>
<th>Failure mode</th>
<th>Failure cause</th>
<th>Component or functional assembly</th>
<th>Next higher assembly</th>
<th>System</th>
<th>Failure detection method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Switch</td>
<td>Initiates motor power function</td>
<td>Fails to open</td>
<td>Release spring failure Contacts fused</td>
<td>None</td>
<td>Maintains energy to circuit relay</td>
<td>Maintains energy to power circuit through relay</td>
<td>Motor continues to run</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Smoke—visual when power circuit wire overheats</td>
</tr>
<tr>
<td>Battery #2 (relay circuit)</td>
<td>Provides relay voltage</td>
<td>Fails to provide adequate power</td>
<td>Depleted battery Plates shorted</td>
<td>None</td>
<td>Battery gets hot and depletes</td>
<td>Fails to operate relay circuit</td>
<td>System fails to operate</td>
<td>Motor not running</td>
</tr>
<tr>
<td>Relay (relay coil)</td>
<td>Closes relay contacts when energized</td>
<td>Coil fails to produce EMF</td>
<td>Coil shorted or open</td>
<td>Does not close relay contacts</td>
<td>Does not energize power circuit</td>
<td>System fails to operate</td>
<td>Motor not running</td>
<td></td>
</tr>
<tr>
<td>Relay contacts</td>
<td>Energizes and de-energizes power circuit</td>
<td>Fails to open</td>
<td>Contacts fused</td>
<td>None</td>
<td>Maintains energy to motor</td>
<td>Overheated power circuit wire if motor is shorted and circuit breaker fails to open</td>
<td>Motor continues to run</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Smoke—visual</td>
</tr>
<tr>
<td>Motor</td>
<td>Provides desired mechanical event</td>
<td>Fails to operate</td>
<td>Motor shorted</td>
<td>Motor overheats</td>
<td>High current in power circuit</td>
<td>Overheated power circuit wire if motor is shorted and circuit breaker fails to open</td>
<td>Smoke—visual</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Circuit breaker</td>
<td>Provides power circuit fusing</td>
<td>Fails to open</td>
<td>Contacts fused</td>
<td>None</td>
<td>Maintains power in motor if relay contacts are closed</td>
<td>Maintains energy to motor</td>
<td>Motor continues to run</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Smoke—visual</td>
</tr>
<tr>
<td>Battery #1 (power circuit)</td>
<td>Provides motor voltage</td>
<td>Fails to provide adequate power</td>
<td>Depleted battery Plates shorted</td>
<td>None</td>
<td>Battery gets hot and depletes</td>
<td>None</td>
<td>System fails to operate</td>
<td>Motor not running</td>
</tr>
</tbody>
</table>

**Remarks**
- Motor continues to run when the power circuit wire overheats.
- Smoke—visual when the power circuit wire overheats.
<table>
<thead>
<tr>
<th>Part name and number</th>
<th>Potential failure mode</th>
<th>Potential effect(s) of failure</th>
<th>Severity</th>
<th>Potential cause(s) of failure</th>
<th>Occurrence</th>
<th>Design verification</th>
<th>Defect R. P. N.</th>
<th>Recommended action(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Load dump to 60V</td>
<td>Device self-protects and protects load</td>
<td>2</td>
<td>Alternator load dump</td>
<td>3</td>
<td>Load dump test at to 60V (final test)</td>
<td>2</td>
<td>Statistical testing</td>
<td></td>
</tr>
<tr>
<td></td>
<td>IC is DC protected to 60V, output turns off at ~35V</td>
<td>8</td>
<td>Alternator load dump and zener failure</td>
<td>2</td>
<td>Characterization test of samples to detect</td>
<td>2</td>
<td>None (outside spec)</td>
<td></td>
</tr>
<tr>
<td>Load dump to &gt;60V</td>
<td>Transient SOA stress on high V. PNPs</td>
<td>8</td>
<td>Alternator load dump and zener failure</td>
<td>2</td>
<td>Characterization test of samples to detect</td>
<td>2</td>
<td>None (outside spec)</td>
<td></td>
</tr>
<tr>
<td>(protection zener failure)</td>
<td>What is probability of this double failure mode?</td>
<td>8</td>
<td>Alternator load dump and zener failure</td>
<td>2</td>
<td>Characterization test of samples to detect</td>
<td>2</td>
<td>None (outside spec)</td>
<td></td>
</tr>
<tr>
<td>S/C to GND (outputs) (pins 1, 2, 14, 15)</td>
<td>Output shorted to ground</td>
<td>1</td>
<td>Shorted load to ground</td>
<td>3</td>
<td>None</td>
<td>2</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Shows up as off-state open CCT fault</td>
<td>1</td>
<td>Shorted load to ground</td>
<td>3</td>
<td>None</td>
<td>2</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>S/C to GND (inputs) (Pins 3, 4, 12, 13, 5, 11)</td>
<td>Inputs shorted to ground</td>
<td>1</td>
<td>Shorted load to ground</td>
<td>3</td>
<td>None</td>
<td>2</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Device permanently off, status shows OK—resolved by status flag change</td>
<td>1</td>
<td>Shorted load to ground</td>
<td>3</td>
<td>None</td>
<td>2</td>
<td>None</td>
<td></td>
</tr>
</tbody>
</table>

Example 2 Fidd Quad LSD.
<table>
<thead>
<tr>
<th>Part name and number</th>
<th>Part function</th>
<th>Potential failure mode</th>
<th>Potential effect(s) of failure</th>
<th>S e v</th>
<th>Potential cause(s) of failure</th>
<th>O c c</th>
<th>Design verification</th>
<th>D e t</th>
<th>R. P. N.</th>
<th>Recommended action(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>S/C to GND (select)</td>
<td>PW select shorted to GND</td>
<td>1</td>
<td></td>
<td>Shorted lead to ground</td>
<td>3</td>
<td>None</td>
<td>1</td>
<td>3</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>(pin 6)</td>
<td></td>
<td></td>
<td></td>
<td>(No note present)</td>
<td></td>
<td>(No note present)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>HLOS mode not available</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>S/C to GND (VCC)</td>
<td>VCC shorted to GND</td>
<td>1</td>
<td></td>
<td>Spanner across battery pin 7</td>
<td>4</td>
<td>None</td>
<td>2</td>
<td>8</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>(pin 7) [also S/C to</td>
<td></td>
<td></td>
<td></td>
<td>and 8 shorted</td>
<td></td>
<td>(No note present)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>VCC (GND)]</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(No note present)</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Let’s hope a fuse blows!</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>S/C to GND (GND)</td>
<td>GND shorted to GND</td>
<td>1</td>
<td></td>
<td>None</td>
<td>3</td>
<td>None</td>
<td>2</td>
<td>6</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>(pin 8) [also S/C to</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(No note present)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>VCC (VCC)]</td>
<td></td>
<td></td>
<td></td>
<td>N/A</td>
<td></td>
<td>(No note present)</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>S/C to GND (test pin)</td>
<td>Test pin shorted to GND</td>
<td>1</td>
<td></td>
<td>Pin 8 and 9 shorted</td>
<td>2</td>
<td>None</td>
<td>3</td>
<td>6</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>(pin 9)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(No notes present)</td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

*Example 2*  
Fidd Quad LSD.
<table>
<thead>
<tr>
<th>Part name and number</th>
<th>Potential failure mode</th>
<th>Potential effect(s) of failure</th>
<th>Potential cause(s) of failure</th>
<th>Design verification</th>
<th>Recommended action(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>S/C to VCC (outputs) (pins 1, 2, 14, 15)</td>
<td>Nonfunctioning load</td>
<td>1</td>
<td>Shorted solenoid, incorrect wiring</td>
<td>3</td>
<td>Final test for S/C operation</td>
</tr>
<tr>
<td><strong>S/C to VCC (IPs select, test pin) (pins 3, 4, 12, 13, 5, 11, 6, 9)</strong></td>
<td>S/C operation applies (I limit then shutdown cycle)</td>
<td></td>
<td>(No note present)</td>
<td>(No note present)</td>
<td></td>
</tr>
<tr>
<td><strong>S/C to 5V rail (output) (pins 1, 2, 14, 15)</strong></td>
<td>Semifunctioning load</td>
<td>1</td>
<td>Incorrect wiring</td>
<td>2</td>
<td>Final test for S/C operation</td>
</tr>
<tr>
<td><strong>Example 2</strong></td>
<td>Fidd Quad LSD.</td>
<td></td>
<td>(No note present)</td>
<td>(No note present)</td>
<td>Spec testing</td>
</tr>
<tr>
<td>Part name and number</td>
<td>Potential failure mode</td>
<td>Potential effect(s) of failure</td>
<td>Severity (S)</td>
<td>Potential cause(s) of failure</td>
<td>Occurrence (O)</td>
</tr>
<tr>
<td>---------------------</td>
<td>------------------------</td>
<td>-------------------------------</td>
<td>-------------</td>
<td>-------------------------------</td>
<td>----------------</td>
</tr>
<tr>
<td>S/C to 5V rail (inputs) (pins 3, 4, 12, 13, 5, 11)</td>
<td>Inputs on permanently</td>
<td>1</td>
<td>Shorted load to 5V rail</td>
<td>3</td>
<td>None</td>
</tr>
<tr>
<td><strong>NOTES</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S/C to 5V rail (select) (pin 6)</td>
<td>Device permanently on, status OK—resolved by status flag change</td>
<td>1</td>
<td></td>
<td>(No note present)</td>
<td>(No note present)</td>
</tr>
<tr>
<td><strong>NOTES</strong></td>
<td>Operation only in PW mode</td>
<td>1</td>
<td>Shorted lead to 5V rail</td>
<td>3</td>
<td>None</td>
</tr>
<tr>
<td><strong>NOTES</strong></td>
<td>Normal mode not available</td>
<td></td>
<td></td>
<td>(No note present)</td>
<td>(No note present)</td>
</tr>
<tr>
<td>S/C to 5V rail (VCC)</td>
<td>System logic functionality</td>
<td>1</td>
<td>Shorted lead to 5V rail</td>
<td>3</td>
<td>None</td>
</tr>
<tr>
<td><strong>NOTES</strong></td>
<td>Essentially no effect on FIDD IC</td>
<td></td>
<td></td>
<td>(No note present)</td>
<td>(No note present)</td>
</tr>
<tr>
<td>S/C to 5V rail (GND)</td>
<td>No 5V rail (grounded)</td>
<td>1</td>
<td>Shorted lead to 5V rail</td>
<td>3</td>
<td>None</td>
</tr>
<tr>
<td><strong>NOTES</strong></td>
<td>Essentially no effect on FIDD IC</td>
<td></td>
<td></td>
<td>(No note present)</td>
<td>(No note present)</td>
</tr>
</tbody>
</table>

**Example 2**  Fidd Quad LSD.
<table>
<thead>
<tr>
<th>Part name and number</th>
<th>Potential failure mode</th>
<th>Potential effect(s) of failure</th>
<th>Se v</th>
<th>Potential cause(s) of failure</th>
<th>Design verification</th>
<th>Recomended action(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>S/C to 5V rail (test pin) (pin 9)</td>
<td>Test pin shorted to GND</td>
<td>2</td>
<td>Shorted load to 5V rail</td>
<td>Characterization out of sample</td>
<td>None, outside spec</td>
<td></td>
</tr>
<tr>
<td>O/C (pins 1, 2, 14, 15) (outputs)</td>
<td>O/C load</td>
<td>1</td>
<td>Open circuit/unconnected load</td>
<td>Final test for O/C operation</td>
<td>Spec testing</td>
<td></td>
</tr>
<tr>
<td>O/C (pins 3, 4, 12, 13, 5, 11) inputs</td>
<td>Nonreporting loads</td>
<td>1</td>
<td>Open circuit unconnected I/P</td>
<td>Modify for “float to zero”</td>
<td>Modify IC design</td>
<td></td>
</tr>
<tr>
<td>O/C (pin 6) (select)</td>
<td>Nonresponding loads</td>
<td>1</td>
<td>Open circuit unconnected select</td>
<td>Modify for “float to zero”</td>
<td>Modify IC design</td>
<td></td>
</tr>
</tbody>
</table>

**Example 2** Fidd Quad LSD.
<table>
<thead>
<tr>
<th>Part name and number</th>
<th>Potential failure mode</th>
<th>Potential effect(s) of failure</th>
<th>Sev</th>
<th>Potential cause(s) of failure</th>
<th>O c c</th>
<th>Design verification</th>
<th>D e t</th>
<th>R. P. N.</th>
<th>Recommended action(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>O/C (pin 7) (VCC) “loss of supply”</td>
<td>Nonfunctional loads</td>
<td>1</td>
<td>O/C VCC connection</td>
<td>3</td>
<td>None</td>
<td>2</td>
<td>6</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>NOTES</td>
<td>If loads connected outputs open CCT (no gate voltage)</td>
<td></td>
<td>(No note present)</td>
<td></td>
<td>(No note present)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>O/C (pin 8) (GND) “loss of GND”</td>
<td>Nonfunctional loads</td>
<td>6</td>
<td>Unconnected ground to IC</td>
<td>3</td>
<td>Modify to protect</td>
<td>2</td>
<td>36</td>
<td>Modify IC design</td>
<td></td>
</tr>
<tr>
<td>NOTES</td>
<td>Incorporate poly resins in input and output lines, modified ESD</td>
<td></td>
<td>(No note present)</td>
<td></td>
<td>(No note present)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>O/C (pin 9) (test pin)</td>
<td>Test pin open—CCT</td>
<td>1</td>
<td>None</td>
<td>2</td>
<td>None</td>
<td>2</td>
<td>4</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>NOTES</td>
<td>Normal operational condition</td>
<td></td>
<td>(No note present)</td>
<td></td>
<td>(No note present)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intermittent load (pins 1, 2, 14, 15)</td>
<td>Intermittent load failure</td>
<td>1</td>
<td>Loose connection to lead</td>
<td>2</td>
<td>None</td>
<td>2</td>
<td>4</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>NOTES</td>
<td>Fault detected during operation</td>
<td></td>
<td>(No note present)</td>
<td></td>
<td>(No note present)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
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</table>

(Continued)
<table>
<thead>
<tr>
<th>Part name and number</th>
<th>Potential failure mode</th>
<th>Potential effect(s) of failure</th>
<th>S e v</th>
<th>Potential cause(s) of failure</th>
<th>O cc</th>
<th>Design verification</th>
<th>D e t</th>
<th>R. P. N.</th>
<th>Recommended action(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Partial short to VCC (all four loads)</td>
<td>Overheating chip</td>
<td>1</td>
<td>Nonapproved loads</td>
<td>1</td>
<td>System design dependent</td>
<td>2</td>
<td>Ford FMEA check</td>
<td></td>
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<tr>
<td>Intermittent switching of load VCC to GND</td>
<td>Not a problem if properly heatsinked (I-just under I-limit point)</td>
<td>1</td>
<td>(No note present)</td>
<td>1</td>
<td>(No note present)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transients &gt;supply — outputs (pins 1, 2, 14, 15)</td>
<td>Nonworking system</td>
<td>1</td>
<td>Loose load connection</td>
<td>1</td>
<td>None</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Transients &gt;supply — inputs etc (pins 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13)</td>
<td>Indicator discharges through output (SOA)</td>
<td>1</td>
<td>(No note present)</td>
<td>1</td>
<td>(No note present)</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transients &gt;supply — outputs (pins 1, 2, 14, 15)</td>
<td>Over V spike on inputs</td>
<td>1</td>
<td>ESD, other transient conditions</td>
<td>3</td>
<td>Final test/ESD</td>
<td></td>
<td></td>
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<tr>
<td>Transients &gt;supply — inputs etc (pins 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13)</td>
<td>Less severe than on/off transient</td>
<td></td>
<td>(No note present)</td>
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<td>(No note present)</td>
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<tr>
<td>Transients &gt;supply — outputs (pins 1, 2, 14, 15)</td>
<td>Over V spike on inputs</td>
<td>1</td>
<td>ESD, other transient conditions</td>
<td>3</td>
<td>ESD</td>
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<tr>
<td>Transients &gt;supply — inputs etc (pins 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13)</td>
<td>Doesn’t induce practice</td>
<td></td>
<td>(No note present)</td>
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<td>(No note present)</td>
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**Example 2** Fidd Quad LSD.
**Part name and number**

<table>
<thead>
<tr>
<th>Part name and number</th>
<th>Potential failure mode</th>
<th>Potential effect(s) of failure</th>
<th>Severity (S)</th>
<th>Potential cause(s) of failure</th>
<th>Occurrence (O)</th>
<th>Design verification (D)</th>
<th>Recommended action(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>NOTES</strong></td>
<td><em>Serious only if zener V becomes &lt; supply V</em></td>
<td>8</td>
<td>(No note present)</td>
<td>3</td>
<td>(No note present)</td>
<td>Spec testing</td>
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<tr>
<td>Device overheating</td>
<td></td>
<td>Output I reduction</td>
<td>8</td>
<td>Non-heatsinked device</td>
<td>3</td>
<td>Characterization</td>
<td></td>
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<tr>
<td></td>
<td><strong>NOTES</strong></td>
<td>Add thermal shutdown!</td>
<td></td>
<td>(No note present)</td>
<td></td>
<td>(No note present)</td>
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<tr>
<td>DMOS VT increase</td>
<td></td>
<td>Output I reduction</td>
<td>8</td>
<td>Lifetime drift</td>
<td>1</td>
<td>Life test</td>
<td>Life test</td>
</tr>
<tr>
<td></td>
<td><strong>NOTES</strong></td>
<td><em>Depends on new turn-on value—affect low V first</em></td>
<td></td>
<td>(No note present)</td>
<td></td>
<td>(No note present)</td>
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</tr>
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**Example 2**  Fidd Quad LSD.
### Example 2  Fidd Quad LSD.

<table>
<thead>
<tr>
<th>Part name and number</th>
<th>Part function</th>
<th>Potential failure mode</th>
<th>Potential effect(s) of failure</th>
<th>Potential cause(s) of failure</th>
<th>Design verification</th>
<th>Det. R. P. N.</th>
<th>Recommended action(s)</th>
</tr>
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<tbody>
<tr>
<td></td>
<td></td>
<td>Non-specified drive could give marginal performance</td>
<td>3 (No note present)</td>
<td>4 (No note present)</td>
<td>(No note present)</td>
<td>1 12</td>
<td>None</td>
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<tr>
<td></td>
<td></td>
<td>Capability to overdrive I/Ps</td>
<td>1 Use of non-approved drive devices</td>
<td>4 System design dependent</td>
<td>(No note present)</td>
<td>None</td>
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<td></td>
<td></td>
<td>Here non-specified driver should not impede performance</td>
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<td>(No note present)</td>
<td>(No note present)</td>
<td>None</td>
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<tr>
<td></td>
<td></td>
<td>Over V liable to trip</td>
<td>1 Use in 24V systems</td>
<td>3 System design dependent</td>
<td>1 3</td>
<td>Inclusion in Ford system FMEA</td>
<td></td>
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<td></td>
<td></td>
<td>Could also be problems in S/C mode (with no thermal trip)</td>
<td>(No note present)</td>
<td>(No note present)</td>
<td>(No note present)</td>
<td>None</td>
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<tr>
<td></td>
<td></td>
<td>Outputs drive limited</td>
<td>1 Dead battery and failed alternator</td>
<td>4 None</td>
<td>2 8</td>
<td>None</td>
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<td></td>
<td></td>
<td>Outside designed operating range</td>
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<tr>
<td>Part name and number</td>
<td>Part function</td>
<td>Potential failure mode</td>
<td>Potential effect(s) of failure</td>
<td>Sev</td>
<td>Potential cause(s) of failure</td>
<td>Occ</td>
<td>Design verification</td>
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<td>Intermittent load failure</td>
<td>1</td>
<td>Loose connection to load</td>
<td>2</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>During “fault” condition</td>
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<td></td>
<td></td>
<td></td>
<td>device is off</td>
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<td>(No note present)</td>
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<td></td>
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<td>Nonworking system</td>
<td>1</td>
<td>Use of nonapproved load</td>
<td>4</td>
<td>System design</td>
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<td>Use of nonspecified load</td>
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<td>dependent</td>
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<td>often causes unforeseen</td>
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<td>(No note present)</td>
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<td>problems</td>
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<td>(No note present)</td>
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<td>Nonworking system</td>
<td>1</td>
<td>Use of nonapproved load</td>
<td>4</td>
<td>System design</td>
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<td>Nonworking system</td>
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<td></td>
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<td>dependent</td>
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<td>Use of nonspecified load</td>
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<td>(No note present)</td>
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<td>often causes unforeseen</td>
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<td>(No note present)</td>
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<td>problems</td>
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<td></td>
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</tr>
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<td></td>
<td></td>
<td></td>
<td>Time vs spec drift — load</td>
<td>1</td>
<td>Use of nonapproved drive</td>
<td>3</td>
<td>System design</td>
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<td></td>
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<td>increased impedance</td>
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<td>devices</td>
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Example 2  Fidd Quad LSD.
Example 3  Throttle body machine. (Continued)
FMEA Samples

<table>
<thead>
<tr>
<th>No.</th>
<th>Process</th>
<th>Failure mode</th>
<th>Effect of failure mode</th>
<th>Cause of failure</th>
<th>Current controls</th>
<th>P</th>
<th>S</th>
<th>D</th>
<th>R</th>
<th>Recommended corrective action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Op 10 Load</td>
<td>Machined incorrectly:</td>
<td>Scrap</td>
<td>Operator loaded part incorrectly</td>
<td>Fixed tooling</td>
<td>1</td>
<td>5</td>
<td>1</td>
<td>5</td>
<td>None</td>
</tr>
<tr>
<td>2</td>
<td>Op 20 Drill 401 407 402 410</td>
<td>Machined incorrectly: oversize, out of position, missing</td>
<td>Scrap Break other tools</td>
<td>Broken or worn tools Gauging error</td>
<td>Tool break detectors SPC chart</td>
<td>1</td>
<td>5</td>
<td>1</td>
<td>5</td>
<td>None</td>
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<tr>
<td>3</td>
<td>Op 30 Mill 561</td>
<td>Machined incorrectly: bad surface finish flatness</td>
<td>Scrap</td>
<td>Broken or worn inserts Chips on fixtures Gauging error</td>
<td>Visual inspection Flush lines SPC chart</td>
<td>2</td>
<td>4</td>
<td>2</td>
<td>16</td>
<td>None</td>
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<tr>
<td>4</td>
<td>Op 40 Ream Drill 401 410 402 407</td>
<td>Machined incorrectly: oversize, out of position, missing</td>
<td>Scrap Break other tools Assembly problems</td>
<td>Broken or worn tools Gauging error</td>
<td>Tool break detectors SPC charts</td>
<td>1</td>
<td>5</td>
<td>3</td>
<td>15</td>
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<tr>
<td>5</td>
<td>Op 50 Rough Bore 605</td>
<td>Machined incorrectly: oversize, out of position</td>
<td>Break finish tool</td>
<td>Incorrectly built roughing tool</td>
<td>Tool layout</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>4</td>
<td>None</td>
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<tr>
<td>6</td>
<td>Op 60 Idle</td>
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<tr>
<td>7</td>
<td>Op 70 Ream 601 603</td>
<td>Machined incorrectly: oversize, out of position, missing</td>
<td>Scrap Primary locator position problems</td>
<td>Broken or worn tools Gauging error</td>
<td>Tool inspection SPC charts</td>
<td>1</td>
<td>4</td>
<td>4</td>
<td>16</td>
<td>None</td>
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</table>

Example 3  Throttle body machine.
<table>
<thead>
<tr>
<th>No.</th>
<th>Process</th>
<th>Failure mode</th>
<th>Effect of failure mode</th>
<th>Cause of failure</th>
<th>Current controls</th>
<th>P</th>
<th>S</th>
<th>D</th>
<th>R</th>
<th>Recommended corrective action</th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td>On 80 Tap 410</td>
<td>Machined incorrectly: not tapped, shallow tap</td>
<td>Scrap</td>
<td>Broken or worn tools</td>
<td>Load monitor</td>
<td>1</td>
<td>1</td>
<td>5</td>
<td>5</td>
<td>None</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Customer failure</td>
<td>Gauging error</td>
<td>Tool detector</td>
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<tr>
<td>9</td>
<td>On 90 Rough Bore 606</td>
<td>Machined incorrectly: oversize, out of position</td>
<td>Break finish tool</td>
<td>Incorrectly built roughing tool</td>
<td>Tool layout</td>
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<td>2</td>
<td>1</td>
<td>4</td>
<td>None</td>
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<tr>
<td>10</td>
<td>Op 110 Load</td>
<td>Machined incorrectly:</td>
<td>Scrap</td>
<td>Operator loaded part</td>
<td>Fixed tooling</td>
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<td>1</td>
<td>5</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td></td>
<td>oversize, out of position,</td>
<td></td>
<td>incorrectly</td>
<td></td>
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<td>11</td>
<td>Op 120 Mill S51</td>
<td>Machined incorrectly:</td>
<td>Scrap</td>
<td>Broken or worn tool</td>
<td>Visual inspection</td>
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<td>2</td>
<td>10</td>
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<td></td>
<td></td>
<td>bad surface finish flatness</td>
<td>Asm problems w/TPS</td>
<td>inserts</td>
<td>Flush lines</td>
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<td></td>
<td></td>
<td></td>
<td>Chips on fixtures</td>
<td>SPC chart</td>
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<td>Gauging error</td>
<td>Throttle efforts</td>
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<td>Op 130 Ream 303</td>
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<td>Scrap</td>
<td>Broken or worn tool</td>
<td>SPC charts</td>
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<td>18</td>
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<td>Asm problems w/shaft</td>
<td>Fixture alignment</td>
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<td>burrs</td>
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<td>Gauging error</td>
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<td>13</td>
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<td>Machined incorrectly:</td>
<td>Scrap</td>
<td>Broken or worn tool</td>
<td>Tool break detector</td>
<td>2</td>
<td>4</td>
<td>2</td>
<td>16</td>
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<td></td>
<td></td>
<td>out of position, missing</td>
<td></td>
<td>Incorrect setup</td>
<td>Part buildup</td>
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<td>SPC charts</td>
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<td>15</td>
<td>Op 170 Load</td>
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<td>Operator loaded part</td>
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<td>5</td>
<td>None</td>
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<td>oversize, out of position,</td>
<td></td>
<td>incorrectly</td>
<td></td>
<td></td>
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**Example 3** Throttle body machine.
<table>
<thead>
<tr>
<th>No.</th>
<th>Process</th>
<th>Failure mode</th>
<th>Effect of failure mode</th>
<th>Cause of failure</th>
<th>Current controls</th>
<th>P</th>
<th>S</th>
<th>D</th>
<th>R</th>
<th>Recommended corrective action</th>
</tr>
</thead>
<tbody>
<tr>
<td>16</td>
<td>Op 180 Bore 302</td>
<td>Machined incorrectly: oversize, out of position, undersized</td>
<td>Scrap</td>
<td>Broken or worn tool</td>
<td>SPC charts</td>
<td>1</td>
<td>5</td>
<td>3</td>
<td>15</td>
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<tr>
<td>17</td>
<td>Op 190 Bore 503</td>
<td>Machined incorrectly: oversize, out of position, undersized</td>
<td>Scrap</td>
<td>Broken or worn tool</td>
<td>SPC charts</td>
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<td>3</td>
<td>15</td>
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<td>18</td>
<td>200 Drill 403</td>
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<td>Scrap</td>
<td>Broken or worn tool</td>
<td>Tool break detector</td>
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<td>3</td>
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<td>19</td>
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<td>Operator loaded part incorrectly</td>
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<td>None</td>
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<td>Op 230 Load</td>
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<td>Broken or worn inserts</td>
<td>Visual inspection</td>
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<td>21</td>
<td>Op 240 Drill 501 502</td>
<td>Machined incorrectly: missing holes oversize</td>
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<td>Broken or worn tool</td>
<td>CNC depth control</td>
<td>2</td>
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<td>22</td>
<td>Op 250 Idle</td>
<td>Machined incorrectly:</td>
<td>Scrap</td>
<td>Setup error</td>
<td>CNC depth control</td>
<td>2</td>
<td>4</td>
<td>2</td>
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<tr>
<td>23</td>
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<td>Setup error</td>
<td>CNC depth control</td>
<td>2</td>
<td>4</td>
<td>2</td>
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<tr>
<td>24</td>
<td>Op 270 Finish bore 605</td>
<td>Machined incorrectly: oversize, out of position, incorrect depth, bad finish</td>
<td>Scrap</td>
<td>Broken or worn tool</td>
<td>CNC depth control</td>
<td>2</td>
<td>4</td>
<td>2</td>
<td>16</td>
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**Example 3** Throttle body machine.
<table>
<thead>
<tr>
<th>No.</th>
<th>Process</th>
<th>Failure mode</th>
<th>Effect of failure mode</th>
<th>Cause of failure</th>
<th>Current controls</th>
<th>P</th>
<th>S</th>
<th>D</th>
<th>R</th>
<th>Recommended corrective action</th>
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<tbody>
<tr>
<td>25</td>
<td>Op 280 Finish bore 606</td>
<td>Machined incorrectly oversize, out of position, incorrect depth, bad finish</td>
<td>Scrap Customer rejects</td>
<td>Broken or worn tool Setup error Gauging error</td>
<td>CNC depth control SPC charts Functional test</td>
<td>2</td>
<td>4</td>
<td>2</td>
<td>16</td>
<td>*INV None</td>
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<tr>
<td>26</td>
<td>Op 300 Washer</td>
<td>Parts not clean: chips, residue</td>
<td>Customer rejects</td>
<td>Incorrect concentration levels Water design</td>
<td>Visual inspection Monitor levels</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>4</td>
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<tr>
<td>27</td>
<td>Op 310 Manual load (4 parts)</td>
<td>Machined incorrectly</td>
<td>Scrap</td>
<td>Operator loaded part incorrectly</td>
<td>Fixed tooling</td>
<td>1</td>
<td>5</td>
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<td>5</td>
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<tr>
<td>28</td>
<td>Op 320 Mill 552</td>
<td>Machined incorrectly: bad surface finish flatness</td>
<td>Scrap Asm problems w/AIS</td>
<td>Broken or worn inserts Chips on fixtures Gauging error</td>
<td>Visual inspection Flush lines SPC chart Throttle efforts</td>
<td>2</td>
<td>3</td>
<td>2</td>
<td>12</td>
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<tr>
<td>29</td>
<td>Op 330 Ream 506</td>
<td>Machined incorrectly: oversize, out of position, incorrect depth</td>
<td>Scrap Asm problems w/AIS</td>
<td>Broken or worn tool Setup error Gauging error</td>
<td>CNC depth control SPC charts Tool inspection</td>
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<td>4</td>
<td>3</td>
<td>12</td>
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<td>30</td>
<td>Op 340 C'Drill 504 505</td>
<td>Machined incorrectly: missing holes</td>
<td>Scrap Drill off location</td>
<td>Broken or worn tool Gauging error</td>
<td>Visual inspection SPC chart</td>
<td>1</td>
<td>2</td>
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Example 3 Throttle body machine.
<table>
<thead>
<tr>
<th>No.</th>
<th>Process</th>
<th>Failure mode</th>
<th>Effect of failure mode</th>
<th>Cause of failure</th>
<th>Current controls</th>
<th>P</th>
<th>S</th>
<th>D</th>
<th>R</th>
<th>Recommended corrective action</th>
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<tr>
<td>31</td>
<td>Op 350</td>
<td>Drill</td>
<td>Scrap</td>
<td>Broken or worn tool</td>
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<td>1</td>
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<td></td>
<td></td>
<td>Drill 504</td>
<td>Asm problems</td>
<td>Chips on fixtures</td>
<td>Flush lines</td>
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<td></td>
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<td>w/screws</td>
<td>Gauging error</td>
<td>SPC chart</td>
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<td>32</td>
<td>Op 370</td>
<td>Washer</td>
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<td></td>
<td></td>
<td>Washer design</td>
<td></td>
<td>Monitor levels</td>
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<td>33</td>
<td>Op 390</td>
<td>Leak test</td>
<td>Scrap</td>
<td>Part not cooled</td>
<td>Allow cooling time</td>
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<td>Example 3</td>
<td>Throttle body machine.</td>
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<td>Part name and number</td>
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<td>Potential cause(s) of failure</td>
<td>Occ</td>
<td>Design verification</td>
<td>Det</td>
<td>R. P. N.</td>
<td>Recommended action(s)</td>
<td>Area/individual responsible &amp; compl. date</td>
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<tr>
<td>Field plating inadequate</td>
<td>Increased leakage/ premature breakdown</td>
<td>8</td>
<td>Excess packing requirements</td>
<td>2</td>
<td>Check DV/manual</td>
<td>2</td>
<td>32</td>
<td>Standard checks</td>
<td>Sept 1990</td>
<td>None</td>
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<tr>
<td>Voltage — drop (routing — excess)</td>
<td>Inaccurate current sources</td>
<td>5</td>
<td>Metal width too narrow</td>
<td>2</td>
<td>Check DV/manual</td>
<td>2</td>
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<td>Standard checks</td>
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<td>Current density (analysis — excess)</td>
<td>Excess density O/P stages</td>
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<td>Excessive packing requirements</td>
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<td>DV, manual check life test</td>
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<tr>
<td>Resistor tolerances &gt;20% positive</td>
<td>Low internal current source</td>
<td>5</td>
<td>Faulty processing</td>
<td>4</td>
<td>Final test (PCS)</td>
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<td>60</td>
<td>Standard checks</td>
<td>Dec 1990</td>
<td>Install process check</td>
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Example 4 Package/layout. (Continued)
## Potential failure mode and effects analysis (design FMEA)

### Suppliers and plants affected
---

### Model year/vehicle(s)
---

### Engineering release date
---

### Potential failure mode and effects analysis

<table>
<thead>
<tr>
<th>Part name and number</th>
<th>Part function</th>
<th>Potential failure mode</th>
<th>Potential effect(s) of failure</th>
<th>Sev</th>
<th>Potential cause(s) of failure</th>
<th>Occ</th>
<th>Design verification</th>
<th>Det</th>
<th>R. P. N.</th>
<th>Recommended action(s)</th>
<th>Area/individual responsible &amp; compl. date</th>
<th>Action results</th>
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<tbody>
<tr>
<td>Resistor tolerances &gt; 20% negative</td>
<td>High internal current source</td>
<td>Faulty processing</td>
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<td>Final test (PCS)</td>
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<td>Standard check</td>
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<tr>
<td>Thermal mismatch</td>
<td>Resistance mismatch due to thermal effects</td>
<td>Poor layout technique</td>
<td>7</td>
<td>Manual layout inspect</td>
<td>3</td>
<td>Standard check</td>
<td>Sept 1990</td>
<td>Install process check</td>
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<tr>
<td>Internal interference (supply V rail)</td>
<td>Intercell interference</td>
<td>Poor design/ layout</td>
<td>3</td>
<td>Suppression design</td>
<td>1</td>
<td>Design-in</td>
<td>June 1990</td>
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<tr>
<td>Spice model failure</td>
<td>Inaccurate spice models</td>
<td>Lack of extreme models</td>
<td>4</td>
<td>Work with worst case models</td>
<td>2</td>
<td>Obtain models</td>
<td>Aug 1990</td>
<td>None</td>
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**Example 4** Package/layout.

---

---
### Potential failure mode and effects analysis (design FMEA)

<table>
<thead>
<tr>
<th>Part name and number</th>
<th>Potential failure mode</th>
<th>Potential effect(s) of failure</th>
<th>S e v</th>
<th>V</th>
<th>Potential cause(s) of failure</th>
<th>O c</th>
<th>Design verification</th>
<th>D e t</th>
<th>R. P. N.</th>
<th>Recommended action(s)</th>
<th>Area/individual responsible &amp; compl. date</th>
<th>Action results</th>
<th>Action taken</th>
<th>S e v</th>
<th>O c</th>
<th>D e t</th>
<th>R. P. N.</th>
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</thead>
<tbody>
<tr>
<td>Inadequate guard ring</td>
<td>Leakage/transient failure</td>
<td>Excess packing/poor layout</td>
<td>5</td>
<td>2</td>
<td>Manual layout inspect</td>
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<td></td>
<td>1</td>
<td>10</td>
<td>Visual inspect</td>
<td>Sept 1990</td>
<td>None</td>
<td>Install process check</td>
<td>5</td>
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<td>Well-understood problem</td>
<td>(No note present)</td>
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<td></td>
<td>(No note present)</td>
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<td>Install process check</td>
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<td>8</td>
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<tr>
<td>Thermal mismatch—transistors</td>
<td>Transistor mismatch due to thermal effects</td>
<td>Poor layout techniques</td>
<td>5</td>
<td>6</td>
<td>Manual layout inspect</td>
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<td>90</td>
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<td>Install process check</td>
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<td>8</td>
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<tr>
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<td>Well-understood problem</td>
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<td></td>
<td></td>
<td>(No note present)</td>
<td></td>
<td></td>
<td></td>
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<td>Install process check</td>
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<td>8</td>
<td>2</td>
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<tr>
<td>Matching resistors</td>
<td>Well-understood problem</td>
<td>Poor layout techniques</td>
<td>5</td>
<td>8</td>
<td>Manual layout check</td>
<td></td>
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<td>3</td>
<td>120</td>
<td>Standard check</td>
<td>Sept 1990</td>
<td>Install inspection check-point</td>
<td>5</td>
<td>8</td>
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<td></td>
<td>Resistors mismatched due to layout effects</td>
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<td></td>
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<td>(No note present)</td>
<td></td>
<td></td>
<td></td>
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<td>Install inspection check-point</td>
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<td>8</td>
<td>2</td>
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<td>Matching transistors</td>
<td>Transistors mismatched due to layout</td>
<td>Poor layout technique</td>
<td>5</td>
<td>8</td>
<td>Manual layout check</td>
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<td>120</td>
<td>Visual inspect</td>
<td>Sept 1990</td>
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<td>8</td>
<td>2</td>
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<td></td>
<td>Well-understood problem</td>
<td>(No note present)</td>
<td></td>
<td></td>
<td>(No note present)</td>
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<td></td>
<td></td>
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<td>Install inspection check-point</td>
<td>5</td>
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**Example 4** Package/layout.
### Potential failure mode and effects analysis (design FMEA)

<table>
<thead>
<tr>
<th>Part name and number</th>
<th>Part function</th>
<th>Potential failure mode</th>
<th>Potential failure of failure</th>
<th>S e v</th>
<th>Potential cause(s) of failure</th>
<th>O c c</th>
<th>Design verification</th>
<th>D e t</th>
<th>R. P. N.</th>
<th>Recommended action(s)</th>
<th>Area/individual responsible &amp; compl. date</th>
<th>Action results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Package: solder voids</td>
<td>Voids in solder behind chip</td>
<td>8</td>
<td>Out of spec soldering</td>
<td>2</td>
<td>Characterization</td>
<td>2</td>
<td>Design evaluation</td>
<td>32</td>
<td>Characterization</td>
<td>Jan 1991</td>
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<tr>
<td>Package/system: shorted bonds 1–2, 3–, 12–13, 14–15</td>
<td>Incorporate thermal trip/theta JC testing</td>
<td>8</td>
<td>Bonding/holding problems</td>
<td>1</td>
<td>Final test</td>
<td>1</td>
<td>Final test check</td>
<td>8</td>
<td>Final test check</td>
<td>Jan 1991</td>
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<tr>
<td>Package/system: shorted bonds 2–3, 13–14</td>
<td>Outputs 1–2 etc. shorted</td>
<td>8</td>
<td>Bonding/holding problems</td>
<td>1</td>
<td>Final test</td>
<td>1</td>
<td>Final test check</td>
<td>8</td>
<td>Final test check</td>
<td>Jan 1991</td>
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<td>Package/system: shorted bonds 11–12, 4–5</td>
<td>Input and output 2, 3 shorted</td>
<td>8</td>
<td>Bonding/holding problems</td>
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<td>Final test check</td>
<td>8</td>
<td>Final test check</td>
<td>Jan 1991</td>
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<tr>
<td>Package/system: In &amp; PW shorted</td>
<td>Nasty!</td>
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<td>1</td>
<td>Final test check</td>
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<td>Final test check</td>
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</table>

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**Example 4** Package/layout.
### Potential failure mode and effects analysis (design FMEA)

<table>
<thead>
<tr>
<th>Part name and number</th>
<th>Potential failure mode</th>
<th>Potential effect(s) of failure</th>
<th>S e v</th>
<th>Potential cause(s) of failure</th>
<th>O c c</th>
<th>Design verification</th>
<th>D e t</th>
<th>R. P. N.</th>
<th>Recommended action(s)</th>
<th>Area/individual responsible &amp; compl. date</th>
<th>Action results</th>
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<td>Package/system: shorted bonds 10–11</td>
<td>Forced into PW2 mode</td>
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<td>Bonding/holding problems</td>
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<td>Final test</td>
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<td>PW1/Select shorted</td>
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<td>Bonding/holding problems</td>
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<tr>
<td>Package/system: shorted bonds 6–7</td>
<td>VDO/select shorted</td>
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<td>Bonding/holding problems</td>
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<td>Final test</td>
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<td>Final test check</td>
<td>Jan 1991</td>
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<tr>
<td>Package/system: shorted bonds 7–8</td>
<td>Shorted VCC to GND</td>
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<td>1</td>
<td>8</td>
<td>Final test check</td>
<td>Jan 1991</td>
<td>None</td>
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</table>

**Example 4**  Package/layout.
### Potential failure mode and effects analysis (design FMEA)

**Suppliers and plants affected**

**Model year/vehicle(s)**

**Engineering release date**

<table>
<thead>
<tr>
<th>Part name and number</th>
<th>Potential failure mode</th>
<th>Potential effect(s) of failure</th>
<th>Sev</th>
<th>Potential cause(s) of failure</th>
<th>occ</th>
<th>Design verification</th>
<th>Rec. action(s)</th>
<th>Area/individual responsible &amp; compl. date</th>
<th>Action results</th>
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<td>Package/system: shorted bonds 8–9</td>
<td>GND shorted to test out</td>
<td>Bonding/holding problems</td>
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<td>Final test</td>
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<td>Final test check</td>
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<td>None</td>
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<td>Failure at test (apparent non-functional OSC)</td>
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<td>(No note present)</td>
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<td>Package/system: shorted bonds 9–10</td>
<td>Status and test out shorted</td>
<td>Bonding/holding problems</td>
<td>3</td>
<td>Final test</td>
<td>1</td>
<td>Final test check</td>
<td>Jan 1991</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td></td>
<td>False status fault flag</td>
<td>(No note present)</td>
<td>(No note present)</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>EPI tank bias</td>
<td>Increased package/manufacturing cells</td>
<td>Misconnected tank on layout/schematic</td>
<td>8</td>
<td>DV/SV check and manual schematic check</td>
<td>16</td>
<td>Standard checks</td>
<td>Sept 1990</td>
<td>None</td>
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<tr>
<td></td>
<td>Well-understood problem</td>
<td>(No note present)</td>
<td>(No note present)</td>
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<tr>
<td>Tunnel (tank) bias</td>
<td>Unexpected biasing at input/output</td>
<td>Ill-considered tunnel bias</td>
<td>8</td>
<td>Manual check</td>
<td>16</td>
<td>Standard checks</td>
<td>Sept 1990</td>
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<td></td>
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<tr>
<td></td>
<td>Also as EPI tank bias</td>
<td>(No note present)</td>
<td>(No note present)</td>
<td></td>
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</tbody>
</table>

**Example 4** Package/layout.
<table>
<thead>
<tr>
<th># Part name</th>
<th>Function</th>
<th>Failure mode</th>
<th>Effect of failure</th>
<th>Cause of failure</th>
<th>Current controls</th>
<th>P</th>
<th>S</th>
<th>D</th>
<th>R</th>
<th>Correct action</th>
<th>Action done</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Armature</td>
<td>Valves the flow of fluid in response to magnetic field</td>
<td>Friction</td>
<td>Slow or no ride switching. Inferior ride</td>
<td>Nicks/scratches in armature O.D. or flange I.D.</td>
<td>Inspection</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>4</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Contaminants in the grooves</td>
<td></td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>4</td>
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<td>None</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Inadequate surface finish</td>
<td>Print spec.</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>None</td>
<td>None</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Inadequate plating</td>
<td>Print spec.</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>None</td>
<td>None</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Inadequate cylindricity</td>
<td>Print spec.</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>None</td>
<td>None</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Bent armature spring</td>
<td>On/off times</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>4</td>
<td>None</td>
<td>None</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Bent or broken air gap spacer</td>
<td>On/off times</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>12</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Small armature to flange assembly clearance</td>
<td>Select fit armature and flange assembly</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>12</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Contaminated oil</td>
<td>Contamination testing</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>None</td>
<td>None</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Armature length too short</td>
<td></td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Thermal expansion of armature and flange assembly</td>
<td>Thermal chamber</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>4</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

**Example 5** Armature. (Continued)
## FMEA Samples

### CD-89

### Failure mode: Friction

- **Armature sticks in open position**
  - Effect of failure: Vehicle sticks in soft ridge state. Difficulty handling
  - Cause of failure: Burr generated by impact with stop
  - Current controls: Durability
  - Correct action: None
  - Action done: None

- **High leakage**
  - Effect of failure: Does not achieve full firm ride. Inferior ride quality
  - Cause of failure: Large armature to flange assembly clearance
  - Current controls: Select fit armature and flange assembly
  - Correct action: None
  - Action done: None

### Function: Valves the flow of fluid in response to magnetic field

1. **Armature**
   - Part name: Armature
   - Number: 1
   - Cause of failure: Burr generated by impact with stop
   - Correct action: None
   - Action done: None

2. **Armature**
   - Part name: Armature
   - Number: 2
   - Cause of failure: Armature or air gap spacer mating surface too large, adhesion occurs
   - Correct action: None
   - Action done: None

3. **Armature**
   - Part name: Armature
   - Number: 3
   - Cause of failure: Armature and stop mating surfaces battered
   - Correct action: None
   - Action done: None

4. **Armature**
   - Part name: Armature
   - Number: 4
   - Cause of failure: Large armature to flange assembly clearance
   - Correct action: None
   - Action done: None

### Effect of failure: Slow or no ride switching. Inferior ride quality

- **High leakage**
  - Does not achieve full firm ride. Inferior ride quality
  - Cause of failure: Large armature to flange assembly clearance
  - Current controls: Select fit armature and flange assembly
  - Correct action: None
  - Action done: None

### Cause of failure: Burr generated by impact with stop

- **Armature**
  - Part name: Armature
  - Number: 1
  - Cause of failure: Burr generated by impact with stop
  - Correct action: None
  - Action done: None

- **Armature**
  - Part name: Armature
  - Number: 2
  - Cause of failure: Armature or air gap spacer mating surface too large, adhesion occurs
  - Correct action: None
  - Action done: None

- **Armature**
  - Part name: Armature
  - Number: 3
  - Cause of failure: Armature and stop mating surfaces battered
  - Correct action: None
  - Action done: None

### Cause of failure: Nicks/scratches in armature O.D. or flange I.D.

- **Armature**
  - Part name: Armature
  - Number: 4
  - Cause of failure: Nicks/scratches in armature O.D. or flange I.D.
  - Correct action: None
  - Action done: None

### Cause of failure: Sachs components misaligned or damaged Surface finish too rough

- **Armature**
  - Part name: Armature
  - Number: 4
  - Cause of failure: Sachs components misaligned or damaged Surface finish too rough
  - Correct action: None
  - Action done: None

### Example 5

Armature.
## Failure mode

- Insufficient force generated
- Cap comes loose
- Poor surface finish quality
- Cracks in encapsulation

## Effect of failure

- Vehicle has difficulty achieving soft ride. Inferior ride quality
- Armature, armature spring, and/or air gap spacer separate from encapsulated housing
- Visual identification. Jeopardize integrity of connection between cable and bobbin coil

## Cause of failure

- Material flux saturated
- Cap improperly installed
- Cap I.D. too large
- Solenoid exposed to cold temperature
- Poor encapsulation operation
- Worn mold

## Function

- Flux core for coil wire
- Hold armature, armature spring, and air gap spacer together during shipment
- Contains and secures in place flange assembly, bobbin assembly, and cable connection

## Correct action

None

## Action done

None

---

### Current controls

<table>
<thead>
<tr>
<th>P</th>
<th>S</th>
<th>D</th>
<th>R</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
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<td>3</td>
<td>6</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>3</td>
<td>12</td>
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</tbody>
</table>

### Example 5

Armature.
## FMEA Samples

### PD SR 22

<table>
<thead>
<tr>
<th># Part name</th>
<th>Function</th>
<th>Failure mode</th>
<th>Effect of failure</th>
<th>Cause of failure</th>
<th>Current controls</th>
<th>Correct action</th>
<th>Action done</th>
</tr>
</thead>
<tbody>
<tr>
<td>Housing encapsulation</td>
<td>Contains and secures in place flange assembly, bobbin assembly, and cable connection</td>
<td>Poor cable retention</td>
<td>Cable pulls free of housing; Jeopardize integrity of connection between cable and bobbin coil</td>
<td>Improper encapsulation fill</td>
<td>Encapsulation setup</td>
<td>2 2 3 12</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>No chemical bond formed between cable and terminal molding</td>
<td>Material choice</td>
<td>1 2 2 4</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>No chemical bond formed between terminal molding and cable</td>
<td>Material choice</td>
<td>1 2 2 4</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Insufficient retention in groove design</td>
<td>Groove design inadequate</td>
<td>1 2 2 4</td>
<td>None</td>
<td>None</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Insufficient cable land to form proper bond between cable and terminal molding</td>
<td>Insufficient cable bond area in design</td>
<td>1 2 2 4</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>Protects components from environmental factors</td>
<td></td>
<td>Locked in firm ride</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
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<td></td>
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<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Erratic ride switching</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Encapsulation seeps between bobbin terminal and cable connection, reducing metal contact areas</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Erratic or no ride response</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Encapsulation pressure is too high</td>
<td></td>
<td></td>
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<tr>
<td>Housing encapsulation</td>
<td></td>
<td></td>
<td>Terminal design not tight enough fit</td>
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</tbody>
</table>

### Example 5

Armature.
### Example 5  Armature.

<table>
<thead>
<tr>
<th># Part name</th>
<th>Function</th>
<th>Failure mode</th>
<th>Effect of failure</th>
<th>Cause of failure</th>
<th>Current controls</th>
<th>Correct action</th>
<th>Action done</th>
</tr>
</thead>
<tbody>
<tr>
<td>Housing encapsulation</td>
<td>Protects components from environmental factors</td>
<td>Improper encapsulation fill</td>
<td>Housing or bobbin shows through encapsulation</td>
<td>Worn mold</td>
<td>Section batch part</td>
<td>2 3 2 12</td>
<td>None</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Improper insertion into mold</td>
<td>Burst test</td>
<td>2 3 2 12</td>
<td>None</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Bobbin terminals not centered in housing</td>
<td>Print spec.</td>
<td>1 3 3 9</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Encapsulation cracks when hit with high pressure. Flange assembly bows</td>
<td>Print spec.</td>
<td>1 3 2 6</td>
<td>None</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td>Encapsulation setup</td>
<td>Encapsulation setup</td>
<td>1 3 2 6</td>
<td>None</td>
</tr>
<tr>
<td>Housing assembly</td>
<td>Hold bobbin, flange, and housing together</td>
<td>Flange, bobbin, and housing misaligned</td>
<td>Erratic or no ride switching</td>
<td>Improper press fit of flange and housing</td>
<td>Print spec.</td>
<td>1 2 2 4</td>
<td>None</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Corrosion on flange assembly</td>
<td>Flange assembly oiled</td>
<td>2 2 3 12</td>
<td>None</td>
</tr>
<tr>
<td>1 Housing</td>
<td>Provides flux path around coil</td>
<td>Insufficient force generated</td>
<td>Vehicle has difficulty achieving soft ride</td>
<td>Material flux saturated</td>
<td>On time</td>
<td>1 2 2 4</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>Houses bobbin and coil assembly</td>
<td>Bobbin and coil assembly does not fit properly in housing</td>
<td>Dysfunctional solenoid</td>
<td>Bobbin cocked</td>
<td>On/off time</td>
<td>1 3 2 6</td>
<td>None</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Coil wire wrapped beyond</td>
<td>On/off time</td>
<td>1 3 2 6</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Improper sizing of bobbin and housing</td>
<td>On/off time</td>
<td>1 3 1 3</td>
<td>None</td>
</tr>
<tr>
<td># Part name</td>
<td>Function</td>
<td>Failure mode</td>
<td>Effect of failure</td>
<td>Cause of failure</td>
<td>Current controls</td>
<td>Correct action</td>
<td>Action done</td>
</tr>
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<td>------------------</td>
<td>------------------</td>
<td>----------------</td>
<td>-------------</td>
</tr>
<tr>
<td>1 Stop</td>
<td>Provides flux path from tube armature</td>
<td>Insufficient force generated</td>
<td>Vehicle has difficulty achieving soft ride</td>
<td>Improper installation into flange assembly</td>
<td>On time</td>
<td>1 2 2 4</td>
<td>None</td>
</tr>
<tr>
<td>Armature spring</td>
<td>Provides the solid base for air gap spacer</td>
<td>Burr development</td>
<td>Difficulty achieving full soft ride. Eventual functional problems</td>
<td>Material saturated</td>
<td>On time</td>
<td>1 2 1 2</td>
<td>None</td>
</tr>
<tr>
<td>Armature spring</td>
<td>Provides the return force to armature</td>
<td>Armature does not seal against sealing post</td>
<td>Does not achieve full firm ride</td>
<td>Wear between armature and stop mating surfaces produces burr</td>
<td>Durability</td>
<td>2 2 3 12</td>
<td>None</td>
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<tr>
<td>Air gap spacer</td>
<td>Sets return time response characteristics</td>
<td>Spring side loads armature</td>
<td>Achieves firm ride slowly</td>
<td>No spring installed</td>
<td>On/off times</td>
<td>2 3 3 18</td>
<td>None</td>
</tr>
<tr>
<td>Air gap spacer</td>
<td>Prevents magnetic and mechanical surface lock between armature and stop from occurring when solenoid is energized</td>
<td>Spring breaks Latching when energized</td>
<td>Erratic ride control Achieves firm ride slowly or erratically</td>
<td>Spring rate too low</td>
<td>Spring rate measured</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Air gap spacer</td>
<td></td>
<td></td>
<td></td>
<td>Wear</td>
<td>Durability</td>
<td>1 3 3 9</td>
<td>None</td>
</tr>
<tr>
<td>Air gap spacer</td>
<td></td>
<td></td>
<td></td>
<td>Air gap spacer not installed</td>
<td>On/off times</td>
<td>1 3 3 9</td>
<td>None</td>
</tr>
<tr>
<td>Air gap spacer</td>
<td></td>
<td></td>
<td></td>
<td>Leg broken on air gap spacer</td>
<td>On time</td>
<td>2 3 3 18</td>
<td>None</td>
</tr>
<tr>
<td>Air gap spacer</td>
<td></td>
<td></td>
<td></td>
<td>Air gap spacer too thin</td>
<td>On/off times</td>
<td>1 3 3 9</td>
<td>None</td>
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<tr>
<td>Air gap spacer</td>
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<td></td>
<td></td>
<td>Air gap spacer too thick</td>
<td>Pressure response for on/off times</td>
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<tr>
<td>Air gap spacer</td>
<td></td>
<td></td>
<td></td>
<td>Leg broken or bent on air gap spacer</td>
<td>On time</td>
<td>2 2 3 12</td>
<td>None</td>
</tr>
</tbody>
</table>

**Example 5** Armature.
### Table of Failure Modes and Causes

<table>
<thead>
<tr>
<th># Part name</th>
<th>Function</th>
<th>Failure mode</th>
<th>Effect of failure</th>
<th>Cause of failure</th>
<th>Current controls</th>
<th>Correct action</th>
<th>Action done</th>
</tr>
</thead>
<tbody>
<tr>
<td>Air gap spacer</td>
<td>Centers and holds armature spring</td>
<td>Spring biases armature position</td>
<td>Achieves firm ride slowly or erratically</td>
<td>Spring not properly seated</td>
<td>Off time</td>
<td>2 3 3 18</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Achieves soft ride slowly or erratically</td>
<td>Leg bent on air gap spacer</td>
<td>On time</td>
<td>2 2 3 12</td>
<td>None</td>
</tr>
<tr>
<td>1 Tube</td>
<td>Provides flux path</td>
<td>Insufficient force generated</td>
<td>Vehicle has difficulty switching to soft ride</td>
<td>Material flux saturated</td>
<td>On time</td>
<td>1 2 1 2</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>Holds stop to disc</td>
<td>Inadequate attachment between disc and stop</td>
<td>Vehicle cannot hold firm ride</td>
<td>Improper braze</td>
<td>Burst</td>
<td>2 3 2 12</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Improper fits</td>
<td>Print spec.</td>
<td>1 3 2 6</td>
<td>None</td>
</tr>
<tr>
<td>1 Disc</td>
<td>Provides flux path for coil</td>
<td>Insufficient force generated</td>
<td>Vehicle has difficulty achieving soft ride</td>
<td>Improper installation into flange assembly</td>
<td>On time</td>
<td>1 2 2 4</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Material flux saturated</td>
<td>On time</td>
<td>1 2 1 2</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Component corrosion</td>
<td>On time</td>
<td>2 2 3 12</td>
<td>None</td>
</tr>
<tr>
<td>1 Molded cable assembly</td>
<td>Accommodates electrical and physical attachment of cable to bobbin coil assembly</td>
<td>Poor electrical connection</td>
<td>Erratic or no ride response</td>
<td>Improper terminal attachment</td>
<td>Resistance check</td>
<td>2 3 2 12</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Water penetrates solenoid</td>
<td>Solenoid becomes inactive after time</td>
<td>Terminals bent too severely</td>
<td>Print spec.</td>
<td>1 3 3 9</td>
<td>None</td>
</tr>
</tbody>
</table>

#### Example 5
Armature.
<table>
<thead>
<tr>
<th># Part name</th>
<th>Function</th>
<th>Failure mode</th>
<th>Effect of failure</th>
<th>Cause of failure</th>
<th>Current controls</th>
<th>P</th>
<th>S</th>
<th>D</th>
<th>R</th>
<th>Correct action</th>
<th>Action done</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Molded cable assembly</td>
<td>Accommodates electrical and physical attachment of solenoid to vehicle</td>
<td>Poor electrical connection</td>
<td>Erratic or no ride control</td>
<td>Crack in wire connector</td>
<td>Resistance check</td>
<td>1</td>
<td>3</td>
<td>3</td>
<td>9</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Improper wire connector attachment to cable</td>
<td>Resistance check</td>
<td>1</td>
<td>3</td>
<td>3</td>
<td>9</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Improper connection to vehicle</td>
<td>Resistance check</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>18</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Insufficient cable retention</td>
<td>Cable grommet does not line up correctly with vehicle connection</td>
<td>Bent or damaged pin terminals</td>
<td>Resistance check</td>
<td>1</td>
<td>3</td>
<td>3</td>
<td>6</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Poor dry crimp of pin terminal to wire</td>
<td>Resistance check</td>
<td>1</td>
<td>3</td>
<td>3</td>
<td>9</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Connector clip missing or cracked</td>
<td>Resistance check</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>18</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Grommet positioned improperly</td>
<td>Print spec. for grommet position</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Cable retention groove design</td>
<td>Pull-out test</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Carries current from vehicle to solenoid</td>
<td>Erratic or no solenoid response after bobbin terminal to cable connection breaks</td>
<td>Cable wires have been nicked or twisted to fracture</td>
<td>Resistance check</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>12</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Cable wire exposed and contacting through insulation</td>
<td>Resistance check</td>
<td>1</td>
<td>4</td>
<td>3</td>
<td>12</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

**Example 5** Armature.
<table>
<thead>
<tr>
<th>Part name</th>
<th>Function</th>
<th>Failure mode</th>
<th>Effect of failure</th>
<th>Cause of failure</th>
<th>Current controls</th>
<th>Correct action</th>
<th>Action done</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flange assembly pre-machined</td>
<td>Provide flux path</td>
<td>Insufficient force generated</td>
<td>Vehicle has difficulty achieving soft ride</td>
<td>Corrosion of flange assembly</td>
<td>Oil flange assembly</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Flange assembly leak</td>
<td>Vehicle cannot hold firm ride</td>
<td></td>
<td></td>
<td>Components damaged during brazing</td>
<td>Burst test</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>1 Flange assembly machined</td>
<td>Seats air gap spacer damaged</td>
<td>Air gap spacer damaged</td>
<td>Difficulty achieving soft ride</td>
<td>Material flux saturated</td>
<td>Print spec.</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Armature guide</td>
<td>Friction between armature and flange assembly</td>
<td>Slow ride responses</td>
<td>Poor surface finish</td>
<td>Poor flange roundness and cylindricity</td>
<td></td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

**Example 5** Armature.
<table>
<thead>
<tr>
<th># Part name</th>
<th>Function</th>
<th>Failure mode</th>
<th>Effect of failure</th>
<th>Cause of failure</th>
<th>Current controls</th>
<th>Correct action</th>
<th>Action done</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 Bobbin terminal</td>
<td>Connects coil wire and cable wire</td>
<td>Poor electrical connection</td>
<td>Erratic or no ride response</td>
<td>Terminal did not scrape insulation away from coil wire to allow proper contact</td>
<td>Resistance check</td>
<td>2 2 2 8</td>
<td>None None</td>
</tr>
<tr>
<td></td>
<td></td>
<td>High resistance</td>
<td>Slow ride response</td>
<td>Twisted terminal</td>
<td>Resistance check</td>
<td>1 2 3 6</td>
<td>None None</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Terminal twisted or damaged</td>
<td>Resistance check</td>
<td>1 2 3 6</td>
<td>None None</td>
</tr>
<tr>
<td>1 Bobbin</td>
<td>Holds coil wire</td>
<td>Nonlevel winding</td>
<td>Improper solenoid operation</td>
<td>Flash on bobbin</td>
<td>2 2 3 12</td>
<td>None None</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Improper winding setup</td>
<td></td>
<td>1 2 3 6</td>
<td>None None</td>
<td></td>
</tr>
<tr>
<td>Part name/part no.</td>
<td>Product function</td>
<td>Potential failure mode</td>
<td>Potential effect(s) of failure</td>
<td>Control critical item</td>
<td>Potential cause(s) of failure</td>
<td>Existing conditions</td>
<td></td>
</tr>
<tr>
<td>-------------------</td>
<td>------------------</td>
<td>-----------------------</td>
<td>-------------------------------</td>
<td>-----------------------</td>
<td>-------------------------------</td>
<td>---------------------</td>
<td></td>
</tr>
<tr>
<td>Fan vibration from imbalance and axial T.I.R.</td>
<td>Audible noise, vibration; increased motor wear</td>
<td>Fan center of gravity off axis of rotation; axial T.I.R. causes 2-plane imbalance</td>
<td>Design lightweight fan with min. band mass; part thickness to favor uniform mold flow. DV tests on vehicles to assess sensitivity to vibration inputs</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Motor</td>
<td>Provide mechanical power to fans; position fans within shroud</td>
<td>Motor burnout, bearing or brush failure</td>
<td>Loss of cooling and A/C function</td>
<td>Vent holes in motor case; fins in fan hub pull air through ES, durability tests</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Misassemble to shroud, off-center or crooked</td>
<td>Loss of cooling function</td>
<td>Fan contact shroud, noise or motor burnout</td>
<td>Design for easy assembly, accurate positioning in shroud</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assemble @ ±120° off-nominal angle, motor wire in wrong location</td>
<td>No-build condition in assy. plant</td>
<td>Symmetrical spacing of screw holes; nonunique mounting interfaces</td>
<td>Power motion motor has unique mounting configuration. Visual inspection during assembly</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Motor wire interferes with engine and shorts; wire is too tight and opens circuit</td>
<td></td>
<td></td>
<td>Power motion motor has unique mounting configuration. Visual inspection during assembly</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fan retainer compression too high</td>
<td>Retainer loose, lost; loose fan and lost cooling function</td>
<td>‘o’ clip too close to shaft and slot</td>
<td>Maintain dimensional capability within limits of tolerance stack-up</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Example 6** Cooling fan assembly. (Continued)
### Fan Retainer
- Compression too low or nonexistent
- Backplate not swaged securely
- Loose after extended service
- Misapplication
- Plastic threads strip out
- Loose fan, contact with shroud
- Loose fan, contact with coil, loss of cooling
- T.I.R. increased; vibration or noise; fan dismounts, loss of cooling

### Control Critical Item
- Retainer loose, excess play between slot and “e” clip; breakage; lost cooling
- Motor & fan loose; fan touches shroud, stalls; fan damages coil; loss of cooling, coolant
- Loose motor allows fan contact with shroud, stalling motor
- Loose motor, fan contact with shroud
- Loose fan, contact with coil, loss of cooling

### Potential Cause(s) of Failure
- “e” clip too far from shaft and slot
- Designed interference of swaged tangs not sufficient; swaging process not capable
- Plastic creep relieves screw tension, allows back-out
- Drive in crooked, miss hole or not fully tight
- Incomplete installation, not fully snapped on
- Retainer not keyed with respect to flats on motor shaft

### Current Controls
- Maintain dimensional capability within limits of tolerance stack-up
- Swage method reviewed; pull out tests; DV testing; ES tests
- Maintain dimensional capability within limits of tolerance stack-up
- Counterbore in screw-hole, torque-to-fail much higher than prevailing
- Counterbore, optimize boss diameter and height
- Design motor and fan for easy clip installation with tactile snap on lock
- ES and DV testing

### Risk Priority No. (RPN)

#### Example 6
Cooling fan assembly.
### Part name/part no.
### Product function
### Potential failure mode
### Potential effect(s) of failure
### Control critical item
### Potential cause(s) of failure
### Existing conditions

<table>
<thead>
<tr>
<th>Part name/part no.</th>
<th>Product function</th>
<th>Potential failure mode</th>
<th>Potential effect(s) of failure</th>
<th>Control critical item</th>
<th>Potential cause(s) of failure</th>
<th>Occurrence</th>
<th>Severity</th>
<th>Detection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Torque plate</td>
<td>Transmit torque from motor to fan</td>
<td>Motor shaft deforms flats in hole</td>
<td>Fan does not reach full RPM, fan bore wears. Loss of cooling, vibration from loose fan</td>
<td></td>
<td>Torque plate hole oversized; steel not proper thickness or hardness</td>
<td>3</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Torque plate not fully seated</td>
<td>Engagement of flats is reduced torque plate hole enlarged from stress</td>
<td></td>
<td>Close tolerances of fan pockets and legs of plate</td>
<td>3</td>
<td>5</td>
<td>7</td>
</tr>
</tbody>
</table>

**Example 6**  
Cooling fan assembly.
### FMEA Samples

**Process:** P.O. nitride etch

<table>
<thead>
<tr>
<th>Process name</th>
<th>Process function</th>
<th>Potential failure mode</th>
<th>Potential effects of failures</th>
<th>Potential causes of failure</th>
<th>Existing conditions (1–10)</th>
<th>Current controls</th>
<th>Recommended actions</th>
<th>Area/ person responsible</th>
<th>Completion date</th>
</tr>
</thead>
<tbody>
<tr>
<td>P.O. nitride etch</td>
<td>P.O. nitride etch</td>
<td>Poor selectivity</td>
<td>Overetch Nitride voids</td>
<td>Chamber leak High O2 flow Low CF4 flow High temperature</td>
<td>Daily and weekly monitors Subsequent wafer inspections</td>
<td>3 6 3 54</td>
<td>Replace A-24-D reactors</td>
<td>Open</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Poor uniformity</td>
<td>Overetch Underetch Nitride voids Dark bond pads</td>
<td>Chamber leak Wrong gas flow Wrong pressure Wrong power</td>
<td>Daily and weekly monitors Subsequent wafer inspections</td>
<td>3 5 3 45</td>
<td>Replace A-24-D reactors</td>
<td>D.S. 3/6/94</td>
<td>3/6/94</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Overetch Nitride voids Dark bond pads</td>
<td>Etch time too long High O2 flow Low CF4 flow High temperature High RF power</td>
<td>Daily and weekly monitors Subsequent wafer inspections</td>
<td>3 7 3 63</td>
<td>Replace A-24-D reactors</td>
<td>Open</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Underetch</td>
<td>Poor bondability</td>
<td>Etch time too short High O2 flow Low RF power</td>
<td>Daily and weekly monitors Subsequent wafer inspections</td>
<td>3 6 3 54</td>
<td>Replace A-24-D reactors</td>
<td>D.S. 3/6/94</td>
<td>3/6/94</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Scratches Nitride voids Metal shorts</td>
<td>Wafer loading and unloading Subsequent wafer inspection</td>
<td>Daily and weekly monitors Subsequent wafer inspections</td>
<td>7 5 4 140</td>
<td>Replace A-24-D reactors Implement wafer-handling system</td>
<td>C.S. Open</td>
<td>T.S. Open</td>
</tr>
</tbody>
</table>

**Example 7** Nitride etch. (Continued)
### Example 7  Nitride etch.

<table>
<thead>
<tr>
<th>Process name</th>
<th>Process function</th>
<th>Potential failure mode</th>
<th>Potential effects of failures</th>
<th>Potential causes of failure</th>
<th>Existing conditions</th>
<th>Recommended actions</th>
<th>Area/ person respons.</th>
<th>Comp date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dark bond pads</td>
<td>Poor bondability</td>
<td>Overetch</td>
<td>Poor bondability, Not rinsed properly after processing</td>
<td>Daily and weekly monitors, Subsequent wafer inspections, SPC</td>
<td>3 1 7 3 63</td>
<td>Replace A-24-D reactors</td>
<td>D.S.</td>
<td>3/6/94</td>
</tr>
<tr>
<td>Device: Process: Backgrind</td>
<td></td>
<td>Too thin</td>
<td>Poor bondability</td>
<td>Improper machine setup</td>
<td>Subsequent thickness measurements</td>
<td>3 4 3 36</td>
<td>Supply computer program to assist operator</td>
<td>D.S.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Grinding wheel dirty</td>
<td>SPC</td>
<td>4 4 3 48</td>
<td>Establish periodic cleaning</td>
<td>D.S.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Poor uniformity within wafer</td>
<td></td>
<td>4 4 2 32</td>
<td>Rebuild slide/ball screw</td>
<td>D.S.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Poor uniformity wafer to wafer</td>
<td></td>
<td>5 4 4 80</td>
<td>Rebuild slide/ball screw</td>
<td>D.S.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Too thick</td>
<td>Poor bondability</td>
<td>Improper machine setup</td>
<td>Subsequent thickness measurements</td>
<td>3 4 4 48</td>
<td>Supply computer program to assist operator</td>
<td>C.S.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Grinding wheel dirty</td>
<td>SPC</td>
<td>4 4 4 64</td>
<td>Establish periodic cleaning</td>
<td>C.S.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Poor uniformity within wafer</td>
<td></td>
<td>4 4 2 32</td>
<td>Rebuild slide/ball screw</td>
<td>C.S.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Poor uniformity wafer to wafer</td>
<td></td>
<td>5 4 5 100</td>
<td>Rebuild slide/ball screw</td>
<td>C.S.</td>
</tr>
<tr>
<td>Part name/part number</td>
<td>Process function</td>
<td>Potential failure mode</td>
<td>Potential effect(s) of failures</td>
<td>Potential cause(s) of failure</td>
<td>Existing conditions</td>
<td>Recommended action(s) and status</td>
<td>Action(s) taken</td>
<td></td>
</tr>
<tr>
<td>-----------------------</td>
<td>------------------</td>
<td>------------------------</td>
<td>-------------------------------</td>
<td>-----------------------------</td>
<td>--------------------</td>
<td>----------------------------------</td>
<td>----------------</td>
<td></td>
</tr>
<tr>
<td>Ford automotive circuits</td>
<td>Slit base laminate/coverlay</td>
<td>Incorrect width</td>
<td>Images will not fit web or web will not fit tooling</td>
<td>Incorrect setup Incorrect documentation</td>
<td>Setup monitored. Inspected at proceeding operations.</td>
<td>Standard web widths used and specified on routing</td>
<td>Completed 1 3 13</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Incorrect material</td>
<td>Unreliable part</td>
<td>Incorrect setup</td>
<td>Compare material part number to routing</td>
<td>BOM cross-check to routing sheet at all operations</td>
<td>Completed 1 5 3 15</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mislabeled material</td>
<td>Incorrect documentation</td>
<td>Engineering maintains route sheets</td>
<td>Verified at laminations operations</td>
<td>Preventative maintenance</td>
<td>Feedback from next operation</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Damaged material (dents, wrinkled, rough edges)</td>
<td>Scrap</td>
<td>Dull blades</td>
<td>Preventative maintenance</td>
<td>Clean equipment</td>
<td>Shutdown procedure implemented</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Foreign material</td>
<td>Cast off</td>
<td>Poor handling</td>
<td>Preventative maintenance</td>
<td>Clean equipment</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Example 8* Slit base laminate.
<table>
<thead>
<tr>
<th>Part name/part number</th>
<th>Process function</th>
<th>Potential failure mode</th>
<th>Potential effect(s) of failures</th>
<th>Potential cause(s) of failure</th>
<th>Existing conditions</th>
<th>Recommended action(s) and status</th>
<th>Action(s) taken</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ford automotive circuits</td>
<td>Pierce and index material web (overlay only)</td>
<td>Incorrect material orientation</td>
<td>Incorrect documentation</td>
<td>Operator training</td>
<td>Orientation specified on routings</td>
<td>Compare material part number to routing</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>Cutline quality</td>
<td>- Slivers</td>
<td>- Slugs</td>
<td>- Incomplete cut</td>
<td>Machine setup and visual tooling wear</td>
<td>Die adjustment and visual inspection</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>New web cleaner planned for indexing</td>
<td>Electrical test for opens due to slugs left in pad area</td>
<td>1st unit implemented</td>
</tr>
</tbody>
</table>

**Example 8** Slit base laminate.
### Example 8  Slit base laminate.

<table>
<thead>
<tr>
<th>Part name/part number</th>
<th>Process function</th>
<th>Potential failure mode</th>
<th>Potential effect(s) of failures</th>
<th>Potential cause(s) of failure</th>
<th>Existing conditions</th>
<th>Current controls</th>
<th>Recommended action(s) and status</th>
<th>Action(s) taken</th>
</tr>
</thead>
<tbody>
<tr>
<td>LED upside down</td>
<td>Assembly</td>
<td>No light</td>
<td>Operator error, Bent wrong</td>
<td>1</td>
<td>10</td>
<td>1</td>
<td>10</td>
<td>None</td>
</tr>
<tr>
<td>LED twisted</td>
<td>Assembly</td>
<td>Won't fit in backer board</td>
<td>Bent wrong, Handling, Pin twisted in fixture</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>None</td>
</tr>
<tr>
<td>Alignment of header assembly</td>
<td></td>
<td>Circuit board misaligned</td>
<td>Board drilled wrong, Operator error</td>
<td>4</td>
<td>10</td>
<td>3</td>
<td>120</td>
<td>A.I. NC drill</td>
</tr>
<tr>
<td>Circuit not bonded to board</td>
<td></td>
<td>Customer return</td>
<td>Didn't roll enough, Bad PSA</td>
<td>3</td>
<td>10</td>
<td>2</td>
<td>60</td>
<td>Inspection and DOE to define the precise material</td>
</tr>
</tbody>
</table>

(Continued)
Process
function

Dome
assembly

Example 8

Potential
effect(s)
of
failures

Potential
failure
mode

Potential
cause(s)
of
failure

Current
controls

*
6

*
7

*
8

*
9

Recommended
action(s)
and status

Action(s)
taken

* * * *
6 7 8 9

Put header Won’t fit
upside
in TI
down
printer

 Operator
oriented
wrong

1 10 2

20

None

None

Wrong
header

Won’t fit
in TI
printer

 Wrong part

1 10 1

10

None

None

Misaligned
dome

Field
failure

 Static
fly-out

Nothing

2 10 10 200 100%
inspect

Done
2/4/94

2 10 3 60

Wrong
shim

Lump in
overlay

 Wrong
material

Incoming
Inspection

2 10 7 140 Incoming
SPC

Done
5/5/94

2 10 2 40

No shim

Cosmetic

Operator error

Inspection

2

Done
2/4/94

2 7 3 42

Misregistered
retainer

Domes
slip

 Operator error

Inspection

2 10 5 100 Redesign part
for foolproof
design

Done
3/4/94

1 1 1 1

Slit base laminate.

7

8 112 Keep good
parts for
comparison

Appendix D

Part
name/
part
number

CD-106

(Continued)
Existing conditions


<table>
<thead>
<tr>
<th>Part name/part number</th>
<th>Process function</th>
<th>Potential failure mode</th>
<th>Potential effect(s) of failures</th>
<th>Potential cause(s) of failure</th>
<th>Existing conditions</th>
<th>Recommended action(s) and status</th>
<th>Action(s) taken</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shield misaligned</td>
<td>Overlay alignment off</td>
<td>Operator error</td>
<td>2, 10, 2, 40</td>
<td>None</td>
<td>None</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shim/circuit not peeled</td>
<td>Overlay could come off</td>
<td>Torn release paper</td>
<td>1, 7, 5, 35</td>
<td>None</td>
<td>None</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Double shim</td>
<td>Cosmetic</td>
<td>2 shims stick together</td>
<td>2, 10, 2, 40</td>
<td>None</td>
<td>None</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Double domes</td>
<td>Force to fire out of spec</td>
<td>Domes stick together</td>
<td>2, 5, 2, 20</td>
<td>None</td>
<td>None</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missing domes</td>
<td>Wont test in house</td>
<td>Operator error</td>
<td>1, 10, 1, 10</td>
<td>None</td>
<td>None</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missing retainer</td>
<td>Domes fall out</td>
<td>Operator error</td>
<td>1, 10, 1, 10</td>
<td>None</td>
<td>None</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Example 8 Slit base laminate.
<table>
<thead>
<tr>
<th>Part name/part number</th>
<th>Process function</th>
<th>Potential failure mode</th>
<th>Potential effect(s) of failures</th>
<th>Potential cause(s) of failure</th>
<th>Existing conditions</th>
<th>Current controls</th>
<th>Potential action(s) and status</th>
<th>Action(s) taken</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overlay assembly/ET</td>
<td></td>
<td>Misaligned overlay to circuit</td>
<td>Customer return</td>
<td>Operator error</td>
<td>Inspection</td>
<td>5 10 7 350</td>
<td>Redesign part for foolproof design</td>
<td>Done 5/10/94</td>
</tr>
<tr>
<td>Overlay loose</td>
<td></td>
<td>Customer return</td>
<td>Void in PSA</td>
<td>Inspection</td>
<td>3 10 7 210</td>
<td>Redesign part for foolproof design</td>
<td>Done 5/10/94</td>
<td></td>
</tr>
<tr>
<td>Missing overlay</td>
<td></td>
<td>Customer return</td>
<td>Operator error</td>
<td>Inspection</td>
<td>3 10 7 210</td>
<td>Redesign part for foolproof design</td>
<td>Done 5/10/94</td>
<td></td>
</tr>
<tr>
<td>LED bent/fail bent at wrapping</td>
<td></td>
<td>Electrical failure</td>
<td>Poor handling</td>
<td>Inspection</td>
<td>2 10 5 100</td>
<td>Redesign part for foolproof design</td>
<td>Done 5/10/94</td>
<td></td>
</tr>
<tr>
<td>Missing keys at testing</td>
<td></td>
<td>Operator error</td>
<td>Inspection</td>
<td>1 5 10</td>
<td>Redesign part for foolproof design</td>
<td>Done 5/10/94</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missing/wrong date code</td>
<td></td>
<td>Operator error</td>
<td>Inspection</td>
<td>1 5 7</td>
<td>Redesign part for foolproof design</td>
<td>Done 5/10/94</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missing/wrong part number</td>
<td></td>
<td>Operator error</td>
<td>Inspection</td>
<td>1 5 7</td>
<td>Redesign part for foolproof design</td>
<td>Done 5/10/94</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Example 8** Slit base laminate.
<table>
<thead>
<tr>
<th>Part name/part number</th>
<th>Process function</th>
<th>Potential failure mode</th>
<th>Potential effect(s) of failures</th>
<th>Potential cause(s) of failure</th>
<th>Existing conditions</th>
<th>Current controls</th>
<th>Potential effect(s) of failure</th>
<th>Potential cause(s) of failure</th>
<th>Existing conditions</th>
<th>Recommended action(s) and status</th>
<th>Action(s) taken</th>
</tr>
</thead>
<tbody>
<tr>
<td>LED assembly</td>
<td>Wrong color LEDs</td>
<td>Customer reject</td>
<td>Operator error</td>
<td>Inspection</td>
<td>9 8 7 10</td>
<td></td>
<td>9 8 7 10</td>
<td>Color code fixture</td>
<td>Done</td>
<td>3/5/94</td>
<td>6 7 8 9</td>
</tr>
<tr>
<td></td>
<td>Cold solder joints</td>
<td>LED intermittent</td>
<td>Operator error</td>
<td>Inspection</td>
<td>5 10 9 450</td>
<td></td>
<td>5 10 9 450</td>
<td>Solder training</td>
<td>Done</td>
<td>3/5/94</td>
<td>2 10 1 20</td>
</tr>
<tr>
<td></td>
<td>Not enough solder</td>
<td>LED intermittent</td>
<td>Operator tech</td>
<td>Inspection</td>
<td>5 10 9 450</td>
<td></td>
<td>5 10 9 450</td>
<td>Solder training</td>
<td>Done</td>
<td>3/5/94</td>
<td>2 10 1 20</td>
</tr>
</tbody>
</table>

Example 9  GDS assembly.

(Continued)
<table>
<thead>
<tr>
<th>Part name/part number</th>
<th>Process function</th>
<th>Potential failure mode</th>
<th>Potential effect(s) of failures</th>
<th>Potential cause(s) of failure</th>
<th>Existing conditions</th>
<th>Current controls</th>
<th>Recommended action(s) and status</th>
<th>Action(s) taken</th>
<th>Action(s)</th>
<th>Action(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrong orientation</td>
<td>Won't light</td>
<td>❌</td>
<td>Operator error</td>
<td>Made wrong</td>
<td></td>
<td>10 10 3 300</td>
<td>Redesign for foolproof design</td>
<td>Done</td>
<td>5/10/94</td>
<td>1 1 1 1 1</td>
</tr>
<tr>
<td>Too much solder</td>
<td>Lump in overlay</td>
<td>❌</td>
<td>Operator tech</td>
<td>Iron temp too high</td>
<td>Inspection</td>
<td>5 7 4 140</td>
<td>Spec operator training</td>
<td></td>
<td>5 7 1 35</td>
<td></td>
</tr>
<tr>
<td>Cracked LEDs</td>
<td>Failure</td>
<td>❌</td>
<td>Bending fixture</td>
<td></td>
<td>Nothing</td>
<td>1 10 10 100</td>
<td>Redesign</td>
<td>Done</td>
<td>5/10 94</td>
<td>1 1 1 1 1</td>
</tr>
<tr>
<td></td>
<td>overtime</td>
<td>❌</td>
<td>Handling</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Too much heat</td>
<td>Circuit delamination (reliability)</td>
<td>❌</td>
<td>Iron not calibrated</td>
<td>Thicker solder</td>
<td>Inspection</td>
<td>1 10 9 90</td>
<td>SPC</td>
<td>Done</td>
<td>5/10/94</td>
<td>1 10 3 30</td>
</tr>
<tr>
<td>Bad LEDs</td>
<td>Won't light</td>
<td>❌</td>
<td>Supplier problem</td>
<td></td>
<td>Inspection</td>
<td>1 10 3 30</td>
<td>Incoming inspection Supplier certification</td>
<td>Done</td>
<td>5/10/94</td>
<td>1 10 2 20</td>
</tr>
</tbody>
</table>

Example 9  GDS assembly.
<table>
<thead>
<tr>
<th>Part name/ part number</th>
<th>Process function</th>
<th>Potential failure mode</th>
<th>Potential effect(s) of failures</th>
<th>Potential cause(s) of failure</th>
<th>Existing conditions</th>
<th>Current controls</th>
<th>Recommended action(s) and status</th>
<th>Action(s) taken</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ford automotive circuits</td>
<td>Copper clean</td>
<td>Poorly cleaned</td>
<td>Poor resist adhesion</td>
<td>Chemical bath concentration</td>
<td>Bath solutions monitored</td>
<td>1 4 3 12</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Incorrect web speed</td>
<td>Operator controls web speed based on cleaning quality</td>
<td></td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Damaged material</td>
<td>Scrap</td>
<td></td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Cast off</td>
<td>Reject/scrap material</td>
<td>1 3 1 3</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Poor handling</td>
<td>Operator training of mechanized handling equipment</td>
<td></td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Part name/ part number</td>
<td>Process function</td>
<td>Potential failure mode</td>
<td>Potential effect(s) of failures</td>
<td>Potential cause(s) of failure</td>
<td>Existing conditions</td>
<td>Current controls</td>
<td>Recommended action(s) and status</td>
<td>Action(s) taken</td>
</tr>
<tr>
<td>-----------------------</td>
<td>------------------</td>
<td>------------------------</td>
<td>-------------------------------</td>
<td>-------------------------------</td>
<td>---------------------</td>
<td>----------------</td>
<td>-------------------------------</td>
<td>----------------</td>
</tr>
<tr>
<td>Ford automotive circuits</td>
<td>Screen resist</td>
<td>Poor image quality</td>
<td>Conductor criteria violated</td>
<td>Dried in ink in screen</td>
<td>Thorough vision inspection every 25 cycles and constant observation</td>
<td>4 4 5 80</td>
<td>100% electrical test</td>
<td>Electrical testers designed and in house</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Incorrect image cure</td>
<td>Incorrect ink adhesion</td>
<td>Foreign material</td>
<td></td>
<td></td>
<td>Web cleaner planned for screening</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Smears</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Incorrect setup</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Tooling wear</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Oven temperature and web speed</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Loss of resistance to etchant chemical</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Pre-set electronic temperature control and visual inspection for correct ink color</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Example 9  GDS assembly.
<table>
<thead>
<tr>
<th>Part name/part number</th>
<th>Process function</th>
<th>Potential failure mode</th>
<th>Potential effect(s) of failures</th>
<th>Potential cause(s) of failure</th>
<th>Existing conditions</th>
<th>Recommended action(s) and status</th>
<th>Action(s) taken</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ford automotive circuits</td>
<td>Incorrect registration</td>
<td>Generates rework and added setup time</td>
<td>Improper setup</td>
<td>Image comparison to film gauge and constant visual inspection</td>
<td>None</td>
<td>None</td>
<td></td>
</tr>
</tbody>
</table>

Example 9  GDS assembly.
<table>
<thead>
<tr>
<th>Part name/ part number</th>
<th>Process function</th>
<th>Potential failure mode</th>
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<th>Potential cause(s) of failure</th>
<th>Existing conditions</th>
<th>Current controls</th>
<th>Recommended action(s) and status</th>
<th>Action(s) taken</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ford automotive circuits</td>
<td>Etch</td>
<td>Over- or under-etched</td>
<td>Violation of conductor width criteria (opens and shorts)</td>
<td>Incorrect web width</td>
<td>SPC—X bar and R charts.</td>
<td>2 5 5 50</td>
<td>Quarterly $C_{pk}$ study computed</td>
<td>2 5 1 10</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>High etchant concentration</td>
<td>Etchant concentrations monitored and maintained routinely</td>
<td></td>
<td>Operators received further SPC training to improve data recording and record maintenance</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Poor etchant resist.</td>
<td></td>
<td></td>
<td>Standard etching coupon implemented to monitor operator</td>
<td></td>
</tr>
</tbody>
</table>

**Example 9** GDS assembly.
<table>
<thead>
<tr>
<th>Complaint</th>
<th>Effect</th>
<th>Diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chest pain</td>
<td>Decreased ventilation</td>
<td>Impaired gas exchange</td>
</tr>
<tr>
<td></td>
<td>Increased carbon dioxide retention and respiratory acidosis</td>
<td>Ineffective breathing pattern</td>
</tr>
<tr>
<td></td>
<td>Discomfort</td>
<td>Fear of chest pain</td>
</tr>
<tr>
<td></td>
<td>Pain</td>
<td>Alteration in comfort</td>
</tr>
<tr>
<td>Cough</td>
<td>Chronic and short term (less than one month)</td>
<td>Alteration in carbon dioxide level</td>
</tr>
<tr>
<td></td>
<td>Hazardous elevation in intrathoracic pressure</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Intracranial pressure and blood pressure</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cough syncope</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fractured ribs</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Musculoskeletal pain</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Forced cough</td>
<td>Impaired gas exchange</td>
</tr>
<tr>
<td>Chronic and long term (longer than one month)</td>
<td>Fatigue</td>
<td>Alteration in comfort</td>
</tr>
<tr>
<td></td>
<td>Weight loss</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Anorexia</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Collapsed airways</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rupture of thin-walled alveoli</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Second-degree irritation of tracheobronchical tree</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hemoptysis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Impaired gas exchange</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fear of seeing blood</td>
<td></td>
</tr>
</tbody>
</table>

Quite often this format is also used for corrective actions in lieu of diagnosis and sometimes numerical values are assigned so that a RPN is calculated.

Example 10  Complaint diagnosis.
### Complaint Diagnosis

<table>
<thead>
<tr>
<th>Complaint</th>
<th>Effect</th>
<th>Diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dyspnea</strong></td>
<td>Acute</td>
<td>• Alteration in comfort</td>
</tr>
<tr>
<td></td>
<td>• Diaphoresis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Restlessness</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Chronic</td>
<td>• Ineffective breathing pattern</td>
</tr>
<tr>
<td></td>
<td>• Barrel chest</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Accessory muscle change</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Acute and chronic</td>
<td>• Fear of breathlessness</td>
</tr>
<tr>
<td></td>
<td>• Emotional distress</td>
<td>• Impaired gas exchange</td>
</tr>
<tr>
<td></td>
<td>• Fatigue</td>
<td>• Impaired physical mobility</td>
</tr>
<tr>
<td></td>
<td>• Exhaustion</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Hypoventilation/hyperventilation</td>
<td></td>
</tr>
<tr>
<td><strong>Increased and abnormal secretions</strong></td>
<td>Hemoptysis</td>
<td>• Ineffective airway clearance</td>
</tr>
<tr>
<td></td>
<td>• Obstruction with blood</td>
<td>• Impaired gas exchange</td>
</tr>
<tr>
<td></td>
<td>• Blood-streaked sputum</td>
<td>• Alteration in tissue perfusion</td>
</tr>
<tr>
<td></td>
<td>Increased sputum</td>
<td>• Fear of seen blood</td>
</tr>
<tr>
<td></td>
<td>• Mucous plugs</td>
<td>• Ineffective airway clearance</td>
</tr>
<tr>
<td></td>
<td>• Increased secretions and/or abnormal fluids retained in lung</td>
<td>• Impaired gas exchange</td>
</tr>
</tbody>
</table>

**Example 10**  Complaint diagnosis.
Example 11  FTA development of an air pumping system. (Top) A typical air pumping system. (Bottom) FTA for the air pumping system.
<table>
<thead>
<tr>
<th>Subsystem name: function and performance requirements</th>
<th>Potential failure mode</th>
<th>Effects of failure</th>
<th>S</th>
<th>Class</th>
<th>Causes</th>
<th>O</th>
<th>Controls</th>
<th>D</th>
<th>R P N</th>
<th>Recommended action</th>
<th>Resp. &amp; completion date</th>
<th>Action taken</th>
<th>S</th>
<th>O</th>
<th>D</th>
<th>R P N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Modular oven to provide heat for a period of 10 minutes at a temperature of 350°F</td>
<td>Does not heat</td>
<td>Downtime 5 hours</td>
<td>6</td>
<td>YC</td>
<td>Flame relay</td>
<td>5</td>
<td>Temperature alarm</td>
<td>6</td>
<td>180</td>
<td>Review relay spec and warranty data</td>
<td>Eng. D. Stamatis 6/4/03</td>
<td>Selected new flame relay with higher temp. ratings</td>
<td>6</td>
<td>2</td>
<td>6</td>
<td>72</td>
</tr>
<tr>
<td>The oven shall circulate air to cure the rocker panels of the vehicle</td>
<td>Does not heat</td>
<td>Downtime 3 hours</td>
<td>3</td>
<td>3</td>
<td>Defective damper</td>
<td>3</td>
<td>Temperature alarm</td>
<td>6</td>
<td>54</td>
<td>Review damper spec and location</td>
<td>Eng. C. Stamatis 6/4/03</td>
<td>None</td>
<td>3</td>
<td>2</td>
<td>6</td>
<td>36</td>
</tr>
<tr>
<td>MTBF—1500 hrs; MTTR—30 min.</td>
<td>Does not heat</td>
<td>Downtime 20 min</td>
<td>2</td>
<td>Temperature alarm and PM</td>
<td>5</td>
<td>Temperature alarm and PM</td>
<td>5</td>
<td>20</td>
<td>No action</td>
<td>None</td>
<td>Review design of flame amplifier manual</td>
<td>Eng. J. Roberson 6/4/03</td>
<td>Redesign flame switch &amp; select new amplifier card</td>
<td>5</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>Availability—99.9%</td>
<td>Does not heat</td>
<td>Downtime 30 min</td>
<td>2</td>
<td>Gas regulator</td>
<td>2</td>
<td>Gas pressure switch &amp; PM</td>
<td>3</td>
<td>12</td>
<td>No action</td>
<td>None</td>
<td>Review relay spec and warranty data</td>
<td>Eng. S. Stamatis 6/4/03</td>
<td>Select a new valve type</td>
<td>2</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>CFM—38000 with 5% contamination</td>
<td>Does not heat</td>
<td>Downtime 30 min</td>
<td>2</td>
<td>Temperature alarm</td>
<td>5</td>
<td>Temperature alarm</td>
<td>3</td>
<td>30</td>
<td>Review warranty &amp; test data</td>
<td>Eng. S. Stamatis 6/4/03</td>
<td>None</td>
<td>3</td>
<td>3</td>
<td>6</td>
<td>36</td>
<td></td>
</tr>
<tr>
<td>Environmental: 90°F 90-99% relative humidity</td>
<td>Over temperature</td>
<td>Overbake Downtime 30 min</td>
<td>9</td>
<td>OS</td>
<td>Flame relay</td>
<td>5</td>
<td>Temperature alarm</td>
<td>6</td>
<td>270</td>
<td>Review design of flame amplifier manual</td>
<td>Eng. J. Roberson 6/4/03</td>
<td>Selected new flame relay with higher temp. ratings</td>
<td>6</td>
<td>2</td>
<td>6</td>
<td>72</td>
</tr>
</tbody>
</table>

**Example 12** Machine FMEA: modular oven.
<table>
<thead>
<tr>
<th>Paint solvents conveyor vibration 80dBA.</th>
<th>Low airflow</th>
<th>Underbake 45 min</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>High fire limit switch</strong></td>
<td>6</td>
<td>None</td>
<td>10</td>
</tr>
<tr>
<td><strong>Flame amplifier</strong></td>
<td>3</td>
<td>None</td>
<td>10</td>
</tr>
<tr>
<td><strong>Defective gas train</strong></td>
<td>3</td>
<td>None</td>
<td>10</td>
</tr>
<tr>
<td><strong>Dirty filter</strong></td>
<td>2</td>
<td>Air flow switch</td>
<td>2</td>
</tr>
<tr>
<td><strong>Closed damper Stuck damper</strong></td>
<td>4</td>
<td>Temperature alarm</td>
<td>6</td>
</tr>
<tr>
<td><strong>Defective fans</strong></td>
<td>2</td>
<td>None</td>
<td>10</td>
</tr>
<tr>
<td><strong>Clogged supply lines</strong></td>
<td>2</td>
<td>None</td>
<td>10</td>
</tr>
<tr>
<td><strong>Defective fan motors</strong></td>
<td>2</td>
<td>None</td>
<td>10</td>
</tr>
<tr>
<td><strong>Broken belt</strong></td>
<td>4</td>
<td>None</td>
<td>10</td>
</tr>
</tbody>
</table>

**Example 12** Machine FMEA: modular oven.
Appendix E

FMEA Forms

This appendix provides a variety of FMEA forms. None of them is a standard for all industries. The intent of this appendix is to give the reader an idea of how to construct an FMEA form with all the essential information for the optimum results. Every one of the FMEA forms may be modified to reflect the specific objective of the organization.
<table>
<thead>
<tr>
<th>System/design/process/service function</th>
<th>Potential failure mode</th>
<th>Potential effect(s) of failure</th>
<th>Potential cause(s) of failure</th>
<th>Detection method</th>
<th>O</th>
<th>C</th>
<th>C</th>
<th>S</th>
<th>E</th>
<th>V</th>
<th>D</th>
<th>E</th>
<th>T</th>
<th>R</th>
<th>P</th>
<th>N</th>
<th>Recommended action</th>
<th>Responsibility &amp; completion date</th>
<th>Action results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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<td></td>
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</tr>
</tbody>
</table>

Figure E1  A generic FMEA form.
### A generic FMEA form

**Figure E.2**

<table>
<thead>
<tr>
<th>System/ design/ process/ service function</th>
<th>Potential failure mode</th>
<th>Potential effect(s) of failure</th>
<th>Potential cause(s) of failure</th>
<th>Detection method</th>
<th>O</th>
<th>S</th>
<th>D</th>
<th>R</th>
<th>C</th>
<th>E</th>
<th>E</th>
<th>P</th>
<th>C</th>
<th>V</th>
<th>T</th>
<th>N</th>
<th>Recommended action</th>
<th>Responsibility and completion date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

**Team**

- Name __________
- FMEA ID __________
- Date __________
- Prepared by __________
- Resp. eng. __________
- Release date __________
- Part __________
- Page __________
- FMEA date __________
- FMEA rev. date __________
- Page of pages __________
- of __________
- pages __________
| System function | Potential failure mode | Potential effect(s) of failure | Potential cause(s) of failure | Detection method | O | C | C | S | E | V | D | E | T | R | P | N | Recommended action | Responsibility and completion date | Action results | Action taken | S | E | V | O | C | C | D | E | T | R | P | N |

**Figure E.3** A generic FMEA form.
<table>
<thead>
<tr>
<th>Part number</th>
<th>Part name</th>
<th>Potential failure mode</th>
<th>Potential effect(s) of failure</th>
<th>Potential cause(s) of failure</th>
<th>Design verification</th>
<th>Recommended action(s)</th>
<th>Responsibility and completion date</th>
<th>Action results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Figure E.4** A design FMEA form.
### Design Failure Mode and Effects Analysis (FMEA) Form

<table>
<thead>
<tr>
<th>Design function</th>
<th>Failure mode</th>
<th>Failure effects</th>
<th>Causes</th>
<th>Validation</th>
<th>OCC</th>
<th>SEV</th>
<th>DET</th>
<th>RPN</th>
<th>Recommended action</th>
<th>Action taken</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>System/assembly</td>
<td>Product</td>
<td>User</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Figure E.5** A design FMEA form.
### Figure E.6  A process FMEA form.
<table>
<thead>
<tr>
<th>Process function</th>
<th>Failure mode</th>
<th>Failure effects</th>
<th>Class</th>
<th>Cause(s)</th>
<th>Design rational/ validation certification</th>
<th>Responsibility</th>
<th>Status/ target date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>System/assembly</td>
<td>Vehicle</td>
<td>User</td>
<td>S</td>
<td>C</td>
<td>U</td>
</tr>
</tbody>
</table>

**Figure E.7** A design FMEA form.
**Figure E.8** A process FMEA form.
**Potential failure mode and effects analysis (process FMEA)**

<table>
<thead>
<tr>
<th>Part number</th>
<th>Part name</th>
<th>Part function</th>
<th>Potential failure mode</th>
<th>Potential effect(s) of failure</th>
<th>Potential cause(s) of failure</th>
<th>Design verification</th>
<th>Recommended action(s)</th>
<th>Responsibility and completion date</th>
<th>Action results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Severity</th>
<th>Occurrence</th>
<th>Detection</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>RPN</th>
<th>Actions taken</th>
<th>Detection</th>
<th>Occurrence</th>
<th>Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Subassembly no./name ____________________________**

**Final assembly no./name _________________________**

**Other areas involved __________________________**

**Suppliers affected ______________________________**

**Prepared by ________________________________**

**FMEA date (original) __________________**

**Revision ______________________________**

---

**Figure E.9** A process FMEA form.
<table>
<thead>
<tr>
<th>Item/ function</th>
<th>Potential failure mode</th>
<th>Potential effect(s) of failure</th>
<th>C R I T</th>
<th>Potential cause(s) mechanism(s) of failure</th>
<th>O C U R</th>
<th>Current design controls</th>
<th>D E T E C T</th>
<th>R P N</th>
<th>Recommended action(s)</th>
<th>Responsibility and target completion date</th>
<th>Action results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Figure E.10** The recommended standard design form for the automotive industry.
Figure E.11 The recommended standard process form for the automotive industry.
<table>
<thead>
<tr>
<th>Line number (7)</th>
<th>Cross reference number (8)</th>
<th>Circuit location (9)</th>
<th>Enter the part/component number/name (10)</th>
<th>Function(s) &amp; specification(s) (11)</th>
<th>Potential failure mode(s) (12)</th>
<th>System effect (0=unsafe condition) (13)</th>
<th>Cause(s) of failure (15)</th>
<th>Internal or external countermeasures (controls) (16)</th>
<th>SEVERITY (17)</th>
<th>Base failure rate x 10^6 (18)</th>
<th>Failure mode ratio (19)</th>
<th>Effectiveness (20)</th>
<th>Risk priority number (21)</th>
</tr>
</thead>
</table>

(1) Part number. Enter the part number under consideration.
(2) Assembly number. Enter the number on the part of drawing or part list.
(3) Responsible engineer. Enter the name of the responsible engineer.
(4) Production release date. Enter the date the product is to be released for production.
(5) Page. Enter the FMCA page number.
(6) Date. Enter the date the page was worked on. Or, enter the revision date, if it is a revised FMCA.
(7) Line number. Identify the part for which the FMCA is to be conducted.
(8) Cross reference number. Enter the number if there is a cross reference with other parts or assemblies.
(9) Circuit location. Describe the location of the part on the circuit.
(10) Enter the part/component number/name. Enter the appropriate name.
(11) Function(s) and specification(s). Describe the function the part is to perform and the specification it is to meet. Make the description as clear and concise as possible. Be sure you include all functions. Include pertinent information about the product specification, such as operating current range, operating voltage range, operating environment and everything else that is applicable.
(12) Potential failure mode(s). A failure mode is a design flaw or change in the product that prevents it from functioning properly. The typical failure modes are a short circuit, open circuit, leak loosening. The failure mode is expressed in physical terms of what the customer will experience.
(13) System effect. The system effect is what a system or module might experience as a result of a failure mode. List all conceivable effects, including unsafe conditions or violations of government regulations. A typical system effect is a system shut-down or a failure of a section of the product.
(14) Unsafe. Enter 0 for unsafe end product condition.
(15) Cause of failure. The root cause (not the symptom) is the real cause. Examples: Insufficient/inaccurate voltage, firmware errors, missing instructions on drawings.
(16) Internal or external countermeasures (controls). Identify the controls and/or measures established to prevent or detect the cause of the failure mode. Examples: Perform a derating analysis, perform transient testing, perform specific testing, identify specific inspection and manufacturing specifications.
### Description of Table Content

<table>
<thead>
<tr>
<th>Line number (7)</th>
<th>Cross-reference number (8)</th>
<th>Circuit location (9)</th>
<th>Enter the part/component number/name (10)</th>
<th>Function(s) and specification(s) (11)</th>
<th>Potential failure mode(s) (12)</th>
<th>System effect (0 = unsafe condition) (13)</th>
<th>U N S A F E (14)</th>
<th>Cause(s) of failure (15)</th>
<th>Internal or external countermeasures (controls) (16)</th>
<th>S E V E R I T Y (17)</th>
<th>Base failure rate AB</th>
<th>Failure mode ratio (19)</th>
<th>Effectiveness (20)</th>
<th>Risk priority number (RPN) (21)</th>
</tr>
</thead>
</table>

#### Notes on Table

- **Severity (17)**: An estimate of how severe the subsystem and/or the end product will behave as a result of a given failure mode. Severity levels are being scaled from 1 to 10. Number 10 is to be used for a definite unsafe condition. Number 0 is to be used for a negligible severity (nuisance). Usually this rating, at this stage, is a very subjective rating.

- **Base failure rate (18)**: A subjective estimate of failure rate (probability of failure in a billion hours). This is also called inherent failure rate.

- **Failure ratio (19)**: A subjective estimate of failure rate (probability of failure in a billion hours). A subjective likelihood in comparison to the other failure modes. The sum of all failure rates for a part/component should be equal to 10 percent.

- **Effectiveness (20)**: A subjective estimate of how effectively the prevention or detection measure eliminates potential failure models. A typical ranking is the following:
  - 1 = The prevention or detection measure is foolproof.
  - 2–3 = Probability of failure occurrence is low.
  - 4–6 = Probability of occurrence is high.
  - 7–9 = Very high probability. The prevention/detection is ineffective.

- **Risk priority number (RPN) (21)**: The product of severity, base failure rate, failure mode ratio, and effectiveness.

---

**Figure E.12** A design FMCA form.
<table>
<thead>
<tr>
<th>Line</th>
<th>Cross-reference number</th>
<th>Circuit location</th>
<th>Enter the part/component number/name</th>
<th>Operation steps</th>
<th>Potential failure mode(s)</th>
<th>Cause(s) of failure</th>
<th>Internal or external countermeasures (controls)</th>
<th>SEVERITY</th>
<th>PPM</th>
<th>Effectiveness</th>
<th>Risk priority number (RPN)</th>
</tr>
</thead>
</table>

1. **Operation name (1)**: Enter the name of the operation.
2. **Workstation (2)**: Enter the name or number of the workstation.
3. **Responsible engineer (3)**: Enter the name of the responsible engineer.
4. **Subassembly number (4)**: Enter the subassembly name or number.
5. **Supplier (5)**: Indicate where the process is performed.
6. **Original date (6)**: Enter the date that the FMCA is due and/or completed.
7. **Production release date (7)**: Enter the date the product is to be released for production.
8. **Page (8)**: Enter the FMCA page number.
9. **Revise date (9)**: Enter the date of the revision.
10. **Line number (10)**: Identify the part for which the FMCA is to be conducted.
11. **Cross-reference number (11)**: Enter the number if there is a cross-reference with other parts or assemblies.
12. **Circuit location (12)**: Describe the location of the part on the circuit.
13. **Enter the part/component number/name (13)**: Enter the appropriate name.
14. **Operation steps (14)**: List all steps of operation in the process. A good tool to use for this is the process flow diagram.
15. **Potential failure mode(s) (15)**: A process-related failure mode is a deviation from specification caused by a change in the variables influencing the process. Examples: Damaged board, misaligned, discolored, missing, bent, and so on.
16. **Cause(s) of failure (16)**: The root cause (not the symptom) is the real cause. Examples: Transient, human error, machine out of tolerance, ESD equipment failure.
17. **Internal or external countermeasures (controls) (17)**: Identify the controls and/or measures established to prevent or detect the cause of the failure mode. Examples: Verify tooling to its specification, effective incoming inspection, testing, and so on.
18. **Severity (18)**: A subjective estimate of how severe the subsystem and/or the end product will behave as a result of a given failure mode. Severity levels are being scaled from 1 to 10. Number 10 is to be used for a definite unsafe condition. Number 0 is to be used for a negligible severity (nuisance).

Figure E.13  A process FMCA form. (Continued)
<table>
<thead>
<tr>
<th>Line number (10)</th>
<th>Cross-reference number (11)</th>
<th>Circuit location (12)</th>
<th>Enter the part/component number/name (13)</th>
<th>Operation steps (14)</th>
<th>Potential failure mode(s) (15)</th>
<th>Cause(s) of failure (16)</th>
<th>Internal or external countermeasures (controls) (17)</th>
<th>SEVERITY (18)</th>
<th>PPM (19)</th>
<th>Effectiveness (20)</th>
<th>Risk priority number (RPN) (21)</th>
</tr>
</thead>
</table>

19) PPM. Is the percent failure per 1 million parts.

20) Effectiveness. A subjective estimate of how effectively the prevention or detection measure eliminates potential failure models. A typical ranking is the following:

1 = The prevention or detection is foolproof.
2–3 = Probability of failure occurrence is low.
4–6 = Probability of occurrence is moderate.
7–9 = Probability of occurrence is high.
10 = Very high probability. The prevention/detection measure is ineffective.

21) Risk priority number (RPN). The product of severity, PPM, and effectiveness.

Figure E.13 A process FMCA form.
<table>
<thead>
<tr>
<th>Case number</th>
<th>Defect definition</th>
<th>Cause category</th>
<th>Cause definition</th>
<th>Stage created</th>
<th>OCC</th>
<th>SEV</th>
<th>DET</th>
<th>RP</th>
<th>Recommended action</th>
</tr>
</thead>
</table>

**Figure E.14** An FMEA and causal analysis form.
| Case number | Defect definition | Cause category | Cause definition | Stage created | Effect of failure | Unit cost of failure | O | C | C | S | E | V | D | E | T | R | P | N | Total dollars for failure* | Recommended action |
|-------------|------------------|----------------|-----------------|---------------|------------------|---------------------|---|---|---|---|---|---|---|---|---|---|---|----------------|------------------|

*Total dollars for failure = Unit cost of failure × occurrence

**Figure E.15** An FMEA and value engineering analysis form.
Appendix F

Guidelines for RPN Calculations and Different Scales

This appendix provides some guidelines for RPN calculations based on different scales. The scales may be modified depending on the industry and the application.
Table F1  Numerical guidelines for 1–5 scale in occurrence, detection, and severity.

<table>
<thead>
<tr>
<th>Rank*</th>
<th>Mechanical or electromechanical industry</th>
<th>Electronics or semiconductor industry</th>
<th>Medical devices</th>
<th>Automotive industry</th>
<th>General guidelines for severity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 = very low</td>
<td>&lt; or = 1 in 10,000</td>
<td>&lt; or = 1 in 1 million</td>
<td>&lt; or = 1 in 100,000</td>
<td>&lt; or = 1 in 10,000</td>
<td>None</td>
</tr>
<tr>
<td>2 = low or minor</td>
<td>2–10 in 10,000</td>
<td>2 to 10 in 1 million</td>
<td>2 to 10 in 100,000</td>
<td>&lt; or = 1 in 2000</td>
<td>Minor</td>
</tr>
<tr>
<td>3 = moderate or significant</td>
<td>11–25 in 10,000</td>
<td>11 to 25 in 1 million</td>
<td>11 to 25 in 100,000</td>
<td>&lt; or = 1 in 500</td>
<td>Significant</td>
</tr>
<tr>
<td>4 = high</td>
<td>26–50 in 10,000</td>
<td>26 to 50 in 1 million</td>
<td>26 to 50 in 100,000</td>
<td>&lt; or = 1 in 50</td>
<td>High</td>
</tr>
<tr>
<td>5 = very high</td>
<td>&gt; 50 in 10,000</td>
<td>&gt; 50 in 1 million</td>
<td>&gt; 50 in 100,000</td>
<td>&gt; or = 1 in 10</td>
<td>Catastrophic</td>
</tr>
</tbody>
</table>

Interpretation of RPN = S × O × D

<table>
<thead>
<tr>
<th>90%</th>
<th>95%</th>
<th>99%</th>
<th>Common scale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minor risk 1–13</td>
<td>Minor risk 1–6</td>
<td>Minor risk 1–2</td>
<td>Minor risk 1–17</td>
</tr>
<tr>
<td>Moderate risk 14–52</td>
<td>Moderate risk 7–24</td>
<td>Moderate risk 3–8</td>
<td>Moderate risk 18–63</td>
</tr>
<tr>
<td>Major risk 53–125</td>
<td>Major risk 25–125</td>
<td>Major risk 9–125</td>
<td>Major risk 64–125</td>
</tr>
</tbody>
</table>

Where:
S = Severity  O = Occurrence  D = Detection

*All the guidelines and rankings may be changed to reflect specific situations.
### Table F.2  Word description for 1–5 scale for design FM E A.

<table>
<thead>
<tr>
<th>Rank*</th>
<th>Probability of occurrence or frequency</th>
<th>Degree of severity</th>
<th>Probability of detection</th>
<th>Likelihood of the defect or defective product reaching the customer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 = very low or none</td>
<td>Rare</td>
<td>Minor nuisance</td>
<td>Detectable before service is released</td>
<td>Very low to none</td>
</tr>
<tr>
<td>2 = low or minor</td>
<td>Infrequent</td>
<td>Product operable at reduced performance</td>
<td>Detectable after release but before production</td>
<td>Low or minor</td>
</tr>
<tr>
<td>3 = moderate or significant</td>
<td>Moderate</td>
<td>Gradual performance degradation</td>
<td>Detectable before reaching the customer</td>
<td>Moderate or significant</td>
</tr>
<tr>
<td>4 = high</td>
<td>Frequent to high</td>
<td>Loss of function</td>
<td>Detectable only by customer and/or during service</td>
<td>High</td>
</tr>
<tr>
<td>5 = very high or catastrophic</td>
<td>Very high to catastrophic</td>
<td>Safety-related catastrophic failures</td>
<td>Undetectable until catastrophe occurs</td>
<td>Very high</td>
</tr>
</tbody>
</table>

*All the guidelines and rankings may be changed to reflect specific situations.*
Table F.3  Word description for 1–5 scale for process FMEA.

<table>
<thead>
<tr>
<th>Rank*</th>
<th>Probability of occurrence or frequency</th>
<th>Degree of severity</th>
<th>Probability of detection</th>
<th>Likelihood of the defect or defective product reaching the customer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 = very low or none</td>
<td>Rare</td>
<td>Minor nuisance; almost no effects on products</td>
<td>Detectable before product is released</td>
<td>Very low to none; outstanding control.</td>
</tr>
<tr>
<td></td>
<td>$&lt; 1 \text{ per } 10^4 \text{ to } 10^6 \text{ or less than once a year}$</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 = low or minor</td>
<td>Infrequent</td>
<td>Reduced product performance and slow creeping in of inefficiency</td>
<td>Detectable after release to production</td>
<td>Low or minor; very good control. 90–95 percent of the time action taken when process out of control and parts within spec at all times.</td>
</tr>
<tr>
<td></td>
<td>$2 \text{ to } 10 \text{ per } 10^4 \text{ to } 10^6 \text{ or about once a month}$</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 = moderate or significant</td>
<td>Moderate</td>
<td>Gradual product degradation; moderate inefficiency; reduced productivity; operator starts to be frustrated</td>
<td>Detectable before reaching the customer</td>
<td>Moderate or significant or mediocre control which is not very effective. Action taken only $&lt; \text{ or } = 50 \text{ percent of the time. Increased percentage or above parts out of print.}$</td>
</tr>
<tr>
<td></td>
<td>$11 \text{ to } 25 \text{ per } 10^4 \text{ to } 10^6 \text{ or about once every two weeks}$</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4 = high</td>
<td>Frequent to high</td>
<td>More than 50–70 percent no build condition. Requires high operator efforts. High inefficiency, low productivity. High scrap; loss of function in field</td>
<td>Detectable only by customer and/or during service</td>
<td>High. Very low control. Action taken infrequently. 90 percent or above parts out of specifications.</td>
</tr>
<tr>
<td></td>
<td>$26 \text{ to } 50 \text{ per } 10^4 \text{ to } 10^6 \text{ or almost every week}$</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 = very high or catastrophic</td>
<td>Very high to catastrophic</td>
<td>No build condition. Line shut down; safety-related or catastrophic.</td>
<td>Undetectable until catastrophe occurs</td>
<td>Very high. No controls. No actions. 100 percent wrong parts built.</td>
</tr>
<tr>
<td></td>
<td>$&gt; 50 \text{ per } 10^4 \text{ to } 10^6 \text{ or every other day or more}$</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*All the guidelines and rankings may be changed to reflect specific situations.
**Table F.4** Word description for 1–5 scale for service FMEA.

<table>
<thead>
<tr>
<th>Rank*</th>
<th>Probability of occurrence or frequency</th>
<th>Degree of severity</th>
<th>Probability of detection</th>
<th>Likelihood of the defect or defective product reaching the customer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 = very low or none</td>
<td>Rare</td>
<td>Minor nuisance; almost no effects on service. Great job</td>
<td>Detectable before service is released</td>
<td>Very low to none; outstanding control.</td>
</tr>
<tr>
<td>2 = low or minor</td>
<td>Infrequent 2 to 10 per 10^4 to 10^6 about once a month</td>
<td>Reduced service performance; no rework. Minor inspection</td>
<td>Detectable after release</td>
<td>Low or minor; very good control. 90–95 percent of the time action taken when process out of control.</td>
</tr>
<tr>
<td>3 = moderate or significant</td>
<td>11 to 25 per 10^4 to 10^6 or about once every two weeks</td>
<td>Moderate inefficiency; reduced productivity; operator starts to be frustrated; aware of problem. May or may not fix</td>
<td>Detectable before reaching the customer</td>
<td>Moderate, significant, or mediocre control which is not very effective. Action taken only 50 percent of the time.</td>
</tr>
<tr>
<td>4 = high</td>
<td>Frequent to high 26 to 50 per 10^4 to 10^6 or almost every week</td>
<td>Operator frustration. Great dissatisfaction. Needs to fix it now. No possible repeat business</td>
<td>Detectable only by customer and/or during service</td>
<td>High. Very low control. Action taken infrequently. Tight schedules and outside forces.</td>
</tr>
<tr>
<td>5 = very high or catastrophic</td>
<td>Very high to catastrophic &gt; 50 per 10^4 to 10^6 or every other day or more</td>
<td>No repeat business. Take it back. Very heavy dissatisfaction level</td>
<td>Undetectable until catastrophe occurs</td>
<td>Very high. No controls. No actions. 100 percent bad service.</td>
</tr>
</tbody>
</table>

*All the guidelines and rankings may be changed to reflect specific situations.*
## Table F.5 Severity guideline for process FMEA (1–10 qualitative scale).

<table>
<thead>
<tr>
<th>Effect</th>
<th>Rank*</th>
<th>Criteria</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>No effect</td>
<td>1</td>
<td>No effect on product or subsequent processes.</td>
<td>If the numerical value falls between two numbers, always select the higher number.</td>
</tr>
<tr>
<td>Very slight effect</td>
<td>2</td>
<td>Customer more likely will not notice the failure. Very slight effect on product/process performance. Nonvital fault noticed sometimes.</td>
<td>If the team has a disagreement in the ranking value, the following may help.</td>
</tr>
<tr>
<td>Slight effect</td>
<td>3</td>
<td>Customer slightly annoyed. Slight effect on product or process performance. Nonvital fault noticed most of the time.</td>
<td>1. If the disagreement is an adjacent category, average out the difference. For example, if one member says 5 and someone else says 6, the ranking in this case should be 6 (5 and 6 are adjacent categories. Therefore $5 + 6 = 11$, $11/2 = 5.5$).</td>
</tr>
<tr>
<td>Minor effect</td>
<td>4</td>
<td>Customer experiences minor nuisance. Minor effect on product/process performance. Fault does not require repair. Nonvital fault always noticed.</td>
<td>2. If the disagreement jumps one category, then consensus must be reached. Even with one person holding out, total consensus must be reached. No average, no majority. Everyone in that team must have ownership of the ranking. They may not agree 100 percent, but they can live with it.</td>
</tr>
<tr>
<td>Moderate effect</td>
<td>5</td>
<td>Customer experiences some dissatisfaction. Moderate effect on product/process performance. Fault on nonvital part requires repair.</td>
<td></td>
</tr>
<tr>
<td>Extreme effect</td>
<td>8</td>
<td>Customer very dissatisfied. Extreme effect on process; equipment damaged. Product inoperable but safe. System inoperable.</td>
<td></td>
</tr>
<tr>
<td>Serious effect</td>
<td>9</td>
<td>Potential hazardous effect. Able to stop product without mishap; safety-related; time-dependent failure. Disruption to subsequent process operations. Compliance with government regulation is in jeopardy.</td>
<td></td>
</tr>
</tbody>
</table>

*All the guidelines and rankings may be changed to reflect specific situations.
### Table F.6  Occurrence guideline for process FMEA (1–10 qualitative scale).

<table>
<thead>
<tr>
<th>Detection</th>
<th>Rank*</th>
<th>$C_{pk}$</th>
<th>Criteria</th>
<th>CNF/1000</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Almost never</td>
<td>1</td>
<td>$&gt;1.67$</td>
<td>Failure unlikely. History shows no failures.</td>
<td>$&lt;.00058$</td>
<td>If the numerical value falls between two numbers, always select the higher number.</td>
</tr>
<tr>
<td>Remote</td>
<td>2</td>
<td>$&gt;1.50$</td>
<td>Rare number of failures likely.</td>
<td>0.0068</td>
<td>If the team has a disagreement in the ranking value, the following may help.</td>
</tr>
<tr>
<td>Very slight</td>
<td>3</td>
<td>$&gt;1.33$</td>
<td>Very few failures likely.</td>
<td>0.0063</td>
<td>1. If the disagreement is an adjacent category, average out the difference. For example, if one member says 5 and someone else says 6, the ranking in this case should be 6 (5 and 6 are adjacent categories. Therefore $5 + 6 = 11$, $11/2 = 5.5 \approx 6$).</td>
</tr>
<tr>
<td>Slight</td>
<td>4</td>
<td>$&gt;1.17$</td>
<td>Few failures likely.</td>
<td>0.46</td>
<td>2. If the disagreement jumps one category, then consensus must be reached. Even with one person holding out, total consensus must be reached. No average, no majority. Everyone in that team must have ownership of the ranking. They may not agree 100 percent, but they can live with it.</td>
</tr>
<tr>
<td>Low</td>
<td>5</td>
<td>$&gt;1.00$</td>
<td>Occasional number of failures likely.</td>
<td>2.7</td>
<td></td>
</tr>
<tr>
<td>Medium</td>
<td>6</td>
<td>$&gt;0.83$</td>
<td>Moderate number of failures likely.</td>
<td>12.4</td>
<td></td>
</tr>
<tr>
<td>Moderately high</td>
<td>7</td>
<td>$&gt;0.67$</td>
<td>Frequent high number of failures likely.</td>
<td>46</td>
<td></td>
</tr>
<tr>
<td>High</td>
<td>8</td>
<td>$&gt;0.51$</td>
<td>High number of failures likely.</td>
<td>134</td>
<td></td>
</tr>
<tr>
<td>Very high</td>
<td>9</td>
<td>$&gt;0.33$</td>
<td>Very high number of failures likely.</td>
<td>316</td>
<td></td>
</tr>
<tr>
<td>Almost certain</td>
<td>10</td>
<td>$&lt;0.33$</td>
<td>Failure almost certain. History of failures exists from previous or similar designs.</td>
<td>$&gt;316$</td>
<td></td>
</tr>
</tbody>
</table>

*All the guidelines and rankings may be changed to reflect specific situations.
### Table F7 Detection guideline for process FMEA (1–10 qualitative scale).

<table>
<thead>
<tr>
<th>Detection</th>
<th>Rank*</th>
<th>Criteria</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Almost certain</td>
<td>1</td>
<td>Current controls almost always will detect the failure. Reliable detection controls are known and used in similar processes.</td>
<td>If the numerical value falls between two numbers, always select the higher number.</td>
</tr>
<tr>
<td>Very high</td>
<td>2</td>
<td>Very high likelihood current controls will detect the failure.</td>
<td>If the team has a disagreement in the ranking value, the following may help.</td>
</tr>
<tr>
<td>High</td>
<td>3</td>
<td>Good likelihood current controls will detect the failure.</td>
<td></td>
</tr>
<tr>
<td>Moderately high</td>
<td>4</td>
<td>Moderately high likelihood current controls will detect the failure.</td>
<td></td>
</tr>
<tr>
<td>Medium</td>
<td>5</td>
<td>Medium likelihood current controls will detect the failure.</td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>6</td>
<td>Low likelihood current controls will detect the failure.</td>
<td></td>
</tr>
<tr>
<td>Slight</td>
<td>7</td>
<td>Slight likelihood current controls will detect the failure.</td>
<td></td>
</tr>
<tr>
<td>Very slight</td>
<td>8</td>
<td>Very slight likelihood current controls will detect the failure.</td>
<td></td>
</tr>
<tr>
<td>Remote</td>
<td>9</td>
<td>Remote likelihood current controls will detect the failure.</td>
<td></td>
</tr>
<tr>
<td>Almost impossible</td>
<td>10</td>
<td>No known controls available to detect the failure.</td>
<td></td>
</tr>
</tbody>
</table>

*All the guidelines and rankings may be changed to reflect specific situations.
<table>
<thead>
<tr>
<th>Effect</th>
<th>Rank*</th>
<th>Criteria</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>No effect</td>
<td>1</td>
<td>No effect on product or subsequent processes.</td>
<td>If the numerical value falls between two numbers, always select the higher number.</td>
</tr>
<tr>
<td>Very slight effect</td>
<td>2</td>
<td>Customer more likely will not notice the failure. Very slight effect on product/process performance. Nonvital fault noticed sometimes.</td>
<td>If the team has a disagreement in the ranking value, the following may help.</td>
</tr>
<tr>
<td>Slight effect</td>
<td>3</td>
<td>Customer slightly annoyed. Slight effect on product or process performance. Nonvital fault noticed most of the time.</td>
<td></td>
</tr>
<tr>
<td>Moderate effect</td>
<td>5</td>
<td>Customer experiences some dissatisfaction. Moderate effect on product/service performance. Fault on nonvital part requires repair.</td>
<td></td>
</tr>
<tr>
<td>Major effect</td>
<td>7</td>
<td>Customer dissatisfied. Major effect on service; rework on service necessary. Product/service performance severely affected but functional and safe. Subsystem incomplete.</td>
<td></td>
</tr>
<tr>
<td>Extreme effect</td>
<td>8</td>
<td>Customer very dissatisfied. Extreme effect on process/service; equipment damaged. Product/service incomplete but safe. System incomplete.</td>
<td></td>
</tr>
<tr>
<td>Serious effect</td>
<td>9</td>
<td>Potential hazardous effect. Able to stop product/service without mishap. Safety-related. Time-dependent failure. Disruption to subsequent process operations. Compliance with government regulation is in jeopardy.</td>
<td></td>
</tr>
</tbody>
</table>

*All the guidelines and rankings may be changed to reflect specific situations.*
Table F9  Occurrence guideline for service FMEA (1-10 qualitative scale).

<table>
<thead>
<tr>
<th>Detection</th>
<th>Rank*</th>
<th>( C_{pk} )</th>
<th>Criteria</th>
<th>CNF/1000</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Almost never</td>
<td>1</td>
<td>&gt;1.67</td>
<td>Failure unlikely. History shows no failures.</td>
<td>&lt;.00058</td>
<td>If the numerical value falls between two numbers, always select the higher number.</td>
</tr>
<tr>
<td>Remote</td>
<td>2</td>
<td>&gt;1.50</td>
<td>Rare number of failures likely.</td>
<td>.0068</td>
<td>If the team has a disagreement in the ranking value, the following may help.</td>
</tr>
<tr>
<td>Very slight</td>
<td>3</td>
<td>&gt;1.33</td>
<td>Very few failures likely.</td>
<td>.0063</td>
<td>1. If the disagreement is an adjacent category, average out the difference. For example, if one member says 5 and someone else says 6, the ranking in this case should be 6 (5 and 6 are adjacent categories. Therefore ( 5 + 6 = 11 ), ( 11/2 = 5.5 \approx 6 )).</td>
</tr>
<tr>
<td>Slight</td>
<td>4</td>
<td>&gt;1.17</td>
<td>Few failures likely.</td>
<td>.46</td>
<td>2. If the disagreement jumps one category, then consensus must be reached. Even with one person holding out, total consensus must be reached. No average, no majority. Everyone in that team must have ownership of the ranking. They may not agree 100 percent, but they can live with it.</td>
</tr>
<tr>
<td>Low</td>
<td>5</td>
<td>&gt;1.00</td>
<td>Occasional number of failures likely.</td>
<td>2.7</td>
<td></td>
</tr>
<tr>
<td>Medium</td>
<td>6</td>
<td>&gt;0.83</td>
<td>Moderate number of failures likely.</td>
<td>12.4</td>
<td></td>
</tr>
<tr>
<td>Moderately high</td>
<td>7</td>
<td>&gt;0.67</td>
<td>Frequent high number of failures likely.</td>
<td>46</td>
<td></td>
</tr>
<tr>
<td>High</td>
<td>8</td>
<td>&gt;0.51</td>
<td>High number of failures likely.</td>
<td>134</td>
<td></td>
</tr>
<tr>
<td>Very high</td>
<td>9</td>
<td>&gt;0.33</td>
<td>Very high number of failures likely.</td>
<td>316</td>
<td></td>
</tr>
<tr>
<td>Almost certain</td>
<td>10</td>
<td>&lt;0.33</td>
<td>Failure almost certain. History of failures exists from previous or similar designs.</td>
<td>&gt;316</td>
<td></td>
</tr>
</tbody>
</table>

*All the guidelines and rankings may be changed to reflect specific situations.


<table>
<thead>
<tr>
<th>Detection</th>
<th>Rank*</th>
<th>Criteria</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Almost certain</td>
<td>1</td>
<td>Current controls almost always will detect the failure. Reliable</td>
<td>If the numerical value falls between two numbers, <em>always</em> select the higher number.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>detection controls are known and used in similar processes.</td>
<td></td>
</tr>
<tr>
<td>Very high</td>
<td>2</td>
<td>Very high likelihood current controls will detect the failure.</td>
<td>If the team has a disagreement in the ranking value, the following may help.</td>
</tr>
<tr>
<td>High</td>
<td>3</td>
<td>Good likelihood current controls will detect the failure.</td>
<td>1. If the disagreement is an adjacent category, average out the difference. For example, if one</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>member says 5 and someone else says 6, the ranking in this case should be 6 (5 and 6 are adjacent</td>
</tr>
<tr>
<td>Moderately high</td>
<td>4</td>
<td>Moderately high likelihood current controls will detect the failure.</td>
<td>categories. Therefore $5 + 6 = 11$, $11/2 = 5.5 \approx 6$).</td>
</tr>
<tr>
<td>Medium</td>
<td>5</td>
<td>Medium likelihood current controls will detect the failure.</td>
<td>2. If the disagreement jumps one category, then consensus must be reached. Even with one person</td>
</tr>
<tr>
<td>Low</td>
<td>6</td>
<td>Low likelihood current controls will detect the failure.</td>
<td>holding out, total consensus must be reached. No average, no majority. Everyone in that team</td>
</tr>
<tr>
<td>Slight</td>
<td>7</td>
<td>Slight likelihood current controls will detect the failure.</td>
<td>must have ownership of the ranking. They may not agree 100 percent, but they can live with it.</td>
</tr>
<tr>
<td>Very slight</td>
<td>8</td>
<td>Very slight likelihood current controls will detect the failure.</td>
<td></td>
</tr>
<tr>
<td>Remote</td>
<td>9</td>
<td>Remote likelihood current controls will detect the failure.</td>
<td></td>
</tr>
<tr>
<td>Almost impossible</td>
<td>10</td>
<td>No known controls available to detect the failure.</td>
<td></td>
</tr>
</tbody>
</table>

*All the guidelines and rankings may be changed to reflect specific situations.
Appendix G

Guidelines for Designing the Reasonably Safe Product

This appendix provides a summary of guidelines for designing the reasonably safe product. Both design and legal considerations are addressed. All areas identified are affected by the use of an appropriate FMEA.

1. Elements of production defect
   - The identification of the flaw or flaws relative to manufacturing or physical property standards
   - The evidence that the failure or malfunction of the product is directly attributable to the flaws
   - The relationship of the failure or malfunction to the expected performance standards of the product
   - The causal link between the failure or malfunction and the injury

2. Elements of design defect
   - The identification of the design flaw or flaws which occasioned the injury
   - The delineation of alternative design features
   - The evaluation of such alternative design features relative to the expected performance standards of the product as well as
     - Their effect upon the subsequent usefulness of the product
     - Their effect upon the subsequent cost of the product
• The comparison of this product with other similar products
• The causal link between the design deficiency and the injury

3. Components of an active system design

• Foreseeable product elements
  – Assembly
  – Testing
  – Shipping
  – Communications
  – Installation
  – Inspection
  – Maintenance
  – Service
  – Performance
  – Foreseeable product environment
  – Foreseeable product users
  – Foreseeable product uses

4. The product as a system

• Component integrity
• Assembly consistency
• Interface compatibility
• Performance and safety standards
• Component specifications
• Product specifications
• Testing: performance, environment, failure

5. Procedure for system design safety

• Identify
  – Product environments
  – Product users
  – Product uses

• Postulate
  – Hazards and estimate
– Probability of occurrence
– Seriousness of harm

• Delineate
  – Design, production, testing alternatives
  – Installation, maintenance, service procedures
  – Effective communications

6. To reduce harm

• Evaluate
  – Alternatives relative to performance, utility, and costs of product

• Incorporate
  – Appropriate alternatives, procedures, communications

7. Product safety audit

• The team
  – Design, production, quality control, testing, service, legal counsel, technical writing, marketing, safety assurance

• The process

• Stages
  – Concept
  – Prototype
  – Pilot line

• Review
  – Claims
  – Complaints
  – Service reports
  – Injury data
  – Court decisions

• Incorporate
  – External and internal standards

• Considerations
  – Product components and features
    a. Human factors
    b. Foreseeable misuses
    c. Warnings and instructions
8. Design and warnings

- Design out the hazard; if not
- Guard against the hazard; if not
- Warn against the hazard

9. Warning design

- Must communicate
  - Type of hazard
  - Magnitude of risk
  - Action to minimize risk

10. Warnings: intrinsic elements

- Fundamental
  - Identification of the need

- Objective
  - Colors
  - Print type
  - Durability
  - Symbols
  - Format

- Subjective
  - Signal words (danger, warning, caution)
  - Content
  - Languages
  - Size
  - Locations
11. Documentation

- Preparation
  - Considers adverse use
  - Develops and maintains comprehensive product history
  - Responses to unfavorable reports
  - Establishes responsibility for control
  - Ease of access

- Retention
  - Assistance in design review
  - Meet legal requirements
    a. Statutes of repose
    b. Useful safe life
      - Guidance in litigation

12. Documenting the reasonably safe product

- Hazard and risk data
  - Historical
  - Field or laboratory
  - Causation analysis

- Design safety formulation
  - Fault-tree
  - Failure modes
  - Effects analysis

- Warnings and instruction formulation
  - Methodology for development and selection

- Standards
  - In-house
  - Voluntary
  - Mandated

- Quality assurance program
  - Methodology for procedure selection

- Performance of product in use
  - Reporting procedures
  - Follow-up data acquisition and analysis
  - Recall
  - Retrofit
  - Instruction and warnings modification
• Decision-making methodology
  – The *how* and *who* of the process

13. Communications

• Warnings/instructions
  – Written for user
  – Communicated directly to user

• Warranties/disclaimers
  – Legally correct
  – Communicated directly to buyer

• Advertising/catalogs/sales talk
  – Consistent with specifications, warranties, contracts

• Basis of the bargain

14. Lessons from the law

• Design must
  – Account for reasonably foreseeable product misuse
  – Acknowledge human frailties and actual users
  – Function in true environment of product use
  – Eliminate or guard against the hazards
  – Not substitute warnings for effective design

15. Legal bases for liability

• Designer/engineer—negligence

• Manufacturer/assembler/seller—negligence

• Express warranty/misrepresentation

• Strict liability
Appendix H
Linkages of FMEA

FMEA LINKAGES:
CONCEPT/SYSTEM — DESIGN — PROCESS

Concept FMEA

• Input information
  – Customer requirements
  – Regulatory requirements
  – Corporate requirements
  a. The input information generates the preliminary design specifications, which in turn generate:
    * Product/service specific QFDs with technical specifications ranked by customer wants
    * Preliminary requirements for the concept FMEA (formal beginning of concept/system FMEA)
    * Preliminary Parameter Design for targets and system performance
    * Evaluation of historical performance information
    * Evaluation and/or conducting benchmarking

• Output deliverables
  – Specific system/subsystem or component design specifications
  – Specific design specifications
  – GDT information
a. Validation of criteria through:
   * Engineering specifications
   * Reliability targets and robustness needs
   * Imperatives
   * Recommendations for new generic testing now required
     DVP input
   * Program target values or recommendations
   * Program target values or recommendations
   * Recommendations for new generic process controls

### Design FMEA

- **Input**
  - Historical design performance information including reliability data/tests
  - Block/boundary diagram
  - $P$-diagram
  - Specific system/subsystem or component design specifications
  - Specific design specifications
  - GDT information
  - Validation of criteria through:
    a. Engineering specifications
    b. Reliability targets and robustness needs
    c. Imperatives
    d. Recommendations for new generic testing now required
    DVP input
    e. Design verification methods and schedule
    f. Interface matrix

- **Output deliverables**
  - Prototype control plan
  - Design information related to potential strategies
  - Potential critical and or significant characteristics
  - Reliability and robustness checklist
  - New design verification specifications; test methods or revised based on FMEA analysis
  - Other recommended action for future products or programs
  - Target performance; review and validation
Process FMEA

- Input
  - Potential critical and/or significant characteristics
  - Prototype control plans
  - Characteristic matrix
  - Process flow and specification information
  - $P$-diagram engineering specification tests and requirements
  - Historical manufacturing/service performance information

- Output deliverables
  - Design and reliability sign-off
  - Confirmed critical and significant characteristics
  - Safety sign-off
  - Production control plans
  - Pre production control plans
  - Recommended manufacturing/service actions for product/service robustness
  - Other recommended actions for future products or programs

Special note 1: To maximize the FMEA meeting the leader of the team must know how to handle questions. That means that the leader of any FMEA team must be able to draw input from all and also be able to guide the team participant to the set goal. The following format is a general template to follow.

<table>
<thead>
<tr>
<th>Types of question</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Engage the audience</td>
<td>• Will someone explain what a histogram shows?</td>
</tr>
<tr>
<td>• Ensure dialogue and</td>
<td>• How do you do that today?</td>
</tr>
<tr>
<td>participation</td>
<td>• Does anyone have a different opinion?</td>
</tr>
<tr>
<td>• Maintain involvement</td>
<td>• Cary, you look troubled by that. What do you think? What are you</td>
</tr>
<tr>
<td></td>
<td>thinking?</td>
</tr>
<tr>
<td>• Invite additional (as</td>
<td>• Stephen, do you agree with what Christine just said?</td>
</tr>
<tr>
<td>needed) participants</td>
<td>• Let’s see a show of hands, how many have created a Pareto chart?</td>
</tr>
<tr>
<td></td>
<td>• Could you say more about that?</td>
</tr>
<tr>
<td>• Probe further</td>
<td>• Would someone else volunteer an example?</td>
</tr>
<tr>
<td></td>
<td>• Who haven’t we heard from yet? Or this may be rephrased in a more</td>
</tr>
<tr>
<td></td>
<td>proactive form by asking: Carla, we have not heard from you, how do</td>
</tr>
<tr>
<td></td>
<td>you feel about what has been said?</td>
</tr>
<tr>
<td>Activity</td>
<td>Questions/Support</td>
</tr>
<tr>
<td>----------</td>
<td>------------------</td>
</tr>
<tr>
<td>Draw out participants’ viewpoints, their experience, knowledge, skills and so on</td>
<td>Would someone explain that to the group in your own words?</td>
</tr>
<tr>
<td>Have participants discuss the issues and concerns with each other (if necessary, sub-divide them into smaller teams)</td>
<td>Jamie, could you come to the flip chart (or overhead projector) and draw that model for the team?</td>
</tr>
<tr>
<td>Have you seen similar situations at your plant? In your department?</td>
<td>What do you agree or disagree with regarding that? Why?</td>
</tr>
<tr>
<td>Does anyone have an example of FMEA being used effectively?</td>
<td></td>
</tr>
<tr>
<td>Check for understanding</td>
<td>What questions do you have about this?</td>
</tr>
<tr>
<td>Reinforce understanding</td>
<td>How would that apply in your department?</td>
</tr>
<tr>
<td>Stimulate thinking</td>
<td>Tell me more.</td>
</tr>
<tr>
<td>Clarify information</td>
<td>Oh?</td>
</tr>
<tr>
<td>Have participants verbalize—as much as possible—connections and learning points</td>
<td>Can you give us an example?</td>
</tr>
<tr>
<td>Draw out participation</td>
<td>Who else has seen that?</td>
</tr>
<tr>
<td>Timothy, what do you think?</td>
<td></td>
</tr>
<tr>
<td>Jamie, would you agree with that?</td>
<td></td>
</tr>
<tr>
<td>Check for agreement</td>
<td>How would you modify that in order to be able to support the statement?</td>
</tr>
<tr>
<td>Build consensus</td>
<td>Who cannot agree with that recommendation?</td>
</tr>
<tr>
<td>What exactly makes you say that?</td>
<td>What can we do to resolve the problem?</td>
</tr>
<tr>
<td>Can you explain why?</td>
<td></td>
</tr>
<tr>
<td>Debrief the discussion and/or task at hand</td>
<td>What were your concerns?</td>
</tr>
<tr>
<td>Obtain participants’ reactions to the activity—encourage them to be honest and forthcoming without any threat or retaliation</td>
<td>What were you thinking half way through the task?</td>
</tr>
<tr>
<td>What went well? What went wrong or not so well?</td>
<td>What would you do differently?</td>
</tr>
<tr>
<td>What learning will you take back?</td>
<td>How did that make you feel?</td>
</tr>
<tr>
<td>Refocus participation</td>
<td>Can you summarize what your concern is?</td>
</tr>
<tr>
<td>Divert disruptive participation</td>
<td>Can someone?</td>
</tr>
<tr>
<td>What if we capture “it” on the “parking lot” so that we can move on?</td>
<td></td>
</tr>
</tbody>
</table>
Special note 2: As already mentioned, it is essential for the DFMEA and the PFMEA to have a block diagram and a process flow diagram before conducting the FMEA. Whereas the block diagram is very easy to draw, the process flow diagram for most practitioners presents a difficult task. The difficulty is due to the level of detail that is necessary for an effective PFMEA. The example in Figure H.1 is for a coffee chopper. The reader will notice that it is indeed very detailed and one may take a long time to conduct an FMEA for each of the functions.

However, in the flow one will notice that the arrows are of two distinct kinds: (1) bold and (2) light. The reason for the distinction is that the bold arrows are primary functions and the FMEA would indeed contribute value. On the other hand, the secondary functions present items that may be of value in doing the FMEA. This is a very critical decision and it is up to the team to define *all* the appropriate functions/activities of the process. It is this reason why the process flow diagram is very critical to the PFMEA and somewhat difficult to draw.

Special note 3: The ultimate goal of any FMEA is to eliminate or at least reduce the failure. If the failure is eliminated, then the FMEA is obviously effective. However, if the failure is reduced, then the team performing the FMEA must plan for implementation and controlling the design and/or process. There are at least three issues here:

1. Just because one thinks something should be done does not mean it will. Part of the plan must be to *ensure* it gets carried out.

2. One study of strategic failures identified the poor implementation of the strategy as the reason for failure rather than the strategy.

3. Turning the plan into action requires that people be assigned the specific tasks to be carried out and a performance monitoring system be put in place to ensure they do them.
Figure H1  Process flow diagram for coffee chopper.
A basic control system may be viewed as follows:

![Diagram of a basic control system]

**Figure H.2** A basic control system.
Linkages of a typical boundary diagram, P-diagram, and interface matrix, DFMEA and PFMEA

Problem: Wall mounted assembly

Figure H.3 Boundary diagram of the mounted enclosure assembly.
**Noise Factors:**

*Manufacturing variation:* Enclosure dimensions; bracket dimensions; enclosure material properties; bracket material properties  
*Customer Usage:* Number of cycles installation  
*Environmental:* Humidity; high temperature (use); low temperature (warehouse storage)  
*Neighboring system:* See interface matrix  
*Changes over time:* Screw thread/hole relationship; bracket angle (weight); enclosure warp or rot

**Control Factors:**
- Design reviews
- FEA modeling
- Development and testing
- Surrogate design
- Material selection
- NVH testing
- Durability testing

**Error States:**
- Does not secure heater unit to intended surface
- Partially withstands some downward force
- Inoperative system damaged wall
- Customer dissatisfaction
- Noncompliance with regulatory requirements
- High repair cost
- Reduction in support
- Damage to interior wall

**Response (Y):**
(Ideal Function) Secure heated unit mount to intended surface

**Figure H.4** Wall mounted enclosure P-diagram.
Figure H.5  Wall mounted enclosure interface matrix.

<table>
<thead>
<tr>
<th>Enclosure</th>
<th>Screw (hanging bracket to enclosure sides)</th>
<th>Hanging bracket</th>
<th>Screw (support brackets to enclosure sides)</th>
<th>Support brackets</th>
<th>Screw (Chassis assembly to enclosure assembly)</th>
<th>Chassis assembly</th>
<th>Wall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enclosure</td>
<td>2</td>
<td>1</td>
<td>2 -1</td>
<td>2 -1</td>
<td>-1 -1 -1 -1 -1</td>
<td>-1 -1</td>
<td></td>
</tr>
<tr>
<td>Screw (hanging bracket to enclosure sides)</td>
<td>2 -1</td>
<td></td>
<td></td>
<td></td>
<td>2 -1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hanging bracket</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Screw (support brackets to enclosure sides)</td>
<td></td>
<td>2 -1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Support brackets</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>-1 -1</td>
<td></td>
</tr>
<tr>
<td>Screw (Chassis assembly to enclosure assembly)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chassis assembly</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wall</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Where 2 = necessary for function (Required items)
1 = beneficial, but not necessary for functionality (Desired items)
0 = does not affect functionality (Indifferent)
-1 = causes negative effects but does not prevent functionality (Undesired items)
-2 = must be prevented to achieve functionality (Detrimental items)
<table>
<thead>
<tr>
<th>Design Function</th>
<th>Potential Failure mode</th>
<th>Potential effect</th>
<th>Crit</th>
<th>Sev</th>
<th>Potential causes of failure</th>
<th>Occ</th>
<th>Design control and or method</th>
<th>Det</th>
<th>RPN</th>
<th>Recommended action</th>
<th>Responsibility/compilition date</th>
<th>Action taken</th>
<th>Sev</th>
<th>Occ</th>
<th>Det</th>
<th>RPN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Secure heater unit to intended wall surface</td>
<td>Heater cannot be secured</td>
<td>Customer dissatisfaction Product return (7)</td>
<td>7</td>
<td>2</td>
<td>Incorrect geometry for case mounting surface;</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Use of carry over fasteners; load drop ABC test; shear test CDE test; thermal cycling test XYZ</td>
<td>24</td>
<td>2</td>
<td>Historic data indicates that no action is required at this time</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Use of carry over fasteners; load drop ABC test; shear test CDE test; thermal cycling test XYZ</td>
<td>22</td>
<td>8</td>
<td>Historic data indicates that no action is required at this time</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heater comes loose, over time</td>
<td>Possible product return; Potential hazard if continued use (9);</td>
<td>YC Incorrect geometry for case mounting surface;</td>
<td>9</td>
<td>2</td>
<td></td>
<td></td>
<td>Use of carry over fasteners; load drop ABC test; shear test CDE test; thermal cycling test XYZ</td>
<td>23</td>
<td>6</td>
<td>Historic data indicates that no action is required at this time</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figure H.6  Wall mounted enclosure—design. (Continued)
<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Internal components are exposed noncompliance with regulations XYZT(6)</td>
<td>9</td>
<td>YC Incorrect case hardness specified</td>
<td>3</td>
<td>Perform accelerated tests 1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>C. Robinson 3/2003</td>
</tr>
<tr>
<td>YC Incorrect case material specified</td>
<td>3</td>
<td>Load drop ABC test; shear test CDE test; thermal cycling test XYZ</td>
<td>38</td>
<td>Jamie 4/2003</td>
</tr>
<tr>
<td>YC Incorrect glue specified</td>
<td>4</td>
<td>Supplier recommendation for glue type; Load drop XYZ</td>
<td>108</td>
<td>C. Stamatis 5/2003</td>
</tr>
<tr>
<td>YC Customer did not follow defined method (including wall surface) to install heater</td>
<td>3</td>
<td>Rotor of fan locked- test 123; load drop test ABC; shear test CDE; thermal cycling test XYZ</td>
<td>25</td>
<td>T. Stamatis 4/2003</td>
</tr>
<tr>
<td>YC Incorrect fasteners specified torque</td>
<td>2</td>
<td>Use of carry over fasteners; load drop ABC test; shear test CDE test; thermal cycling test XYZ</td>
<td>23</td>
<td>Historic data indicates that no action is required at this time</td>
</tr>
<tr>
<td>YC Customer placed heavy load on top of unit</td>
<td>3</td>
<td>Rotor of fan locked – test 123; Use of carry over fasteners; load drop ABC test; shear test CDE test; thermal cycling test XYZ</td>
<td>38</td>
<td>Investigate adding label at attachment surface to remind user of installation requirements; review user guide and revise as required</td>
</tr>
</tbody>
</table>

**Figure H.6** Wall mounted enclosure—design.
<table>
<thead>
<tr>
<th></th>
<th>YC Incorrect fasteners specified length</th>
<th>2</th>
<th>Use of carry over fasteners; load drop ABC test; shear test CDE test; thermal cycling test XYZ</th>
<th>23</th>
<th>6</th>
<th>Historic data indicates that no action is required at this time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sudden separation from wall</td>
<td></td>
<td>Operation hazard (10); Noncompliance with BEAB regulations</td>
<td></td>
<td></td>
<td>Review user guide and revise as required; Investigate adding label at attachment surface to remind user of installation requirements</td>
</tr>
<tr>
<td></td>
<td>Customer did not follow defined method (including wall surface) to install heater</td>
<td>4</td>
<td>Rotor of fan locked- test 123; load drop test ABC; shear test CDE; thermal cycling test XYZ</td>
<td>28</td>
<td>0</td>
<td>C. Robertson and S. Stamatis 4/2003</td>
</tr>
<tr>
<td></td>
<td>Customer placed heavy load on top of unit</td>
<td>3</td>
<td>Rotor of fan locked- test 123; load drop test ABC; shear test CDE; thermal cycling test XYZ</td>
<td>2</td>
<td>60</td>
<td>F. Stamatis 4/2003</td>
</tr>
</tbody>
</table>

**Figure H.6** Wall mounted enclosure—design.
### Process FMEA

<table>
<thead>
<tr>
<th>Item/Function</th>
<th>Potential Failure mode</th>
<th>Potential effect</th>
<th>Crit</th>
<th>Sev</th>
<th>Potential causes of failure</th>
<th>Occ</th>
<th>Current Process Controls</th>
<th>Det</th>
<th>RPN</th>
<th>Recommended action</th>
<th>Responsibility/ completion date</th>
<th>Action taken</th>
<th>Sev</th>
<th>Occ</th>
<th>Det</th>
<th>RPN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apply a continuous bead of STU glue to specified location — X bead width, Y bead height</td>
<td>No glue</td>
<td>Rework and repair</td>
<td>5</td>
<td></td>
<td>Nozzle fully clogged</td>
<td>3</td>
<td>Process sheets visual aids set up procedures; Obvious operator visual of glue application; Obvious visual at subsequent operations; case will spring open after release of clamps</td>
<td>2</td>
<td>30</td>
<td>None at this time</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Figure H.7** Example of process FMEA. (Continued)
|   |   | Container empty | 2 | Process sheets visual aids set up procedures; Obvious operator visual of glue application; Obvious visual at subsequent operations; case will spring open after release of clamps | 2 | 20 | Add alarm to container pump and or apply Poka Yoke to the process | Carla 5/2003 |
|---|---|---|---|---|---|---|---|---|---|
|   |   | Low or no pressure | 2 | Process sheets visual aids set up procedures; Obvious operator visual of glue application; Obvious visual at subsequent operations; case will spring open after release of clamps | 4 | 40 | Add low pressure sensor to cut off pump or gun | Jamie 4/2003 |

**Figure H.7** Example of process FMEA.
Intermittent application  | 4 | Process sheets visual aids set up procedures; Obvious operator visual of glue application; Obvious visual at subsequent operations; case will spring open after release of clamps | 4 | 80 | Review design of nozzle and surface to be glued | Stephen Stamatis and Timothy Stamatis 5/2003

**Figure H.7** Example of process FMEA.
Appendix I

Example of a Concern Resolution, Block (Boundary) Diagram, Function Tree, and a P-Diagram for a Spark Plug
### Table I.1 Concern resolution.

<table>
<thead>
<tr>
<th>Problem statement: Tracking between Zetec/sigma spark plug and boot to earth</th>
<th>IS</th>
<th>IS NOT</th>
<th>Get Information</th>
<th>Differences and changes</th>
<th>Possible causes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>What</strong></td>
<td>All Zetec and sigma engine</td>
<td>16v DOHC, 8v DOHC, HCS, CVH</td>
<td>Zetec and sigma architecture: AYRF plug different plug gap 1.4 mm (higher voltage required to generate spark); Plug polarity 1 and 2 - ve polarity, 3 and 4 - ve polarity; unique boot design, hard rubber on HCS boot. Looseenson supported seal of boot onto Plug ceramic, shorter physical contact length; unique lead design.</td>
<td>NONE</td>
<td>1. 1.4mm gap requires higher voltage, thus stressing system more --&gt; Tracking. 2. Plugs 3 and 4 are -ve polarity and require higher voltage, thus stressing system more --&gt; Tracking. 3. 3 and 4 less dielectric strength due to positive polarity --&gt; Tracking. 4. Boot design has different material and therefore gives reduced dielectric sealing effect at high mileage. 5. Boot design has different dimensions and therefore gives reduced dielectric strength at high usage</td>
</tr>
<tr>
<td><strong>Where</strong></td>
<td>Cylinders 3 and 4 vertical burn. Any orientation relative to the engine. Over the complete length of the boot/plug interface</td>
<td>Cylinders 1 and 2. One particular orientation</td>
<td>Positive polarity of spark. Shorter leads. Leads 1 and 2 un over the top of cylinders 3 and 4.</td>
<td>NONE</td>
<td>Short 3 and 4 plug leads difficult to remove, not allowing the boot/plug seal interface --&gt; reduced dielectric seal</td>
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<td><strong>When</strong></td>
<td>October 2002 build (Zetec introduction) after lead removal. When vehicle is under load</td>
<td>After plug and lead replacement before plug lead removal</td>
<td>In vehicle testing (at Lommel) may increase the likelihood of dirt contamination versus Dyno testing</td>
<td>NONE</td>
<td>Fully enclosed (in cylinder head) plug --&gt; corona staining --&gt; reduced dielectric effect. Rejected on 1/30/03 meeting</td>
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<td><strong>What pattern since</strong></td>
<td>Stable</td>
<td>Increasing or decreasing trend</td>
<td>Breaking seal upon plug removal. Rejected at 1/30/03 meeting</td>
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<td><strong>How Big</strong></td>
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Figure I.1  Block diagram.

Ask How?  Asking How?

Spark plug  Produce a spark  Only allow energy to flow through the center of the electrode  Provide dielectric seal to the lead boot

Lead Boot  Provide dielectric insulation between the plug and head  Provide an air and water tight seal to the plug

Silicon Grease  Easy assembly of lead-boot to plug  Allow lead-boot to slide

Figure I.2  Function tree.
**Control Factors:**
- Engagement of boot to plug
- Internal diameter of the boot
- Length of the seal of the boot
- Amount of silicon grease in boot
- Material composition of the boot
- Plug gap
- Finished diameter of the plug
- Length of plug ceramic
- Diameter of terminal stud
- Variation in boot internal diameter over time

**Input Signal:**
- Energy at coil

**Coil/lead/grease/plug/head**

**Ideal Function:**
- Energy at plug gap

**Error State:**
- Tracking: Energy to earth via plug’s interface to boot

**Noise Factors:**
- *System to system interaction:* voltage demand
- *External environment:* contamination of boot; contamination of plug
- *Piece to piece variation:* variation in: engagement of boot to plug; internal diameter of the boot; length of the seal of the boot; amount of silicon grease in boot; material composition of the boot; plug gap; glaze thickness of the plug; finished diameter of the plug; surface finish of the plug; length of plug ceramic; taper of plug seat; roll-over of plug; concentricity of terminal stud; length of terminal stud; diameter of terminal stud
- *Customer usage:* Service not applying silicon grease to boots; Method of replacing lead (coil connection versus plug fitment first); amount of high load cycles by vehicles drivers; steam cleaning of engine compartment; use of nonauthorized service; number of lead removals
- *Wear out (degradation):* variation in boot internal diameter over time; Silicon grease and seal interface face dries out over time; rubber degraded by temperature; rubber degraded by temperature ozone; rubber degraded by U.V. light; rubber degraded by fuel contact; rubber degraded by oil contact; rubber degraded by coolant contact; plug gap erosion

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**Figure I.3** P-Diagram.
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See also Process

Capability Index

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occurrence

OEM

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