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The ASQ Pocket Guide to Failure Mode and Effect Analysis (FMEA)

D. H. Stamatis

ASQ Quality Press
Milwaukee, Wisconsin

American Society for Quality, Quality Press, Milwaukee 53203
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Printed in the United States of America
20 19 18 17 16 15 14 5 4 3 2 1

Library of Congress Cataloging-in-Publication Data

Stamatis, D. H., 1947–
The ASQ pocket guide to failure mode and effect analysis (FMEA) / D. H. Stamatis.
pages cm
Includes bibliographical references and index.
ISBN 978-0-87389-888-1 (soft cover : alk. paper)
1. Failure analysis (Engineering) 2. Reliability (Engineering) 3. Quality control. I. Title.

TS176.S7516 2014
620'.00452—dc23 2014024342

ISBN: 978-0-87389-888-1

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Preface

Change rarely comes in the form of a whirlwind, despite the currently popular notion to the contrary. Change is not "creative destruction" as 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 11 did not change everything. Nor did Enron, WorldCom, or any other company with similar innovations or problems. 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. Along 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 can not 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.)

Our intent in this "Pocket FMEA" is to provide the reader with a booklet that makes the FMEA concept easy to understand and provide some guidelines as to why FMEA is used in many industries with positive results.

The booklet is not a complete reference on FMEA, but rather it is a summary guide for everyone who wants some fast information regarding failures and how to deal with them. Specifically, we cover the following topics:

- Risk
- Reliability and FMEA
- Prerequisites of FMEA
- What an FMEA is
- Robustness
- The FMEA form and rankings
- Types of FMEAs, including the most common

- Failure mode, effects, and criticality analysis (FMECA)
- Health FMEA
- Control plans
- Linkages
- Tools
- Troubleshooting an FMEA
- Getting the most from FMEA
- FMEAs used in selected specific industries
- ISO, Six Sigma, lean, and FMEA

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1

Risk

Risk is everywhere. It does not matter where we are or what we do. It affects us on a personal level, but it also affects us in our world of commerce and our business. No matter what the risk is and how we analyze it, there is always a benefit associated with it. In the final analysis, all types of risks are generated for a variety of reasons, such as customer requests, continual improvement philosophy, and competition.

Why do we do a risk analysis? Primarily to answer the following two questions:

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

In the past, these questions were focused on "problem fixing." The primary analysis was to

focus on "who" did it. Of course, by focusing on problems, it was assumed that somebody was to blame, and action was taken. In other words, we operated on the principle of "If it's not broken, don't fix it." Today, that paradigm has changed. The focus is on prevention. In other words, "If it's not broken, improve it." And if there is a problem, the focus is on "how it happened" and "why it happened."

In this pocket guide we will explore the process of evaluation of risk by utilizing one of the core methodologies available, the *failure mode and effect analysis* (FMEA).

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2

Reliability and FMEA

OVERVIEW

When one talks about reliability, the implication is that there is some specification for a product that no failures will be present in the system, subsystem, component, or process. Therefore, reliability is an engineering discipline that focuses on prevention of failures by design, people, hardware, production and maintenance personnel, or processes.

It is impossible to create something 100% reliable (because reliability at time t is equal to 1 minus the failure rate: $R[t] = 1 - F[t]$). Therefore, in practice we achieve acceptable failure rates only if the risk is mitigated to provide benefits that are within the definition of the acceptability guidelines that the customer and/or the team have identified. This is possible if there is a thorough understanding of all of the potential failure modes and then appropriate steps are taken

to prevent them from occurring. Understanding potential failure modes is achieved by analyzing and testing during both the design and the production phases of a project. Of course, there are several ways to do the analysis. Here we focus on FMEA. Other ways include, but are not limited to:

- Reliability centered maintenance (RCM): program development and implementation
- Equipment criticality analysis
- Reliability engineering analysis and support, including FMEA, failure code development, root cause analysis, and lean tools such as 6S
- Reliability engineering training: processes, methods, and tools
- Preventive maintenance (PM) optimization
- Predictive maintenance program
- Calibration program and optimization
- Maintenance engineering staff augmentation: planners, schedulers, work preparers, maintenance supervisors, RCM engineers

NEED TO UNDERSTAND THE CONCEPT OF FAILURE

Criteria

A *failure*, by strict definition, is a deviation from a standard and/or specification. However, the criteria for defining a failure are heavily dependent on context of use, and may be relative to a particular observer or belief system. A situation considered to be a failure by one might be considered a success by another, particularly in cases of direct competition or a zero-sum game. Similarly, the degree of success or failure in a situation may be differently viewed by distinct observers or participants, such that a situation that one considers to be a failure, another might consider to be a success, a qualified success, or a neutral situation.

It may also be difficult or impossible to ascertain whether a situation meets criteria for failure or success due to ambiguous or ill-defined definition of those criteria. Finding useful and effective criteria, or heuristics, to judge the success or failure of a situation may itself be a significant task. That task depends on a clear, simple, and concise operational definition, as well as a team that has both knowledge and some ownership (either direct or indirect) of the system, subsystem, or component under consideration.

Therefore, in cases where there is a difference of opinion about the failure, the FMEA team should decide to treat the failure under discussion in the most conservative way. This means that the failure exists and needs to be understood by all stakeholders, especially from the customer's perspective.

Types

Once the criteria for failure have been identified, then the team is ready to proceed with the analysis, always remembering that failure can be perceived differently from the viewpoints of the evaluators. A person who is only interested in the final outcome of an activity would consider it to be an *outcome failure* if the core issue has not been resolved or a core need is not met. A failure can also be a *process failure*, where although the activity is completed successfully, a person may still feel dissatisfied if the underlying process is perceived to be below an expected standard or benchmark. Fundamentally, there are three types of failures. They are:

1. Failure to perceive
2. Failure to anticipate
3. Failure to carry out a task

The first two generally account for the concept and design FMEAs. The third one accounts for process and service FMEAs.

DESIGN FOR RELIABILITY

Reliability is, of course, an issue of design. Therefore, to minimize failures, a good design must have at least the following items evaluated before the release of that design. The reader should note that the steps identified here are indeed part of a detailed FMEA analysis. The steps are:

- Step 1. Design for maintainability
- Step 2. Perform functional analyses to determine failure modes as well as their consequences, severity, and ways of early detection
- Step 3. Analyze components with potential failures and determine their failure models
- Step 4. Determine maintenance tasks, their frequency, and effectiveness
- Step 5. Define and optimize maintenance implementation plan

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3

Prerequisites of FMEA

CREATE AN EFFECTIVE FMEA TEAM

Perhaps one of the *most* important issues in dealing with 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 (five to seven individuals).
- Multi-level/consensus-based.
- Representing *all* relevant stakeholders (those who have ownership).
- Membership may change as work progresses.

- Cross-functional and multidisciplinary membership (one person doing his/her best can not approach the knowledge of an effective cross-functional and multidisciplinary team).
- Appropriate and applicable empowerment.
- Inclusion of the operator for PFMEA.

The Structure of the FMEA Team

Core Team. This includes the experts on the project and those closest to the project. They facilitate honest communication and encourage active participation. Support membership may vary depending on the stage of the project. The leader for the *design failure mode and effects analysis* (DFMEA) should be the design engineer, and for the *process failure mode and effects analysis* (PFMEA) the manufacturing engineer.

Champion/Sponsor.

- Provides resources and support
- Attends some meetings
- Supports team
- Promotes team efforts and implements recommendations
- Shares authority/power with team

- Kicks off team
- The higher up in management, the better
- Removes any bottlenecks that may surface

Team Leader. The team leader is the "expert" 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/she has no stake in the project, possesses FMEA process expertise, and communicates assertively.

Team Considerations

- Continuity of members
- Receptive and open-minded members
- Committed to success
- Empowered by sponsor
- Cross-functional
- Multidisciplinary
- 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-initiating, voluntary members.
- Offer incentives!
- Establish ground rules, and so on.

- One individual must be responsible for coordination and accountability of the FMEA project. Typically, for the design, the design engineer is that person, and for the process, the manufacturing engineer assumes 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 to the process. Useful information may be derived through education, experience, training, or a combination of these.

Three areas that are usually underutilized for useful information are (1) background information, (2) surrogate data, and (3) operator input:

1. *Background information* and supporting documents that may be helpful to complete the system, design, or process FMEAs are:
   - Customer specifications (OEMs)
   - Previous or similar FMEAs
   - Historical information (warranties, recalls, and so on)
   - Design reviews and verification reports
   - Product drawings/bills of material

- Process flowcharts/manufacturing routing
- Test methods
- Preliminary control and gage plans
- Maintenance history
- Process capabilities

2. *Surrogate data* are data generated from similar projects, which may be helpful in the initial stages of the FMEA. When surrogate data are used, extra caution should be taken. They should be replaced with the actual data as soon as possible.
3. *Operator input* is very essential, since he or she is the closest to the operation and therefore he or she is the most qualified to discuss assignable causes.

Potential FMEA Team Members

- Design engineers
- Manufacturing engineers
- Quality engineers
- Test engineers
- Reliability engineers

- Maintenance personnel
- Operators (from all shifts)
- Equipment suppliers
- Customers
- Materials suppliers
- Anyone who has a direct or indirect interest

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 specifications.

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, team consensus will identify the high-risk areas that 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 just typical menus for choosing an appropriate team for your project. The actual team composition for your organization will depend on your individual project and resources.

Once the team is chosen for the given project, spend 15–20 minutes creating a list of the biggest (however you define "biggest") concerns for the product or process. This list will be used later to make sure you have a complete list of functions.

MIND-SET OF MINIMIZING FAILURES

The second prerequisite for conducting an FMEA is to recognize that failures should be eliminated and/or minimized. As noble a goal as that proposition is, we all know, however, that it is difficult to achieve. So, what we often end up doing is minimizing as much as possible the potential for any system, process, subsystem, or component failure. This is a team trade-off that may be difficult to achieve. As a reminder, a failure is a nonconformance from a standard and/or specification. These nonconformances may or may not be a concern for the customer and/or the design and/or the process. In fact, the design and/or process may indeed operate with a given nonconformance.

Even though the previous statement is correct, it is imperative that all of us should be concerned with failures. Our goal is and should be to have

failure-free designs and processes. This will facilitate customer satisfaction and improve efficiency within the organization that is undertaking the FMEA practice.

In the end, this translates to more profitability!

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4

What Is an FMEA?

DEFINITION

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 interdepartmental dialogue. (It is much more than a design review.)
4. Is a mental discipline "great" engineering teams go through when critiquing what might go wrong with the design, product, or process.

5. Provides a living document that reflects the latest design, product, and process actions.
6. Ultimately helps prevent problems, rather than react to them.
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 be implemented to reduce risk.

IS FMEA NEEDED?

If any answer to the following questions is positive, then you need an FMEA:

- Are customers becoming more quality conscious?

- Are reliability problems becoming a big concern?
- Are regulatory requirements harder to meet?
- Are you doing too much problem solving?
- Are you addicted to problem solving? This is a very important consideration in the application of an active FMEA program. This is so because when the thrill and excitement of solving problems become dominant, your organization is addicted to problem solving rather than preventing the problem to begin with. A proper FMEA will help break your addiction by:
  - Reducing the percentage of time spent on problem solving
  - Increasing the percentage of time spent on problem prevention
  - Increasing the efficiency of resource allocation

Note: Emphasis is always on reducing complexity and engineering changes.

In more general terms, we need an FMEA to emphasize the need to improve our designs and/or processes to be more effective (satisfy our customers) and efficient (optimize our resources).

However, the most important reason for conducting an FMEA is the need to improve. This strongly implies that in order 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 a customer, company, and supplier requirement for world-class quality. Specifically, any FMEA can help the improvement process in the following areas:

- Superior competitive advantage:
  - Best-in-class value
  - Quality performance
  - Sustainable cost advantage
  - Flawless launch at the start of production or commencement of a program
- Superior organizational capability:
  - Brings best-in-class design
  - Breakthrough technology
  - Moves fast
- Superior culture:
  - "Can do" attitude

  - Obsession with continual improvement
  - Team spirit
  - Saying "no" the right way—discuss/debate questionable design or process characteristics without being intimidated

This translates into:

- Faster development time
- Reduction of overall cost
- Improved quality throughout the life of the product and/or service

BENEFITS OF FMEA

When properly conducted, *all* types of FMEAs should lead to:

1. Confidence that all (reasonable) 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 of risks and actions for future designs and/or processes

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, equipment, and service FMEAs. The steps are:

1. *Select the team and brainstorm.* Make sure the appropriate individuals are going to participate. The team must be cross-functional and multidisciplinary, and the team members must be willing to contribute (share their experience and knowledge).

After the team has been identified and is in place, the team tries to prioritize the opportunities for improvement. Is the concern in a system, design, product, process, or service? What kind of problems are there, and/or what kind are anticipated in a particular situation? Is the customer and/or supplier involved, or is contin-

ual improvement being pursued independently? If the customer and/or supplier have 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 brainstorming, affinity diagram, and storybook methods, and/or a cause-and-effect diagram may prove to be the best tools to identify some direction.

2. *Create a functional block diagram and/or process flowchart.* For system and design FMEAs, the functional block diagram is applicable. For 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?

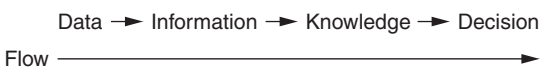
The functional block diagram focuses the discussion on the system and design, while the process flowchart focuses the discussion on the process and service. Both of these tools also provide an overview and a working model of the relationships and interactions of the systems, subsystems, components, processes, 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 background, the actual analysis begins. Frequent questions include "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 on 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:



The analysis may be qualitative or quantitative. The team may use brainstorming, cause-and-effect analysis, quality function deployment (QFD), design of experiments (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 in 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 risk priority number (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 document 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 in achieving these goals has to be taken into consideration in relationship to the needs of the organization, costs, customers, and competition. The philosophy of continual improvement embedded in the FMEA is that *all* the types of FMEAs are living documents. (Here we must note, however, that due to the short- versus long-term expectations, the short-term results may be sufficient, and therefore the team may initiate a new FMEA so that the long-term results may come to fruition.)

Getting Started

Just like anything else, before the FMEA begins, there are some preliminaries that must be taken care of:

1. Define the FMEA project and scope
2. Know your customers and their needs
3. Know the function
4. Understand the concept of priority

5. Develop and evaluate conceptual designs/processes based on your *customer's needs* and *business strategy*
6. Must be committed to continual improvement
7. Create an effective team

A general overview of the DFMEA and PFMEA may be seen in Figures 4.1 and 4.2 respectively.

Timing

The FMEA should be performed and/or updated whenever:

- A new cycle begins (new product/process)
- Changes are made to the operating conditions
- A change is made in the design/process
- New regulations are instituted
- Customer feedback indicates a problem

Uses

- Development of system requirements that minimize the likelihood of failures
- Development of designs and test systems to ensure that the failures have been

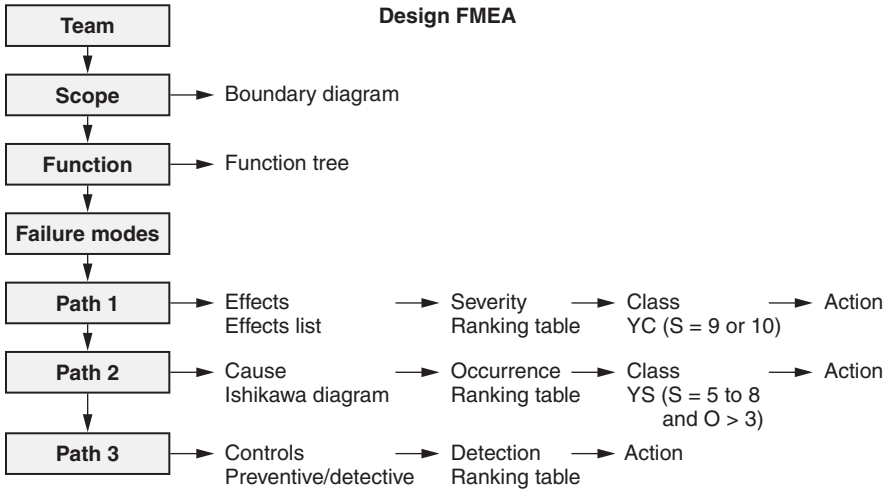


Figure 4.1 Overview of a DFMEA.

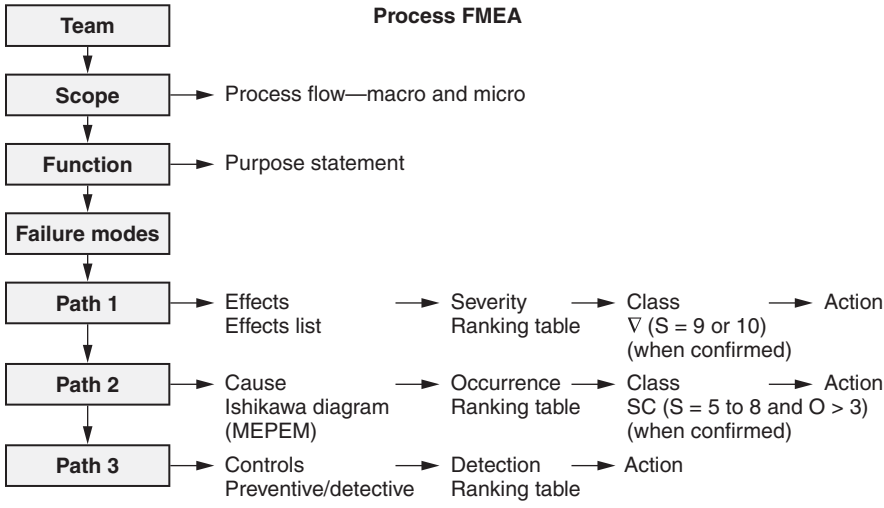


Figure 4.2 Overview of a PFMEA.

eliminated or the risk is reduced to an acceptable level

- Development and evaluation of diagnostic systems
- To help with design choices (trade-off analysis)

Advantages

- Improve the quality, reliability, and safety of a product/process
- Improve company image and competitiveness
- Increase user satisfaction
- Reduce system development time and cost
- Collect information to reduce future failures and capture engineering knowledge
- Reduce the potential for warranty concerns
- Early identification and elimination of potential failure modes
- Emphasize problem prevention

- Minimize late changes and associated cost
- Catalyst for teamwork and idea exchange between functions
- Reduce the possibility of the same kind of failure in future
- Reduce impact on company profit margin
- Improve production yield

UNDERSTAND YOUR CUSTOMERS AND THEIR NEEDS

A product or a process may perform functions flawlessly, but if the functions are not aligned with customer's needs, you may be wasting your time. Therefore, you must:

- 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:

- Edible toothpaste
- Smokeless cigarettes
- Celery flavored gum

In FMEA, a customer is anyone or anything that has functions or needs from your product or manufacturing process. An easy way to determine customer needs is to understand the Kano model and QFD, especially for design issues.

WHAT HAPPENS AFTER COMPLETION OF THE FMEA?

Generally, there are seven steps that the team must follow:

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. Questions to address in this review include:

- 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?
- Has a control plan been developed and linked to the critical and significant characteristics in the FMEA?

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 equal to or higher than 7; and in the RPN column a number equal to or higher than 100 (on a 1 to 10 scale) usually will indicate that there might be a high-risk item. In some industries this is not recognized as a valid identification process for a high-risk item. In some cases the high-risk item is identified by the numerical value of severity regardless of the value of the RPN (see next 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 in the *failure* and *severity* columns. Great care should be taken when reviewing the RPN column because these numbers will indicate whether or not action should be taken. Here we must emphasize that even though many industries use the RPN as a clearing point for evaluating risks (the higher the number, the riskier the failure mode cause), there is a better way to do the evaluation based on (1) severity, (2) criticality (Severity × Occurrence), and (3) RPN (Severity × Occurrence × Detection).

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 study or a long-term capability study must be performed.

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

7. *Work on processes that have a C_{pk} or P_{pk} greater than or equal to 1.33.* After the minimum standard is reached in step 6, try to go beyond that standard for further improvement. Reduce variation and try to reach or exceed a C_{pk} or P_{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} or P_{pk} targets.

VOCABULARY

As in every methodology, there is a special jargon that is used in FMEA to communicate functions,

failures, and appropriate actions to remove or minimize these failures. It is imperative, therefore, to be familiar with the vocabulary and its significance to FMEA. Key terms used in all FMEAs are:

function—Here the focus is on what the intent of the design or process is. Specifically, have the following items been addressed?:

- Design/process intent or engineering requirement
- Written in verb-noun measurable format
- Representation of all wants, needs, and requirements, both spoken and unspoken, of all customers and systems

failure mode—The focus here is on how the function can fail. There are usually six minimum failures for each function:

1. No function: it does not work.
2. Degradation: the function fails over time.
3. Intermittent: the function sometimes works and sometimes does not.
4. Partial: the function does not work at full cycle.

5. Unintended: the function acts in a surprising manner.
6. Over function: the function does more than intended.

effect of failure—The consequence(s) of failure. Typical considerations for design are:

- Part/subcomponent
- Next higher assembly
- System
- Total product (as in an automobile)
- Government regulations
- Customer (internal and end user)

Typical considerations for process are:

- Operator safety
- Next user
- Downstream users
- Machines/equipment
- Total process operation
- Ultimate customer
- Compliance with government regulations

severity (S)—How serious the effect is on the failure mode. Generally, the severity is the worst numerical effect value. Severity is a relative ranking, within the scope of the individual FMEA. A reduction in severity ranking index can be effected only through a design change.

classification—If severity values are 9 or 10, that is where safety and/or government regulations are affected. This means that the classification column should reflect the potential critical characteristics. When that happens, the team must:

- Develop a proactive design recommended action
- Assure that information is communicated to the PFMEA after causes have been generated

If the severity is > 4, this implies that the item is significant, and therefore proactive actions should be recommended. In some industries if the severity is 4–8 and the occurrence is > 3, the item is considered to be significant, and appropriate proactive actions are necessary.

possible cause(s)—An indication of a design weakness, the consequence of which is the failure mode. In other words, what causes

the function to fail? A good source for answering this question may be found in the P-diagram and the interface matrix. For design concerns, a good rule to follow is to assume that the:

- Item is manufactured and assembled within engineering specifications
- Design may include a deficiency that may cause unacceptable variation (misbuilds, errors, and so on)

For process concerns, address the following questions:

- Assuming incoming parts are correct, what would cause the operation to fail in this manner?
- What incoming sources of variation could cause the operation to fail in this manner?

Common ways to determine causes are:

- Brainstorming
- 5 whys
- Fishbone diagram
- Fault tree analysis (FTA)—a model that uses a tree-like structure to show the cause-and-effect relationships between a failure mode and the various

contributing causes. The tree illustrates the logical hierarchy of branches from the failure at the top to the root causes at the bottom.

- Classic five-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 Tregoe (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 the specific cause is unknown:
  - Classical
  - Taguchi methods

occurrence (O)—How often does the cause of the function happen? Occurrence is the likeli-

hood that a specific cause/mechanism (listed in the previous column) will occur during the life of the function (design or process). The *likelihood of occurrence* ranking number has a relative meaning rather than an absolute value. Preventing or controlling the causes/mechanisms of the failure mode through a design change or design process change (for example, design checklist, design review, design guide) is the only way a reduction in the occurrence ranking can be effected. At this point, the highest S × O (criticality) failure mode/cause combinations determine whether an appropriate recommended action can be taken. An action should be posted for any cause that received an occurrence rating of 10 (where the team could not reach consensus or where occurrence could not be estimated).

prevention controls—This item is part of the planning controls in order to avoid the cause happening or reduce the rate of occurrence.

detection controls—This item identifies the effectiveness of the planning controls—which may be analytical, physical methods—before the item is released to production.

detection (D)—Detection is the rank associated with the best type of design control from

the list in the previous column. Detection is a relative ranking within the scope of the individual FMEA. In order to achieve a lower ranking, the planned design control (for example, validation, and/or verification activities) generally has to be improved.

risk priority number (RPN)—This is the result of S × O × D. Based on the highest number, the priority is set for recommended action. However, RPN is not always the best importance indicator since the severity or occurrence sometimes dominates the RPN factor. A better way to set priorities for a completed FMEA might be to first use the high severity number (9 or 10, and in some organizations 5 and higher by agreement of the customer and supplier) followed by the highest criticality indices (S × O), and then the highest RPN numbers. Each failure cause *must* have its own RPN calculated. Be sure to recognize that some failure modes have the same solution or follow-up activity.

recommendations—These are actions that must be taken to minimize or eliminate the cause of the failure. To be effective the actions must be (1) appropriate, (2) applicable, (3) completed within a reasonable time, and (4) cost-effective. This means that each action *must* be assigned to an individual and with

a specific due date. If no action is planned, enter "None" or "None at this time." *All* identified corrective actions should first be directed at the highest-ranked concerns and critical items. In fact, the focus should be on prevention and not on increasing detection methods.

actions taken—Here we identify the specific action that is taken from the list of recommendations. An FMEA without positive and effective actions to prevent failures is not of much use. Once the actions have been implemented, the estimated values—"the future"—become "the present" and can be incorporated into the left-hand side of the form on the next FMEA. After action has been taken, enter a brief description of the action and its effective or actual completion date. At this point, re-rate the severity, occurrence, or detection based on the actions taken and enter the data into the *revised severity*, *revised occurrence*, or *revised detection* columns as applicable.

new severity—In order for a new number to be entered here, one, some, or all of the following must happen: (1) change the design, (2) change standards, (3) change procedures and/or instructions, (4) change policies, and (5) process changes. Warning! There are two schools of thought here. One is that once the severity is identified, it remains the same

unless the design is changed. The second one is that the severity may change if redundant systems are in place and/or a combination of the five items mentioned.

new occurrence—The number may change if redundant systems or one of the following items are incorporated in the design or process: (1) change the design, (2) change standards, (3) change procedures and/or instructions, (4) change policies, and (5) process changes.

new detection—The number may change if controls are added or one of the following items is incorporated in the design or process: (1) change the design (2) change standards, (3) change procedures and/or instructions, (4) change policies, and (5) process changes.

new RPN—The number will change if any of the contributing factors change in any way. The factors that make up the RPN are *severity*, *occurrence*, and *detection*. Any change in these will change the RPN.

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5

Robustness

All FMEAs have a robustness focus. This means that robustness tools are inputs to a good FMEA. A pictorial view is shown in Table 5.1.

BOUNDARY DIAGRAM

The idea of a boundary diagram is to identify as well as represent other components in the higher-level assembly. Typically, it includes all system attachments and mechanisms as well as interfaces with:

- Other systems
- Manufacturing/assembly tools
- Servicing/customer adjustment

Remember to consider all user interfaces.

Table 5.1 Robustness focus in FMEA.

DFMEA with robustness linkages process	
Boundary diagram	Qualifies and clarifies the relationships between systems
Interface matrix	Identifies and quantifies the strength of system interactions
P-diagram	Identifies and quantifies the strength of system interactions
FMEA with robustness linkages	
Robustness checklist	A DFMEA process output, it summarizes error states, noise factors, and the associated design controls. It is also an input for DVP.
Design verification plan (DVP)	

Once that representation has been accomplished, the boundary diagram is constructed, usually with dotted lines around the item of concern for the FMEA. This means that the boundary diagram considers what is best included and excluded in the analysis of the particular FMEA.

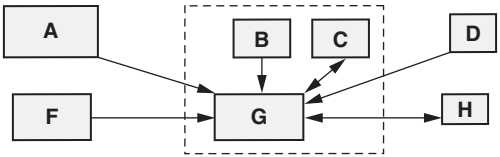


Figure 5.1 A typical boundary diagram.

The boundary in essence has two functions: (1) to aid the identification of the possible effects of failures, and (2) once the scope is defined, it should be used to focus the support team on the process of conducting the FMEA. A typical boundary diagram is shown in Figure 5.1. In this case, items G, B, and C will be considered for the FMEA.

INTERFACE MATRIX

The interface matrix is used to identify and prioritize interactions between items of concern and their four parameters. Specifically, an interface matrix:

- Acts as an input to a design FMEA
- Identifies and quantifies the strength of system interactions by:
  - Showing whether the relationship is necessary or adverse

  - Identifying the type of relationship

A typical interface matrix is shown in Table 5.2.

P-DIAGRAM

The P-diagram is a method for identifying the ideal function as well as the parameters that will prevent the ideal function from occuring. It is recommended for the design FMEA because it:

- Is a structured tool for identifying intended inputs and outputs for a function
- Describes noise factors, control factors, ideal function, and error states
- Assists in the identification of:
  - Potential causes of failure
  - Failure modes
  - Potential effects of failure
  - Current controls
  - Recommended actions

The relationship of input → process → output is the ideal function. This means that all inputs are utilized for the expected output. No waste! The P-diagram is based on the following parameters:

Table 5.2 FMEA interface matrix.

Individual items of concern	**A**		**B**		**C**		**D**	
A	P	E	P	E	P	E	P	E
	I	M	I	M	I	M	I	M
B	P	E	P	E	P	E	P	E
	I	M	I	M	I	M	I	M
C	P	E	P	E	P	E	P	E
	I	M	I	M	I	M	I	M
D	P	E	P	E	P	E	P	E
	I	M	I	M	I	M	I	M

P = Physical touching

I = Information exchange

E = Energy transfer

M = Material exchange

Each of the letters may be represented with numbers such as:

+2 = Interaction is necessary

+1 = Interaction is beneficial, but not absolutely necessary for functionality

0 = Interaction does not affect functionality

–1 = Interaction causes negative effects but does not prevent functionality

–2 = Interaction must be prevented to achieve functionality

- *Input* is the items that are used in the process. They may be: manpower, machine, method, material, measurement, and environment.
- *Process* is the "value-added" activity under consideration. It is the reason for the process's existence.
- *Output* is the expected result of the process.
- *Errors* are the items that contribute to output of less than 100%—the failures.
- *Control* items are the items that we can have in the process to make sure that the output is at optimum—the actions that mitigate the failures so that the output is reached.
- *Noise* factors are the factors that contribute to customer usage, piece-to-piece variation, external environment, interactions, and changes over time without an adverse reaction to the process.

A pictorial view is shown in Figure 5.2.

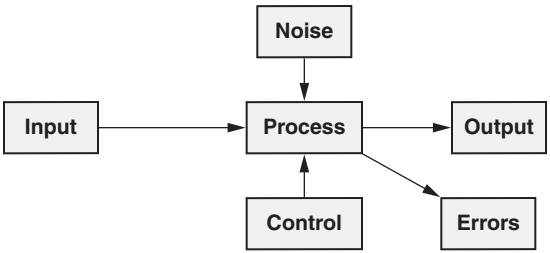


Figure 5.2 A typical P-diagram.

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6

The FMEA Form and Rankings

The generic form for all types of FMEA is very simple and straightforward. For certain industries, however, this form may be modified to reflect the needs of that industry. In Figure 6.1 we present a generic form that identifies all needed information for reducing or eliminating a root cause of failure from a design and/or a process. The reader should note that the only difference between the design and process forms is the header that identifies whether it is a design or process FMEA.

The rankings, or *criteria* as they are commonly known, are not standardized. In other words, there are *no* criteria that everyone is using for all FMEAs and industries. What is important to know is that the criteria must be based on logic, knowledge, and experience about the task at hand. Having said that, it is also important for the reader to recognize that certain industries, such as aerospace, nuclear, automotive, and

FMEA Form																									
System: Subsystem: Component: Process:		Page __ of __					Team:					Original date:			Revised date:			FMEA number							
Function	Failure	Effect	Severity	Class	Cause	Occurrence	Prevention controls	Detection controls	Detection	RPN	Recommendations	Actions taken	Severity	Occurrence	Detection	RPN	Comments								

Figure 6.1 A typical FMEA form.

others, have indeed recommended criteria lists for severity, occurrence, and detection. If your industry has these guidelines, and you want to deviate from them, it is acceptable to do so, but you must attach an addendum to the FMEA to show the different criteria. The reason for this is so that when someone else reads the FMEA, they will know the deviations from the suggested guidelines.

In the section for design FMEA and process FMEA we will identify criteria that are considered very common and used in several industries. Here, we summarize some key items of concern for any FMEA and present a general strategy for reducing risk. A more detailed analysis of this will be covered in the section on the specific FMEAs.

SEVERITY RATING (SERIOUSNESS OF THE EFFECT)

- *Severity rating* is a numerical rating of the failure's impact on customers.
- When multiple effects exist for a given failure mode, enter the worst-case severity on the worksheet to calculate risk. (This is the accepted method for the automotive industry and for the SAE J1739 standard.

It should also be recognized that some companies, while they will accept this approach, will prefer to have individual ratings for each of the effects.)

- In cases where severity varies depending on timing, use the worst-case scenario.

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

OCCURRENCE RATING

The *occurrence rating* is an estimated frequency 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 pick Balsa wood, but a 2 if we choose oak.

Just like severity, there are standard tables for occurrence for each type of FMEA. The

ratings on these tables are estimates based on experience and/or similar products or processes. Nonstandard 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, C_{pks}, theoretical distributions, and reliability statistics.)

Reducing the Occurrence Rating (Or Reducing the Frequency of the Cause)

- Design or manufacturing process changes are necessary
- Much more proactive than detection rating

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 and prevent bad parts from leaving the operation/facility or getting to the ultimate customer.
- Assuming that the cause of the failure did occur, assess the capabilities of the

controls to find the design flaw or prevent the bad parts 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 FMEAs. 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.

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

These characteristics must be classified according to risk impact:

- Severity 9, 10: highest classification (Critical). *These are product- or process-related characteristics that:*
  - May affect compliance with government or federal regulations (EPA, OSHA, FDA, FCC, FAA, and so on)
  - May affect safety of the customer.
  - Require specific actions or controls during manufacturing to ensure 100% compliance
- Severity between 5–8 and occurrence greater than 3: secondary classification (Significant). *These are product- or process-related characteristics that:*
  - Are noncritical 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, and so on.

Process Parameters/"Root Causes"

Examples include pressure, temperature, current, torque, speeds, feeds, voltage, nozzle diameter, time, chemical concentrations, cleanliness of incoming part, ambient temperature, and so on.

UNDERSTANDING AND CALCULATING RISK

Without risk, there is very little progress! Risk is inevitable in any system, design, or manufacturing process.

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*. In the analysis of the RPN, make sure to look at risk patterns rather than just a high RPN.

The RPN is the product of severity, occurrence, and detection, or:

$$\text{Risk} = \text{RPN} = S \times O \times D$$

Obviously, the higher the RPN number, the more the concern. A good rule of thumb analysis to follow is the 95% rule. That means that you will address all failure modes with a 95% confidence. It turns out the magic number is 50 [(S = 10 × O = 10 × D = 10) – (1000 × .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.

Special risk priority patterns require special attention through specific action plans that will reduce or eliminate the high risk factor. They are identified through:

1. High RPN
2. Any RPN with a severity of 9 or 10 and occurrence > 2
3. Area chart—see Figure 6.2

The area chart uses only severity and occurrence, which is more proactive.

The reader should recognize that this is the traditional and most common method of determining risk. However, there are other ways that are, in fact, more sensitive and beneficial. For example: The priority may be identified by:

1. Severity ranking of > 5

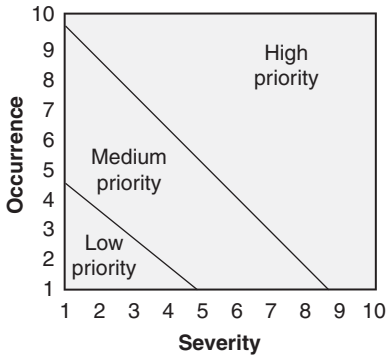


Figure 6.2 Area chart showing priority levels.

2. Severity 3–4 and occurrence > 4 (criticality)
3. RPN

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 "Actions Taken" column should *not* be filled out before the actions are totally complete.

Record final outcomes in the Action Plan and Action Results sections of the FMEA form. Remember, because of the actions you have taken you should expect changes in severity, occurrence, detection, and RPN, and new characteristic designations.

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7

Types of FMEAs

There are many types of FMEAs, each one specifically relating the causes of failures to a specific industry. For example, one may encounter an FMEA in areas such as pharmaceutical, environmental, industrial, defense, service, healthcare, software, equipment, aerospace, automotive, petroleum, oil/gas, transportation, nuclear, marine, and many other specialized forums.

However, as variable as the FMEAs may be, fundamentally, they all are the same because they all try to prevent failures from happening or minimize their effect if they do. Because of the similarity in both analysis and reaction approach, these different FMEAs may be categorized primarily in the categories shown in Table 7.1.

The reader will notice that even though we said that there are many FMEAs, only five are identified in the table. The reason for this is

Table 7.1 Types of FMEAs.

	Design	**Process**	**Service**	**Equipment**	**Concept**
Characteristics	Component	Machines	Machines	Component	Component
	Subsystem	Methods	Methods	Subsystem	Subsystem
	System	Material	Material	System	System
		Manpower	Manpower		
		Measurement	Measurement		
		Environment	Environment		

Continued

Table 7.1 Types of FMEAs.

	Design	Process	Service	Equipment	Concept
Focus	Minimize failure effects on the system	Minimize production process failure effects on the system	Minimize issues and problems interfering with the service	Minimize safety issues	Minimize failure effects on the system, process, or product from safety and governmental regulations
Objective	Maximize system quality, reliability, cost, and maintainability	Maximize the system quality, reliability, cost, maintainability, and productivity	Maximize quality and customer satisfaction	Minimize production issues and protect operator safety	Maximize system quality, reliability, cost, and maintainability in design, process, or product

because all others fall into the design or process category of FMEA. The difference is in the application and specific terminology used for the specific application. For example, in the pharmaceutical industry we may use an FMEA to:

- Implement a plan that introduces redundancy into the process and interventions that are best suited to minimize risks of a product by utilizing multiple stakeholders in the medication use process
- Prepare strategic contingency plans to respond promptly to FDA questions and requests that come late in the approval process
- Establish a rigorous framework for the underlying approach to risk mitigation in the development of a proposed risk management process for a drug or biologic
- Assess the risk management process performance through identified safety signals and adverse events of interest to assist in the overall understanding of how, when, and where those risks may occur and ways to improve either the design and/or the process

FMEA CHALLENGES

An FMEA is a living document, and as such, it must be reviewed and updated as needed, or at least once a year. Because of this constant possibility of review, the process of conducting an FMEA is considered to be:

- A continuous brainstorming activity
- A lengthy consensus-building process
- A process that may not capture all possible issues
- Possible in a team-dependent environment only
- A process that determines and implements actions that drive reduction in risk
- A process that ensures that the high-risk failure modes are addressed
- A process that includes interfaces

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8

The Most Common Types of FMEAs

There are many types of FMEAs. However, the most common ones are (1) concept FMEA, (2) design FMEA, and (3) process FMEA. All of them, without exception, follow very much the same methodology except for specific failures in the specific industries. For example, failures in the nuclear industry will be different than the health industry's failures, and in turn they will be different from the automotive industry's failures.

CONCEPT FMEA

Purpose

Fundamentally, any FMEA is a risk assessment methodology. However, in the case of a *concept FMEA* (CFMEA), the focus is on the feasibility phase for the new, innovative, or updated designs.

In a concept FMEA *only* potential customers are considered.

Use

A concept FMEA is used as part of an early engineering assessment to identify the potential feasibility of a system/subsystem/component.

Benefit

The concept FMEA is a way to test "what-if" situations for new, revolutionary, innovative ways of doing things. The benefits of this up-front nature of a concept FMEA are:

- It identifies the success of potentiality of engineering as well as economic feasibility
- It identifies the necessity for redundant systems in the design
- It identifies potential interaction and adverse effects of system/subsystem/components
- It helps in the selection of optimized alternatives for a particular design

- It helps identify as early as possible all potential effects of a proposed concept's failure modes
- It identifies potential system-level testing requirements
- It helps determine the serious and/or catastrophic failures for the system/subsystem/component

Form and Risk Criteria

For all intents and purposes, the form for the CFMEA is exactly the same as the one used for the design FMEA. However, most CFMEAs are never completed because of timing requirements. They usually stop after identifying major shortcomings in the proposed design such as safety and/or government regulatory issues. Another reason is that the timing requirements are overlapping with the DFMEAs, and therefore the DFMEA is completed instead.

The criteria are also the same as those for the DFMEA. Very seldom will they be different. If they are, that is a result of accommodating the specific requirements of the industry.

Tools

- Computer simulation
- Functional diagrams
- Mathematical models
- Force-field analysis
- Breadboard tests
- Laboratory tests on surrogate elements
- QFD
- Benchmarking
- Internal past corporate knowledge

DESIGN FMEA

Purpose

The purpose of a *design FMEA* (DFMEA) is to perform a risk analysis of all reasonable design flows of the proposed product prior to manufacturing. To do this, there are two assumptions in determining flaws/failures:

1. The item is manufactured and assembled within engineering specifications.

2. The design may include a deficiency that may cause unacceptable variation (misbuilds, errors, and so on) and may be addressed in the PFMEA.

Use

The primary use of DFMEA is to facilitate, with the appropriate and applicable team, the following:

- Prevention planning
- Changing requirements
- Cost reduction
- Increased throughput
- Decreased waste
- Decreased warranty costs
- Reduced non-value-added operations

Benefit

There are many benefits to conducting a DFMEA. However, the following are some of the key ones:

- Increases the probability that potential failure modes and their effects have been

considered in the design/development process

- Helps in the objective evaluation of design requirements and design alternatives
- Establishes a priority system for design improvements based on potential failure modes ranked according to their effect on the customer—generally the external customer
- Provides additional information to help plan thorough and efficient test programs for control
- Helps in the initial design for manufacturing and assembly requirements
- Provides an open-issue format for recommending and tracking risk-reducing actions in both design and process
- Provides future reference to aid in analyzing field concerns

Form and Ratings

The form for the design FMEA is the same as the one discussed earlier. However, the ratings may differ from industry to industry and organization to organization; the ones in Tables 8.1 through

Table 8.1 DFMEA—severity.

Effect	Description	Rating
None	No effect noticed by customer. The failure will not have any perceptible effect on the customer.	1
Very minor	Very minor effect, noticed by discriminating customers. The failure will have little perceptible effect on discriminating customers.	2
Minor	Minor effect, noticed by average customers. The failure will have minor perceptible effect on average customers.	3
Very low	Very low effect, noticed by most customers. The failure will have some small perceptible effect on most customers.	4
Low	Primary product function is operational, but at a reduced level of performance. Customer is somewhat dissatisfied.	5
Moderate	Primary product function is operational, but secondary functions are inoperable. Customer is moderately dissatisfied.	6

Continued

Table 8.1 *Continued.*

Effect	Description	Rating
High	Failure mode greatly affects product operation. Product or portion of the product is inoperable. Customer is very dissatisfied.	7
Very high	Primary product function is nonoperational but safe. Customer is very dissatisfied.	8
Hazard with warning	Failure mode affects safe product operation and/or involves nonconformance with government regulation *with* warning.	9
Hazard with no warning	Failure mode affects safe product operation and/or involves nonconformance with government regulation *without* warning.	10

8.3 are very common and used as a default guideline.

Special note: There is nothing special about these guidelines. They may be changed to reflect the industry, the organization, the product/design, and/or process. To modify these guidelines, keep in mind:

1. List the entire range of possible consequences (effects)

Table 8.2 DFMEA—occurrence.

Occurrence	Description	Frequency	Rating
Remote	Failure is very unlikely	< 1 in 1,500,000	1
Low	Relatively few failures	1 in 150,000	2
		1 in 15,000	3
Moderate	Occasional failures	1 in 2000	4
		1 in 400	5
		1 in 80	6
High	Repeated failures	1 in 20	7
		1 in 8	8
Very high	Failure is almost inevitable	1 in 3	9
		> 1 in 2	10

Table 8.3 DFMEA—detection.

Detection	Description	Rating
Almost certain	Design control will almost certainly detect the potential cause of subsequent failure modes	1
Very high	Very high chance the design control will detect the potential cause of subsequent failure mode	2

Continued

Table 8.3 *Continued.*

Detection	Description	Rating
High	High chance the design control will detect the potential cause of subsequent failure mode	3
Moderately high	Moderately high chance the design control will detect the potential cause of subsequent failure mode	4
Moderate	Moderate chance the design control will detect the potential cause of subsequent failure mode	5
Low	Low chance the design control will detect the potential cause of subsequent failure mode	6
Very low	Very low chance the design control will detect the potential cause of subsequent failure mode	7
Remote	Remote chance the design control will detect the potential cause of subsequent failure mode	8
Very remote	Very remote chance the design control will detect the potential cause of subsequent failure mode	9
Very uncertain	There is no design control, or control will not or can not detect the potential cause of subsequent failure mode	10

2. Force-rank the consequences from high to low
3. Resolve the extreme values (rating 10 and rating 1)
4. Fill in the "other" ratings
5. Use *consensus*

Strategies for Lowering Risk: (Concept/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 the cause less likely or impossible to *occur*.
- Eliminate the function or eliminate the part! (functional analysis)

Some "tools" to consider:

- Quality function deployment (QFD)
- Fault tree analysis (FTA)
- Benchmarking
- Brainstorming

- TRIZ, and so on

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: (Concept/Design)—High Detection Rating

Change the evaluation/verification/tests to:

- Make the failure mode easier to perceive
- Detect causes prior to failure

Some "tools" to consider:

- Benchmarking
- Brainstorming
- Process control (automatic corrective devices)
- TRIZ, and so on

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

Tools

- Reliability modeling
- QFD
- Benchmarking
- Block diagram
- P-diagram
- Interface diagram
- Cause-and-effect diagram
- Function tree

PROCESS FMEA

Purpose

The purpose of a PFMEA is to resolve issues/concerns/problems in the process that result in

low-quality product being shipped to the customer. Here the customer may be internal or external. In order for this to happen, there are two assumptions that must always be considered for optimum results. They are:

1. Assuming incoming parts are correct, what would cause the operation to fail in this manner? In other words, the design is OK as is.
2. What incoming sources of variation could cause the operation to fail in this manner? As a last resort, evaluate issues that may be associated with design.

Use

Fundamentally, the PFMEA is used to identify each manufacturing step and to determine what functions are associated with each manufacturing process step, and then ask:

1. What does the process step do to the part?
2. What are you doing to the part/assembly?
3. What is the goal, purpose, or objective of this process step?

There is no standardized form for a PFMEA. One may use the one we discussed earlier or a simplified one as shown in Figure 8.1. Any organization

__ System
__ Subsystem
__ Component
Model year(s)/Program(s): _____
Team: _____

Process responsibility: _____
Key date: _____

FMEA name/number: _____
Prepared by: _____
FMEA date (orig.): _____ (Rev.): _____

												Action results				
Item/ function	Potential failure mode	Potential effect(s) of failure	Severity	Class	Potential cause/ mechanism of failure	Occurrance	Current process controls (Prevent/ direct)	Detection	RPN	Recommended action(s)	Responsibility and target completion date	Actions taken	Severity	Occurrence	Detection	RPN
What is the process step?	In what ways does the key input go wrong?	What is the impact on the key output variables (customer requirements) or internal requirements?	How severe is the effect to the customer?		What causes the key input to go wrong?	How often does cause of FM occur?	What are the existing controls and procedures that prevent either the cause or the failure mode?	How well can you detect cause or FM?		What are the actions for reducing the occurrence of the cause, or improving detection?	Who's responsible for the recommended action?	What are the completed actions to take with the recalculated RPM? Be sure to include completion month/ year				

Figure 8.1 A typical PFMEA.

may modify these forms to reflect their own processes and needs.

Benefit

- Identifies potential product-related process failure modes
- Assesses the potential customer effects of the failures
- Identifies the potential manufacturing or assembly process causes and identifies process variables on which to focus controls or monitoring
- Develops a ranked list of potential failure modes, establishing a priority system for corrective action considerations
- Documents the results of the manufacturing or assembly process
- Identifies process deficiencies
- Identifies confirmed critical characteristics and/or significant characteristics
- Identifies operator safety concerns
- Feeds information on design changes required and manufacturing feasibility back to the designers

Ratings

There are no standard or universal criteria for ranking any FMEA. However, typical rating guidelines are shown in Tables 8.4 through 8.6.

Table 8.4 PFMEA—severity.

Effect	Description	Rating
None	No effect noticed by customer. The failure will not have any effect on the customer.	1
Very minor	Very minor disruption to production line. A very small portion of the product may have to be reworked. Defect noticed by discriminating customers.	2
Minor	Minor disruption to production line. A small portion (much < 5%) of product may have to be reworked online. Process up, but minor annoyances exist.	3
Very low	Very low disruption to production line. A moderate portion (< 10%) of very low product may have to be reworked online. Process up, but minor annoyances exist.	4

Continued

Table 8.4 *Continued.*

Effect	Description	Rating
Low	Low disruption to production line. A moderate portion (< 15%) of product may have to be reworked online. Process up, but some minor annoyances exist.	5
Moderate	Moderate disruption to production line. A moderate portion (> 20%) of product may have to be scrapped. Process up, but some inconveniences exist.	6
High	Major disruption to production line. A portion (> 30%) of product may have to be scrapped. Process may be stopped. Customer dissatisfied.	7
Very high	Major disruption to production line. Close to 100% of product may have to be scrapped. Process unreliable. Customer very dissatisfied.	8
Hazard with warning	May endanger operator or equipment. Severely affects safe process operation and/or involves noncompliance with government regulations. Failure will occur with warning.	9
Hazard with no warning	May endanger operator or equipment. Severely affects safe process operation and/or involves noncompliance with government regulations. Failure occurs without warning.	10

Table 8.5 PFMEA—occurrence.

Occurrence	Description	Frequency	C_{pk}	Rating
Remote	Failure is very unlikely. No failures associated with similar processes	< 1 in 1,500,000	> 1.67	1
Low	Few failures. Isolated failures associated with like processes	1 in 150,000	1.50	2
		1 in 15,000	1.33	3
Moderate	Occasional failures associated with similar processes, but not in major proportions	1 in 2000	1.17	4
		1 in 400	1.00	5
		1 in 80	0.83	6
High	Repeated failures. Similar processes have often failed	1 in 20	0.67	7
		1 in 8		8
Very high	Process failure is almost inevitable	1 in 3	0.51	9
		> 1 in 2	0.33	10

Table 8.6 PFMEA—detection.

Detection	Description	Rating
Almost certain	Process control will almost certainly detect or prevent the potential cause of subsequent failure mode	1
Very high	Very high chance process control will detect or prevent the potential cause of subsequent failure mode	2
High	High chance the process control will detect or prevent the potential cause of subsequent failure mode	3
Moderately high	Moderately high chance the process control will detect or prevent the potential cause of subsequent failure mode	4
Moderate	Moderate chance the process control will detect or prevent the potential cause of subsequent failure mode	5
Low	Low chance the process control will detect or prevent the potential cause of subsequent failure mode	6
Very low	Very low chance the process control will detect or prevent the potential cause of subsequent failure mode	7

Continued

Table 8.6 *Continued.*

Detection	Description	Rating
Remote	Remote chance the process control will detect or prevent the potential cause of subsequent failure mode	8
Very remote	Very remote chance the process control will detect or prevent the potential cause of subsequent failure mode	9
Very uncertain	There is no process control, or control will not or can not detect the potential cause of subsequent failure mode	10

Special Note: There is nothing special about these guidelines. They may be changed to reflect the industry, 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 (rating 10 and rating 1)
4. Fill in the "other" ratings
5. Use *consensus*

Manufacturing Process Control Matrix

In any process there are several dominant factors that should be evaluated for failures. Table 8.7 shows some of the factors involved and the appropriate data used in the evaluation and control of these failures.

Manufacturing Process Control Examples

Statistical process control (SPC):

- *X*-bar/*R* control charts (variable data)
- Individual *X*-moving range charts (variable data)
- *p*-, *n*-, *u*-, *c*-charts (attribute data)

Nonstatistical control:

- Check sheets, checklists, setup procedures, operational definitions/instruction sheets

Table 8.7 A typical control matrix for a manufacturing process.

Dominance factor	Attribute data	Variable data
Setup	Check sheet	*X*-bar and *R* chart
	Checklist	*X*-MR chart
Machine	*p*- or *c*-chart	Run chart
	Check sheet	*X*-bar and *R* chart
		X-MR chart
Operator	Check sheet	*X*-bar and *R* chart
	Run chart	*X*-MR chart
Component/ material	Check sheet	Check sheet
	Supplier information	Supplier information
Tool	Tool logs	Tool logs
	Check sheet	Capability study
	p- or *c*-chart	*X*-MR chart
Preventive maintenance	Time-to-failure chart	Time-to-failure chart
	Supplier information	Supplier information
		X-MR chart

Continued

Table 8.7 *Continued.*

Dominance factor	Attribute data	Variable data
Fixture/pallet/ work holding	Time-to-failure chart	Time-to-failure chart
	Check sheet	*X*-bar and *R* chart
	p- or *c*-chart	*X*-MR chart
Environment	Check sheet	Run chart
		X-MR chart

- Preventive maintenance
- Tool usage logs/change programs (preventive maintenance [PM])
- Mistake-proofing/error-proofing/ poka-yoke
- Training and experience
- Automated inspection
- Visual inspection

It is very important to recognize that inspection is not a very effective control because it is a reactive task and quite often very subjective, especially with attribute data.

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, and so on

Evaluate ideas using Pugh concept selection. Some specific examples:

- Develop a "robust design" (insensitive to manufacturing variations)
- Change 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 the failure mode easier to perceive
- Detect causes prior to failure mode

Some "tools" to consider:

- Benchmarking
- Brainstorming, and so on

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, you are now ready to 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" (identification) 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

Guidelines for Process Control System

1. Select the process

2. Conduct the FMEA on the process
3. Conduct gage system analysis
4. Conduct process potential study
5. Develop control plan
6. Train operators in control methods
7. Implement control plan
8. Determine long-term process capability
9. Review the system for continual improvement
10. Develop audit system
11. Institute improvement actions

Tools

- Mistake-proofing
- Inspection
- Cause-and effect-diagram
- Affinity diagram
- Engineering testing (specific to the cause being evaluated)

EQUIPMENT FMEA

An *equipment FMEA* (EFMEA) is a systematic approach that applies the generic form of an FMEA to aid the thought process used by engineers to identify the equipment's potential failure modes and their effects. The focus, however, is on the operator's safety.

Purpose

The basic purposes of any EFMEA are to:

1. Identify potential failure modes and rate the severity of their effects
2. Rank-order potential design and process deficiencies
3. Help engineers focus on eliminating equipment design and process concerns and help prevent problems from occurring

Use

Fundamentally, there are three reasons for using EFMEA. They are to:

1. Identify potential failure modes that may adversely affect environment safety

2. Identify potential failure modes that may adversely affect operator safety
3. Identify potential design deficiencies before releasing machinery to production

Benefit

There are at least five basic benefits in completing an EFMEA. They are:

1. Improve the quality, reliability, and safety of the customer's equipment
2. Improve the company's image and competitiveness
3. Help to increase customer satisfaction
4. Reduce equipment development time and cost
5. Document and track actions taken to reduce risk

General Information About EFMEA

The EFMEA is a special FMEA, and as such, some items have to be addressed specifically for the equipment. These are:

- *How is an EFMEA prepared?* The equipment supplier is responsible for preparing

the initial EFMEA. The customer generally *only* assists as a team member.

- *When is an EFMEA started?* Generally, there are four points of concern where the EFMEA should be started. They are:

  1. When new systems, subsystems, components, equipment, and processes are being designed
  2. When existing equipment or processes are modified in any way
  3. When carryover equipment and/or processes are used in new applications or new environments
  4. After completing a problem-solving methodology (for example, 8D) to prevent recurrence of problem

- *Who prepares the EFMEA?* The EFMEA process is a team effort between the supplier and customer. The team should be cross-functional and multidisciplinary. The responsible equipment engineer is the leader of any EFMEA team. However, the supplier's equipment design engineer is expected to involve representatives from all affected activities. It is suggested that at a minimum the following representation should be part of an active team:

  - Purchasing
  - Supervisors
  - Testing
  - Skilled trades
  - Quality engineering
  - Operators
  - Industrial engineering
  - Reliability engineering
  - Customer representative

  It is imperative that the team realize that the team members may change as the equipment matures through the design, build, and test phases. Also, team members may be added as ad hoc personnel to aid in specific issues but not be core members.

- *Who updates the EFMEA?* The supplier's design engineer is responsible for keeping the EFMEA up to date. It is also the responsibility of the suppliers to keep their own copy of the EFMEA.
- *When is an EFMEA updated?* There are at least three conditions for updating the EFMEA:

1. Whenever a new machine's project timeline changes
2. Whenever design modifications or new failure modes are discovered
3. Whenever a change is being considered to a machine's design, application, environment, material usage, or operational process

- *When is an EFMEA completed?* It is considered complete when the equipment is installed, has passed its reliability testing, and is signed off by the plant staff. However, it must be remembered that an EFMEA, just like the traditional FMEA, is a living document and must be updated whenever significant changes occur in the equipment's design and/or application.
- *When can an EFMEA be discarded?* Depending on the industry, it varies from cradle to grave (nuclear industry) to specific years as defined in the record retention requirement of the organization's policies and procedures. The retention period is reviewed regularly for effectiveness and appropriateness and is part of the organization's quality system.

- *What is the form that may be used in an EFMEA?* A typical form for the EFMEA is shown in Figure 8.2. Obviously, it may be modified to reflect specific issues with a particular industry and/or equipment.

The form in Figure 8.2 is coded with numbers from 1 to 23. The explanations below follow the form:

- *FMEA number (1)*: Each FMEA must have a number to help track the document and its information. After all, the FMEA is a controlled document.
- *Equipment name (2)*: Used to identify the equipment's name for reference and accountability.
- *Design responsibility (3)*: This is the place where the design responsibility is identified. For example, it may be the supplier and/or specific department or group responsible for the design of the particular equipment.
- *Prepared by (4)*: This item must identify the leader of the EFMEA's name, phone, as well as e-mail for contact, if necessary.
- *Model (5)*: This identifies the model of the equipment, if applicable.

FMEA number (1)			Prepared by (4)							Page ___ of ___							
Equipment name (2)			Model (5)							FMEA date (7)							
Design responsibility (3)			Review date (6)							Core team (8)							
													Action results				
System, subsystem, component (9a)	Function or performance requirements (9b)	Potential failure mode (10)	Severity (12)	Classification (13)	Potential causes of failure (14)	Occurrence (15)	Prevention controls and equipment controls (16)	Current design and equipment controls (17)	Detection (18)	RPN (19)	Recommended action(s) (20)	Responsibility and target completion date (21)	Action taken (22)	Severity	Occurrence	Detection	RPN (23)

Figure 8.2 Example of the equipment FMEA form.

- *Review date (6)*: The initial date the EFMEA started. This date should fall within the design and development phase of the equipment's life cycle process. Sometimes this is called *original date*.
- *Page__ of __*: Identifies all pages of the FMEA for reference purposes.
- *FMEA date (7)*: The initial date the EFMEA is completed, or the revision date.
- *Core team (8)*: This item covers all the team members that participate in the EFMEA. It should identify: name, department, telephone, e-mail, and address.
- *System, subsystem, component (9a)*: This is the item where the information is used to classify the analyzed machine's subsystem. The intent here is to identify the hierarchy of the machine so that it is quickly formulated and then transferred to the column listing all of the subsystems in the appropriate order. (Note: The *subsystem name* column and the *function and performance requirements* column have the same location. However, to make the distinction easier, it is suggested that the two be separated.)

- *Function or performance requirements (9b)*: This column relates directly to the subsystem name information and lists all of the subsystem's associated functions and the design intent of that system. This column provides information that corresponds to each of the machine's identified subsystems. In addition, using the four following recommended steps to fill out this column simplifies subsystem function identification: (1) brainstorming, (2) evaluating the results of brainstorming, (3) converting to verb-noun format, and (4) establishing the appropriate and applicable measurement system.
- *Potential failure mode (10)*: Defined as the manner in which the equipment could potentially fail to meet the design intent. These failures are generally the ones that the operator sees. Typically, there are two approaches to identifying these failures: (1) functional, which relates to some form of loss of function, and (2) hardware, when detailed part designs are available. If the failures are identified as part of a static model, that means that the identified failures have no effect on other failures of other subsystems or components under investigation. It is very important for

the team to identify as many failures as possible in the design phase because this action will reduce the number of failures that may be seen during debug phase, start-up, and the useful life of the equipment.

- *Potential effects of failure (11)*: These represent the potential consequences of the failure mode. Typical areas of concern may be: breakdowns, reduced cycle time, tooling, setup and adjustments, defective parts, government regulations, idling and minor stoppages, and safety. Of these, special attention must be given to the government regulations and safety issues.
- *Severity (12)*: Represents the seriousness of the effects listed in column 11 and is made up of three components: (1) safety, (2) equipment downtime, and (3) product scrap. Each effect (in column 11) is assigned a ranking between 1 and 10 from the agreed-on criteria, and the highest ranking is entered in this column. *Only* the highest ranking is entered because it represents the most serious effect that may occur, *if* the failure mode occurs.
- *Classification (13)*: In the EFMEA the only time that this column is used is if the

severity is 9 or 10, which has to do with government regulations or operator safety. If indeed it is used, then action must be taken to correct the problem. Typical designations are OS, which stands for *operator safety*, and Y, which stands for *government regulations*.

- *Potential causes of failure (14)*: This column represents design deficiency or process variation that results in the failure mode. To have an effective EFMEA, all first-level failure mode causes must be identified and listed in this column. This may be accomplished by considering the following three questions: (1) What would cause the subsystem/component to fail in this manner? (2) What circumstances could cause the subsystem/component to fail to perform its function? and (3) What can cause the subsystem/component to fail to deliver its intended function? To help in this identification process, the team should consider the causes relating to the highest-risk failure modes and then review the following for validating their selected options: (1) historical test reports, (2) warranty data reports, (3) surrogate EFMEAs, (4) concern reports, (5) field reports, and (6) product recalls. The team

must remember that *all* 9 or 10 severity rankings *must* identify the root cause of the failure mode. A root cause is the underlying reason for a first-level cause to occur. To identify the root cause(s), one may use simple or difficult methodologies/tools such as (a) a problem-solving methodology such as 8D or DOE, (b) cause-and-effect diagrams, and (c) fault tree analysis.

- *Occurrence (15)*: This column contains the rating relating to the likelihood a particular failure mode cause will occur within a specific time period. To identify a reasonable occurrence, the team may use the Poisson distribution for theoretical numbers, historical data, maintenance records, surrogate data, and warranty data. Each cause *must* have its own occurrence number.
- *Prevention controls and equipment controls (16)*: This column documents all the prevention controls that are planned to minimize the risk of the failure mode.
- *Current design and equipment controls (17)*: This column documents the effectiveness of the planning controls in column 16. For detection purposes, the best control

item will be carried over to column 18. For example, if there are four controls with individual ratings such as 8, 5, 6, 7, and 2, then the 2 will be carried over to column 18. The reason for this is that the control with a 2 rating is the strongest of them all and therefore the most effective.

- *Detection (18)*: It is the column indicating the likelihood that the prevention controls in item (17) can detect and prevent the failure from reaching the customer. This evaluation is based on preset criteria that everyone has agreed on. A numerical value of 1 indicates that the problem is caught at the source whereas a 10 indicates that the failure reaches the customer.
- *RPN: risk priority number (19)*: The RPN is the product of severity, occurrence, and detection. It is very important here to remember that each root cause must have its own RPN. The RPN often is used as a value that determines the priority for either design improvements and/or operational changes.
- *Recommended actions (20)*: This column documents all the possible (appropriate) alternatives that may reduce the risk of

the failure mode's RPN. There should be more than one action available. The focus should be on reducing safety concerns, then on modes with high severity and occurrence, and finally on the combination of severity, occurrence, and detection (RPN).

- *Responsible individual and target date (21)*: This column documents who is assigned the responsibility to review or implement the recommended action—if appropriate. A target date must also be identified. Without a name and/or date, no one is responsible and the due date becomes infinity.
- *Action taken (22)*: This column briefly describes the specific action taken from the alternatives identified in column 20, with the intent to lower the risk of a failure mode. A completed EFMEA is of very limited value without positive actions to eliminate potential injury, safety issues, government regulation violations, and machine downtime, or prevent part defects. The action taken here is essential to implementing high-failure risk solutions. Here it must be also

mentioned that the primary design responsibility belongs to the supplier, and therefore all EFMEA updating remains the supplier's responsibility even after installation at the customer's facilities. (Obviously, if the design is the responsibility of the customer, then the customer bears the responsibility of the design EFMEA.)

- *Revised RPN (23)*: The revised RPN is calculated from the new severity, occurrence, and detection values resulting from the implemented actions in item 22. These new numerical values are a result of the team consensus. If there were no actions taken, then these new columns are left blank. If the actions have indeed reduced any of the three numbers, or all of them, then the EFMEA team must repeat steps 20 through 23 on a new EFMEA form, and a new revision number must be assigned. A cautionary note here is appropriate. In order to change the severity number, a design change must occur, otherwise the occurrence and/or the detection may be the only items that will change.

Ratings

Generally, the ratings for the EFMEA are the same as those of the design FMEA.

Tools

As machine builders design new equipment, a variety of techniques and tools exist to improve quality, safety, and performance. However, from experience, an effective EFMEA can produce very good results if the EFMEA and fault tree analysis (FTA) are used in combination. The reader should remember that the EFMEA identifies all of the machine's potential failure modes and their first-level causes. In other words, it tries to identify the breadth of problems with a new design (or a modified one). On the other hand, the FTA is used to analyze the root cause of significant failures and establish the probabilities of each cause. The importance of this approach lies with the fact that in the process of evaluating the probabilities, it shows graphically the relationship of each of the causes. In other words, the FTA focuses on the depth of each individual failure. The fundamental question in any FTA is "What are all possible causes for one failure?"

Other typical tools that may be used are:

- Block diagrams
- Interface matrix
- P-diagram
- Brainstorming
- Cause-and-effect diagram
- Reliability formulas (for defining failure)
- Poisson distribution (for identifying specific failure rates)
- DOE
- And others—see chapter on tools

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9

Health FMEA

Just like any other industry, the health industry is very much interested in reducing failures and becoming "fault tolerant" as much as possible. To this end, The Joint Commission (TJC), has addressed these issues and has identified several proactive risk assessment risk standards. One of them is failure mode and effect analysis (FMEA). In healthcare it is designated as HFMEA. The H is for *health*.

For healthcare organizations, the basic definition of FMEA is still appropriate as it is being recognized as a systematic method of identifying and preventing product and process problems before they occur. This definition, of course, is a drastic "mind-set" change for most health organizations. It is drastic because in the past the practice was to reactively change in response to the errors and/or failures that were encoun-

tered and *not* to deal in proactive action to either prevent or absorb errors in a systematic pro-designed fashion for medical or healthcare errors, or even risks to patient safety.

Prevention in healthcare means that the organization must have policies and procedures that prevent adverse occurrences rather than simply reacting when they occur. In addition, it means that barriers created by hindsight bias, fear of disclosure, embarrassment, blame, or retaliation (punishment in any form) must be identified, and corrective action must be in place.

Some major issues that may be minimized or even be avoided if an FMEA is used, are:

- Medical gas usage
- Patient safety (bed rail and Vail bed entrapment)
- MRI incident—ferromagnetic objects
- Major medical center power failure

In healthcare, a barrier that eliminates or substantially reduces the likelihood of a hazardous event occurring is considered an effective control measure. Therefore, in order to have a good system for preventing issues, problems, concerns, and hazardous situations, there are six steps that a health organization must follow to be successful:

1. Identify high-risk processes
2. Prioritize these processes
3. Identify potential failure modes
4. Identify the effect(s) for each failure mode
5. Conduct a *root cause analysis* (RCA) for each critical effect
6. At least once a year, select one high-risk area for evaluation

Typical actions resulting from the above six items are:

- Redesign the process to minimize or eliminate the risk of the failure mode or to protect patients from its effects
- Test the redesigned process
- Validate that the process is working
- Implement the change
- Identify and implement measures of effectiveness (remember that *effectiveness* is an issue of customer satisfaction, and *efficiency* is an issue of optimizing resources)
- Implement a control and monitoring strategy for maintaining the effectiveness of the "new" process over time

COMPARISON OF RCA AND HFMEA

The purpose of RCA is to get to the root cause and escape point. The purpose of the HFMEA is to simulate potential failure modes and remove them from the process or minimize them as much as possible. Table 9.1 shows some similarities and differences between RCA and HFMEA.

Yet another significant difference is the use of hazard analysis as part of the FMEA. In health-

Table 9.1 Similarities and differences between RCA and HFMEA.

Similarities	Differences
• Interdisciplinary and cross-functional team • Focus on systems issues • Use of flow diagram • Actions and outcomes expected • Matrix scoring card expected • Usage of triage to develop or trigger questions, cause-and-effect diagram, brainstorming, and so on	• Focus on process versus chronological flow diagram • Prospective analysis, for example, "what-if" • Choose specific topic for evaluation • Include and consider detectability and criticality in evaluation • Focus on testing intervention

care it is common to use the term "hazard analysis" to identify the process of collecting and evaluating information on hazards associated with a particular process(es). The idea here is to develop a list of significant and reasonable items likely to cause injury and/or illness if not effectively controlled.

By contrast, the FMEA proper is about evaluating different ways that a process or subprocesses can fail to provide the anticipated ideal function (anticipated result without any errors). A good source for finding areas of improvement, especially in healthcare, is to evaluate the classic eight wastes as well as study 6S. A simple overview is shown in Table 9.2.

THE PROCESS OF THE HFMEA

Fundamentally, there are six steps in conducting an HFMEA. They are:

1. Define the topic
2. Assemble the team
3. Graphically describe the process
4. Conduct the analysis
5. Identify actions and outcome measures
6. Repeat as needed

Table 9.2 Eight wastes and 6S.

Item	Eight wastes	6S
1	Unused human potential: untapped creativity or talent, injuries. How does this affect the healthcare organization?	Sort: Remove items not needed daily (red tag process).
2	Waiting: patients/provider/material. What is the effect of these on the healthcare organization?	Set in order: label items and make it obvious where they belong.
3	Inventory: stacks of work/piles of supplies. How does this affect the efficiency of the healthcare organization?	Shine/sweep: clean and inspect everything inside and out. Visually sweep area to make sure everything is in its place.
4	Transportation: transporting people and/or paperwork. Does this hinder productivity? If so, how it can be improved, and what are the bottlenecks?	Safety: *all* required safety information is posted. *All* exits and emergency equipment are clearly marked and functional.
5	Defects: wrong information/rework. What is causing the wrong information and rework? What can we do about it?	Standardize: establish policies and standard work to ensure 6S.

Continued

Table 9.2 *Continued.*

Item	Eight wastes	6S
6	Motion: finding information/ double entry/searching. What is causing the extra work in searching and double entry? Why can we not find the information when it is needed?	Sustain: provide and/or make sure that training, discipline, daily activities, and self-audits are part of the new system so that improvements are continued and/or improved.
7	Overproduction: duplication/ extra information. Why does the system allow the organization to have duplicate and/ or extra information beyond the legal requirements?	
8	Processing: extra steps/ checks/workarounds. Where is the inefficiency that creates this extra processing?	

Define the Topic

Perhaps the most important step in conducting an HFMEA is to define the scope and have a good as well as clear definition of the process to be evaluated. It is highly recommended that the

evaluation at this stage be defined as a measurable output.

The items of interest may be organizational and/or process oriented. For process orientation issues, it is easy to identify the gaps(s) for analysis. The reason for this is that you know where you are and you also know where you want to be. That difference is the gap, and it can be measured in time, money, material utilization, and many more ways. For organizational change, that may be little more difficult, but it can be accomplished if there is a willingness of management to change. A typical comparison is shown in Table 9.3.

Assemble the Team

The team by definition must be cross-functional and multidisciplinary. *All* FMEAs and HFMEAs must be completed by a team. Team members must have ownership and knowledge about the process. *All* decisions must be made on a consensus basis.

Graphically Describe the Process

To understand the process with all its activities, the team must be able to use some type of a graphical form, such as a flowchart, emphasiz-

Table 9.3 A typical comparison of process redesign and organizational change.

Process redesign	Organizational change
• Fail–safe designs • Simplicity of a process • Standardization • Elimination of excess sound/noises • Simulate • Looser coupling of systems (interaction and interfacing) • Forcing functions where they do not belong • Usability testing • Redundancy • Reduce reliance on memory • Reduce complexity	• Leadership commitment • Drive out fear • Teamwork • Empowerment • Free flow of information • Feedback (horizontal and vertical) • Encouragement of ideas to improve

ing the process sequence rather than the chronological one. If the process is complex, break down the area of concern and focus on "doable," manageable activities. All activities of a simple or

complex process must be numbered and related to the HFMEA, as well as to the control/reaction plan. In case of a very complex area, break down each sub-area, do its own process flow diagram, and evaluate accordingly.

Conduct the Analysis

A systematic approach is necessary here. A typical one is the following:

- List failure modes by following the function and the process flow diagram
- Determine both severity and probability
- Decide on a course of action based on some formal method, for example, decision tree, fault tree analysis, and so on
- Determine *all* failure mode causes
- Determine the frequency of these causes
- Identify actions and outcome measures

To accomplish these tasks as part of the analysis, the team needs appropriate and applicable forms, worksheets, scoring criteria, and a formal RCA methodology.

Identify Actions and Reaction Measures

The purpose of the previous step is to basically decide whether to "eliminate," "reduce," or "accept" the failure mode cause. As such, the analysis will drive the team to a particular action and/or reaction depending on the expected outcome. It is important here to realize that each failure mode cause needs its own action and/or reaction. The action and/or reaction *must* be measurable so that the redesign or improvement may be measured appropriately and without individual bias. When the root cause is identified, then the effort must be made to make sure that the escape point is also identified and the specific action is assigned to a specific individual with a specific due date. Finally, in this stage, management must agree with the root cause and appropriate action taken. (Note: An escape point is where the failure occurred and could have been caught but was not).

Repeat as Needed

In the spirit of continual improvement, the cycle must be repeated until the failure mode is completely eliminated or another failure is identified with a higher risk to pursue.

FORMS

A. Worksheet

A worksheet is a temporary form that is used to facilitate the discussion of an HFMEA. There is no standard for such a form. Figure 9.1 shows a typical worksheet.

B. Ranking

Typical severity rankings for an HFMEA are shown in Table 9.4.

Typical probability rankings for an HFMEA follow. There are many ways to rank probability ratings. However, the most common one for HFMEA is the one based on MIL-STD 1629, which is combined with the severity ranking to give a numerical value for setting a priority. The rankings are:

- *Frequent*: Likely to occur immediately or within a short period (may happen several times in one year)
- *Occasional*: Probably will occur (may happen several times in one to two years)
- *Uncommon*: Possible to occur (may happen sometime in two to five years)
- *Remote*: Unlikely to occur (may happen sometime in five to 30 years)

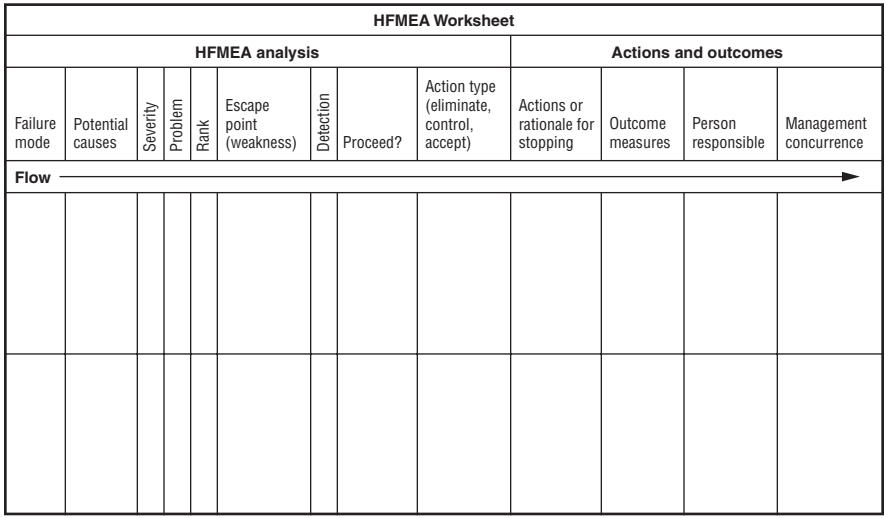


Figure 9.1 A typical HFMEA worksheet.

Table 9.4 Typical severity rankings for an HFMEA.

Severity rating			
Catastrophic event (Traditional FMEA rating of 9 or 10 indicates government regulations or safety—death or injury—with or without warning)	**Major event** (Traditional FMEA rating of 7 or 8 means that the failure causes a high degree of customer dissatisfaction)	**Moderate event** (Traditional FMEA rating of 3 to 6 means that the failure may be overcome with modifications to the process or product or service, but there is a minor performance loss)	**Minor event** (Traditional FMEA rating of 1 or 2 means failure would not be noticeable to the customer and would not affect delivery of the service or product)
Patient outcome: Death or major permanent loss of function (sensory, motor, physiologic or	*Patient outcome:* Permanent lessening of bodily functioning (sensory, motor, physiologic or	*Patient outcome:* Increased length of stay or increased level of care for one or two patients	*Patient outcome:* No injury, not increased length of stay or increased level of care

Continued

Table 9.4 *Continued.*

Severity rating ***(continued)***			
intellectual), suicide, rape, hemolytic transfusion reaction, surgery/procedure on the wrong patient or wrong body part, infant abduction or infant discharge to the wrong family *Visitor outcome:* Death or hospitalization of three or more Staff outcome: Death or hospitalization of three or more staff	intellectual), disfigurement, surgical intervention required, increased length of stay for three or more patients, increased level of care for three or more patients *Visitor outcome:* Hospitalization of one or two visitors	*Visitor outcome:* Evaluation and treatment for one or two visitors—less than hospitalization) *Staff outcome:* Medical expenses, lost time or restricted duty injuries or illness for one or two staff *Fire:* Very small or insignificant *Equipment or facility:* Damage between	*Visitor outcome:* Evaluation and no required or refused treatment *Staff outcome:* First aid treatment only with no lost time, nor restricted duty injuries nor illness *Fire:* Not applicable *Equipment or facility:* Damage less than $10,000 or loss of any utility without

Continued

Table 9.4 *Continued.*

Severity rating *(continued)*			
Fire: Any fire that is more than an incident *Equipment or facility:* Damage over $250,000	*Staff outcome:* Hospitalization of one, two, three, or more staff experiencing lost time or restricted duty due to injuries or illness *Fire:* Not applicable *Equipment or facility:* Damage over $100,000	$10,000 and $100,000	adverse patient outcome, for example, power, natural gas, electricity, water, communications, transport, heat/air conditioning

These items are multiplied with the following severity levels:

- *Category I—Catastrophic*: A failure that may cause death or a system loss (9–10)
- *Category II—Critical*: A failure that may cause severe injury, major property damage, or major system damage (7–8)
- *Category III—Marginal*: A failure that may cause minor injury, minor property damage, or minor system damage resulting in delay or loss of availability of the system, or even degradation of the system (3–6)
- *Category IV—Minor*: A failure not serious enough to cause injury, property damage, or system damage. However, it will cause some unscheduled delays (1–2).

As a result of this multiplication, Table 9.5 is generated and appropriate action is taken based on the numerical value of Severity × Probability.

DETECTION

In a typical HFMEA, detection is based on the effectiveness or ability to control the failure. So,

Table 9.5 A typical matrix showing severity and probability.

		Severity			
		Catastrophic	Major	Moderate	Minor
Probability	Frequent				
	Occasional				
	Uncommon				
	Remote				

the ranking is generally the same as in the traditional FMEA.

TOOLS

There are many tools one may use in any FMEA and/or HFMEA. However, the most common ones are:

- Process flowchart
- Brainstorming
- Check sheets
- Affinity chart
- Statistical process control charts

- Correlation analysis
- Scatter plots
- Box plots
- Decision tree

For more advanced tools and methodologies see Chapter 13.

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10

Failure Mode, Effects, and Criticality Analysis (FMECA)

DEFINITION

FMEA is a bottom-up, inductive analytical method that may be performed at either the functional or piece/part level. FMECA extends FMEA by including a *criticality analysis*, which is used to chart the probability of failure modes against the severity of their consequences. The result highlights failure modes with relatively high probability and severity of consequences, allowing remedial effort to be directed where it will produce the greatest value.

UNIQUE TERMS AND DEFINITIONS

function—The intent of the design or process

function failure—How this function will fail

failure mode—What specific failure is identified for this function

failure effect—What the consequence(s) of this failure mode is

severity classification—How serious this failure mode is

occurrence—Frequency of the cause of the failure mode

mean time between failures—What the average time between failures is

failure detection—How effective the detection mechanism to "catch" the cause of the failure is

In addition to these primary definitions, the following considerations must be made in order to identify the function of concern:

- Consider all functions of concern
- Describe the functions with a verb and a noun in very specific terms
- State the function in terms of its utility rather than capability
- Consider separating functions if they are complicated and convoluted

For secondary considerations of the function, the following should be considered:

- Control
- Warning and status of failure mode
- Environmental issues
- Safety (both operational and personnel)
- Fluid and gas containment
- Explosions
- Support (structural)
- Comfort and blending of the environment

POSSIBLE SOURCES FOR IDENTIFYING FUNCTIONS

Functions for potential failure modes are all over an organization. However, for an FMECA, the common function sources may be found in the following areas:

- Maintenance (both from experience and theory)
- Operating manual, procedures, and instructions
- Data from system descriptions (with past failures or questionable practices)

These three areas are very fundamental and should be explored with an FMECA so that

errors may be avoided. Typical errors as a result of overlooking the above items are:

- Missing either or both primary and secondary functions
- Listing simple and insignificant functions of lower priority
- Confusion of potential failures
- Lack of specificity
- Failure to apply common sense in the name of expediency
- Failure to discuss thoroughly all functions
- Missing the opportunity to include compensating and/or restorative actions
- Missing the opportunity to catch effects at the point of functional failure

THE PROCESS OF CONDUCTING AN FMECA

Every methodology used to solve a problem of any kind is a process, and therefore it must have the appropriate planning. This is achieved through:

- Planning and preparation:
  - Identify task

  - Identify team and responsibilities
  - Ground rules and assumptions
  - Identify analysis items (functions)
  - Prioritize items
  - Identify and document review process
  - Orientation and training
- Analysis:
  - Equipment kickoff meeting
  - Initial gathering
  - Block diagram—hardware partition
  - Function
  - Function failure
  - Failure mode
  - Failure effects
  - Failure consequences
  - Task evaluation
  - Task selection
  - Identify person responsible for action
  - Identify due date of resolution
- Implement results

  - Packaging maintenance task
  - Implement other pertinent actions
- Sustain
  - Emergency issues
  - Hardware changes
  - Document reviews and update
  - Trend and degradation analysis
  - Time effects as necessary

Criticality analysis is a very special way of dealing with a failure. The basic difference between the FMEA and the FMECA is that in FMECA the priority of taking action is based on the product of effect (severity) and occurrence (frequency of the root cause). In some cases the FMECA will include an analysis of a "significant function (SF)." This means that the FMECA will include items that may have an adverse effect on the end task with respect to either individual effects or interaction effects with other items. Some of the items include but are not limited to:

- Safety
- Financials
- Operations
- Environmental health

There are four basic questions that may identify an SF if the answer is a "yes." They are:

1. Does the loss of function have an adverse effect on environment and/or safety?
2. Does the loss of function have an adverse effect on operations?
3. Does the loss of function have an adverse financial impact?
4. Does the function have a protection by an existing control to prevent a failure?

There are two approaches to this action:

1. Qualitative analysis
2. Quantitative analysis

The qualitative analysis is primarily used when specific item failures are not available. On the other hand, a quantitative analysis is used when sufficient failure rate is available to calculate criticality numbers.

Qualitative Analysis

Since there are no failure rate data available, failure mode probabilities are not used. This means that the criticality, or risk, associated with each failure is subjectively classified by the team members. The ranking subjectivity is for both

severity and occurrence of the failures. The probability of occurrence of each failure is grouped into discrete levels that establish the qualitative failure probability level for each entry based on the judgment of the team. In addition, this analysis may provide the initial steps for root cause analysis, fault tree analysis, and logistical analysis, as necessary. Typical probability levels are:

- Frequent
- Reasonably probable
- Occasional
- Remote
- Extremely unlikely

The generic form for the qualitative analysis is the same as for the DFMEA or the PFMEA depending on the task. However, there is also an alternative to this form, and it looks like Figure 10.1.

Quantitative Approach

The quantitative method is used when failure rates, failure modes, failure ratios, and failure effects probabilities are known. These numbers are used to calculate a *criticality number* to be used to prioritize items of concern. It is important here to mention that these numbers are usually

Qualitative Failure Mode, Effects, and Criticality Analysis													
System:												Original date:	
Part name:												Revised date:	
Reference drawing:												Team:	
Objective:												Approved by:	
FMECA number:												Page ___ of ___	
						Single component			Redundant system				
Item number	Item function	Potential failure mode	Failure cause	Failure effects	Occurrence	Severity	RPN (O × S)	Have (N)	Need (M)	Occurrence	Severity	RPN (O × S)	Remarks

Figure 10.1 A typical qualitative failure mode, effects, and criticality analysis.

used after the design has been completed, when confident data on the system can be used. (Often, surrogate data are used for these numbers but they are substituted as soon as possible with the actual data.) The quantitative analysis is based on the failure mode criticality (Cm), which is the portion of the criticality number for an item due to one of its failure modes. This results in a particular severity classification. Typical classifications based on the MIL-STD 1629 standard are:

- *Category I—Catastrophic*: A failure that may cause death or complete system failure
- *Category II—Critical*: A failure that may cause severe injury, major property damage, or major system failure
- *Category III—Marginal*: A failure that may cause minor injury, minor property damage, or delay/loss, which will result in a delay or degradation of the system
- *Category IV—Minor*: A failure not serious enough to cause injury, property damage, or system damage, but which will result in unscheduled delays of any kind

This analysis provides a substantial confidence for the risk being evaluated and may be used for other types of analyses, including fault

tree analysis and reliability centered maintenance (RCM).

Mathematically, one may use several formulas to identify criticality. However, before we introduce the formulas, let us examine some of the variables:

N = The amount of components that are redundant

M = The required amount of components necessary

Beta (β) is the failure effect probability and is used to quantify the described failure effect for each failure mode shown in the FMECA. This beta value represents the conditional probability or likelihood that the described failure effect will result in the identified criticality classification, given that the failure mode occurs. The beta value also represents the team's best judgment as to the likelihood that the loss or end effect will occur. (For most items, this probability will be 1 to indicate the worst possible end effect as a result of a failure mode.)

Alpha (α) is the probability—expressed as a decimal fraction—that the given part or item will fail in the identified mode. Determining alpha is done as a two-part process for each component being analyzed. First, the failure modes are determined, and secondly, modal probabilities

are assigned. (If all alphas are identified for each item considered, their sum will be equal to 1.) Modal failures represent the different ways a given part is known, or has been observed, to fail. On the other hand, a failure mechanism is a physical or chemical process flaw caused by design defects, quality defects, part misapplication, wear-out, or other processes. It describes the basic reason for failure, or the physical process by which deterioration proceeds to failure. Once common part failure modes have been identified, modal probabilities (alpha) are assigned to each failure mode. This number represents the percentage of time, in decimal format, that the device is expected to fail in that given mode. (Because the alpha and beta are very commonly confused, it is best to memorize that alpha is the failure mode ratio, the percentage of time how or in what manner an item is going to fail. Beta, on the other hand, is the conditional probability of a failure effect occurring given a specific failure mode. When a failure mode occurs, what percentage of the time is this going to be the end effect?)

Failure rate (λ_p) of an item is the number of failures per unit of time and is typically expressed in failures per million hours, or failures/10^6 hours. At the beginning of the evaluation, this failure rate is based more often than not on surrogate data. However, as information becomes available, the surrogate data are replaced with the actual

data. When analyzing system failure rates where redundant like components are used to accomplish a task, the failure rate must be adjusted to reflect the *system failure rate*. Furthermore, the source of the failure rate should be identified and recorded so that the validity of the data may be proved if there is a question or challenge about it.

Now that we know the variables, let us see the actual formulas.

Let us begin with the failure mode (modal):

1. *Modal failure rate* is the fraction of the item's total failure rate based on the probability of occurrence of that failure mode. It is presented in a formula format as

$$\lambda_m = \alpha\lambda_p$$

where

λ_m = The modal failure rate

α = The probability of occurrence of the failure mode (failure mode ratio)

λ_p = The item failure rate

(Note: If there are three different failure modes, then all failure rates will equal the item failure rate.)

2. *Failure mode (modal) criticality number.* This is a relative measure of the frequency of a

failure mode. In other words, it is a mathematical calculation to figure the rank importance based on its failure rate. It is shown in a formula format as

$$\mathrm{Cm} = \beta\alpha\lambda_p t$$

where

Cm = Failure mode criticality

β = Conditional probability of occurrence of next-higher failure effect

α = Failure mode ratio

λ_p = Part failure rate

t = Duration of applicable task

3. *To identify a single failure probability*, one may use the Poisson distribution.

A Poisson distribution is a discrete distribution with parameter (usually this is the mean) $\lambda > 0$, if for $k = 0, 1, 2, \ldots$ the probability mass function of X is given by

$$f(k;\lambda) = \Pr(X = k) = \frac{\lambda^k e^{-\lambda}}{k!}$$

where

e is the base of the natural logarithm ($e = 2.71828\ldots$)

k! is the factorial of *k* (Remember that 0! = 1)

The positive real number λ is equal to the expected value of *X* and also to its variance:

$$\lambda = E(X) = \mathrm{Var}(X)$$

The Poisson distribution can be applied to systems with a large number of possible events, each of which is rare. The Poisson distribution is sometimes called a *Poissonian distribution*.

4. *To identify an item with criticality within a particular severity level*. In other words, this approach identifies the item *criticality* (Cr). It is the criticality number associated with the item under analysis. One may think of Cr as the sum of the item's failure mode criticality numbers, Cm, which result in the same severity classification. It is represented as

$$\mathrm{Cr} = \sum_{n=1}^{j} \left(\beta\alpha\lambda_p t\right)_n = \sum \left(\mathrm{C_m}\right)$$

where

Cr = Item criticality

n = The current failure mode of the item being analyzed

j = The number of failure modes for the item being analyzed

β = Conditional probability of occurrence of next higher failure effect

α = Failure mode ratio

λ_p = Part failure rate

t = Duration of applicable task

Cm = Failure mode criticality number

Once the functions have been completed, then the failure mode has to be identified. Typical avenues for this identification are:

- Identify all known and potential (reasonable) failure modes
- Be descriptive and as specific as possible
- Realize that "significant" and "reasonable" vary by project
- Identify all possible failure causes

5. *Mean time between failures* (MTBF) is the average time between failures. It is used in maintenance and equipment failures. The equation for MTBF is the sum of the operational periods divided by the number of observed failures. If the "Down time" (with space) refers to the start

of "downtime" (without space) and "up time" (with space) refers to the start of "uptime" (without space), the formula will be

$$\text{Mean time between failures} = \text{MTBF} = \frac{\sum(\text{Start of downtime} - \text{Start of uptime})}{\text{Number of failures}}$$

The MTBF is often denoted by the Greek letter θ or MTBF = θ. The MTBF can also be defined in terms of the expected value of the density function $f(t)$:

$$\text{MTBF} = \int_0^\infty tf(t)dt$$

where f is the density function of time until failure, satisfying the standard requirement of density functions

$$\text{MTBF} = \int_0^\infty f(t)dt = 1$$

When redundancy is employed to reduce system vulnerability and increase uptime, failure rates need to be adjusted prior to using the preceding formula. This can be accomplished by using formulas from various locations depending on the application. As an example, here we use the exponential distribution with constant time

between failures. Mathematically, the formula with repair is:

$$\lambda_{(n-q)/n} = \frac{n!(\lambda)^{q+1}}{(n-q-1)!(\mu)^{q}}$$

where

n = Number of active online units

$n!$ = n factorial

q = Number of online units that can fail without system failure

μ = Repair rate (μ = 1/MTTR, where MTTR is the mean time to repair in hours)

λ = Failure rate for online unit (failures/hour)

The formula for without repair is:

$$\lambda_{(n-q)/n} = \frac{\lambda}{\sum_{i=n-q}^{n} \frac{1}{i}}$$

For detailed methodologies and specific tests the reader is encouraged to see RAC (1995).

If there is a situation of one standby off-line unit with n active online units required for

success, with the off-line spare assumed to have a failure rate of zero, then the equations with and without repair are respectively shown as:

$$\lambda_{n/n+1} = \frac{n\left[n\lambda + (1-\mathrm{P})\mu\right]\lambda}{\mu + n(\mathrm{P}+1)\lambda}, \text{ with repair}$$

$$\lambda_{n/n+1} = \frac{n\lambda}{\mathrm{P}+1}, \text{ without repair}$$

where

n = Number of active online units

$n!$ = n factorial

q = Number of online units that can fail without system failure

μ = Repair rate (μ = 1/MTTR, where MTTR is the mean time to repair in hours)

λ = Failure rate for online unit (failures/hour)

P = Probability that the switching mechanism will operate properly when needed (P = 1 with perfect switching)

On the other hand, if two active online units have different failure and repair rates, and one of the two is required for success, then we have:

$$\lambda_{1/2} = \frac{\lambda_A \lambda B\left[\left(\mu_A + \mu_B\right) + \left(\lambda_A + \lambda_B\right)\right]}{\left(\mu_A\right)\left(\mu_B\right) + \left(\mu_A + \mu_B\right)\left(\lambda_A + \lambda_B\right)}, \text{ with repair}$$

$$\lambda_{1/2} = \frac{\lambda_A^2 \lambda_B + \lambda_A \lambda_B^2}{\lambda_A^2 + \lambda_B^2 + \lambda_A \lambda_B}, \text{ without repair}$$

These last two failure rates (λ), once calculated, should be substituted in the above item 4

$$\mathrm{Cr} = \sum_{n=1}^{j} \left(\beta \alpha \lambda_p t\right)_n$$

to calculate the new criticality number, which accounts for redundancy.

Form

The generic form for the quantitative analysis is the same as for the DFMEA or the PFMEA depending on the task. However, there is also an alternative to this form—taking advantage of the formulas just discussed—shown in Figure 10.2.

Sources for the Failure Mode

- Existing preventive maintenance task records
- Operating records

Quantitative Failure Mode, Effects, and Criticality Analysis

System:	Original date:
Part name:	Revised date:
Reference drawing:	Team:
Objective:	Approved by:
FMECA number:	Page ___ of ___

Item number	Item function	Potential failure mode	Failure cause	Severity	Redundancy		Failure rate (λ_p) (Source)	Failure effect probability (β)	Failure mode ratio (α)	Operating time	Failure mode criticality number (Cr)	Item criticality number (Cm)	Remarks
					Have (N)	Need (M)							

Figure 10.2 A typical quantitative failure mode, effects, and criticality analysis.

- Operator inputs
- Prior FMEAs, fault tree analysis, and FMECAs
- Engineering and subject matter experts' input
- Simulation studies data

Errors may be due to:

- Overdependence on data from simulation, experts, and nonspecific failure data
- Lack of specificity of the failed part/location
- Expediency—tackling insignificant as opposed to important problems
- Confusing failures with effects and vice versa

Avenues for identifying effects:

- List most severe effects
- List reasonable effects
- Differentiate between potential and possible effects
- Identify effects at point of functional failure

When the effects are properly identified, good things happen in the totality of the analysis. The effects must be evaluated as (a) local—effect on the local part, (b) next higher—effect on the function of the system/subsystem being analyzed, and (c) end—what the failure means to the task at hand. Specifically:

- The analysis for the FMECA becomes much easier
- Secondary damages are easier to identify
- Hidden failures are more easily identified
- Functional failures are addressed more efficiently with the appropriate effects assigned to them

Sources for Effects

- Operating manuals
- Operator/engineer input
- Troubleshooting charts
- Test reports
- Failure/engineering investigations
- Subject matter experts
- Maintenance operators

Common Errors

When appropriate effects are not identified, some of the problems may be attributed to:

- Assuming preventive maintenance exists
- Ignoring secondary issues
- Ignoring treatment of hidden failures
- Ignoring appropriate level of the effect

Detection

Detection describes the method(s) by which functional failures are detected. It is important to remember that the planned activities for control are not counted for the control ranking. What counts in the ranking is how effective the control is at minimizing or eliminating the root cause of the failure. Typical controls are:

- Mistake-proofing
- Visual alarms
- Reliability testing
- Specific testing at the end of the line (EOL)
- Gages and/or indicators

Of note here is the fact that (a) inspection *is not* a good control, and (b) operator error and training are not good control items.

RPN

Generally, the RPN is *not* the final word in taking a specific action. The decision is based on a priority based on the following order:

1. Severity
2. Severity × Occurrence
3. Severity × Occurrence × Detection

In other words, if we have the following situations,

$$\text{(First option) } 10 \times 2 \times 2 = 40$$
$$\text{(Second option) } 10 \times 3 \times 2 = 60$$
$$\text{(Third option) } 3 \times 10 \times 4 = 120$$

the priority will be to solve the first item because of the high severity. Then we will address the second one because the severity and occurrence product is critical. Notice that the S × O product of the third option is also 30, but the second option has a high severity, which takes precedence. Lastly, we will evaluate the third one with the highest total RPN. (If one chooses the quantitative form, then the priority will be based on the Cr or Cm depending on the specific project.)

BENEFITS

There are many benefits of conducting FMECA, including:

- Prevents accidents
- Increases customer satisfaction
- Reduces costs for late changes
- Optimizes both design and process robustness
- Documents the system and/or process in addition to equipment
- Standardizes the methodology of risk assessment
- Allows for "free" exchange of ideas and knowledge
- Reduces potential warranty costs
- Documents all the evidence of "due care" for liability concerns
- Improves the goodwill of the organization as it satisfies the corporate citizenship requirement for accountability for potential failures as well as catastrophic failures

TOOLS

Some of the common tools used in FMECA are:

- Scenario
- Brainstorming
- Simulation methods
- Reliability methods
- Affinity charts
- Cause-and-effect diagram
- Checklists

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Control Plans

A *control plan* (CP) is a written description of the systems used to control and minimize product and process variation. In addition, it specifies the process monitoring and control methods used to control special characteristics. *Special characteristics* are the critical and significant characteristics for the product and/or process. They are usually identified in the drawings and the FMEAs.

Generally speaking, a control plan includes provisions for ongoing monitoring of process control, stability, and capability.

PURPOSE OF CONTROL PLAN

The purpose of a control plan is to ensure that the customer requirements are met by supporting the manufacturing of quality products. This is done by having a plan that the operator

follows, monitoring the key process input variables (KPIV) as well as the key process output variables (KPOV).

As deviations from the plan occur, the control plan also includes a reaction plan that allows the operator to react to a given problem.

The primary intent of a control plan is to create a structured approach for control of process and product characteristics, while focusing the organization on the characteristics that are important to the customer. Because of this, a CP must define the necessary systems that need to be in place to control the process and minimize the occurrence of the failure modes identified in the FMEA.

WHEN CONTROL PLAN IS USED

The control plan feeds into the operator work instructions, which must answer the following four questions:

1. What is to be monitored?
2. How often must the monitoring occur?
3. How is the monitoring performed?
4. How does the operator react when a deviation occurs?

TYPES OF CONTROL PLANS

There are three types of CPs. They are:

1. Prototype
2. Preproduction
3. Production

During the product development cycle, CPs are used to document and communicate the initial plan for process control. All of them are considered legal documents as well as being living documents. Therefore, if you are constructing and/or reviewing these documents, make sure they are correct, as they are used often in legal disputes. A good practice is to initial all pages of the CP and FMEA.

In the automotive industry there is also a Dynamic Control Plan. This one is a combination of the FMEA and the control plan. No additional requirements are needed. The left side of the form is the FMEA proper, and the right side is exclusively for the CP.

BENEFITS

Fundamentally, the CP contributes to two basic benefits. They are:

1. Assurance that the customer will receive what they are paying for
2. Assurance that the operator will know what to do if there is a deviation in their process or product

CONTENT OF A CP

There are several items that a CP may cover. However, the most often included and important items are pretty much standardized. They are:

1. Part/process number
2. Process name/operation description
3. All machines, devices, templates, tools, jigs for manufacturing
4. Characteristics to be controlled
5. Process/product specifications/tolerances
6. Evaluation/measurement techniques, including gage number and calibration information
7. Sampling plan including size and frequency
8. Control method including chart type, chart champion, chart location
9. Reference to the reaction plan

All these are usually in a tabular format. In some cases, depending on the industry, they may include more information.

FMEA/CONTROL PLAN LINKAGE

There must be a linkage between an FMEA, a CP, and a reaction plan. That linkage is based on three things:

1. Engineering documents such as:
   a. Government regulations
   b. Design requirements
   c. Engineering material specifications
   d. Critical manufacturing process parameters (if applicable) that is, casting, welding, heat treat
2. Quality data such as:
   a. Warranty
   b. Capability
   c. Productivity
   d. First-time throughput
   e. Scrap
   f. Things gone wrong (TGW)

   g. Customer concerns
   h. Employees and customer safety
   i. Quality rejects
   j. Field actions and or/stop ships
3. Process knowledge such as:
   a. Lessons learned
   b. Installation drawings
   c. Process sheets

It is very important to remember that CPs, DFMEAs, and PFMEAs are both legal and living documents; therefore, these documents must be updated whenever changes are made. Consequently, appropriate signatures must validate these changes.

Figure 11.1 shows a typical linkage of DFMEA to PFMEA to CP.

DEFICIENCIES IN A TYPICAL CONTROL PLAN

- Special characteristics are not included on the FMEA or the control plan.
- Special controls are not included on the FMEA.

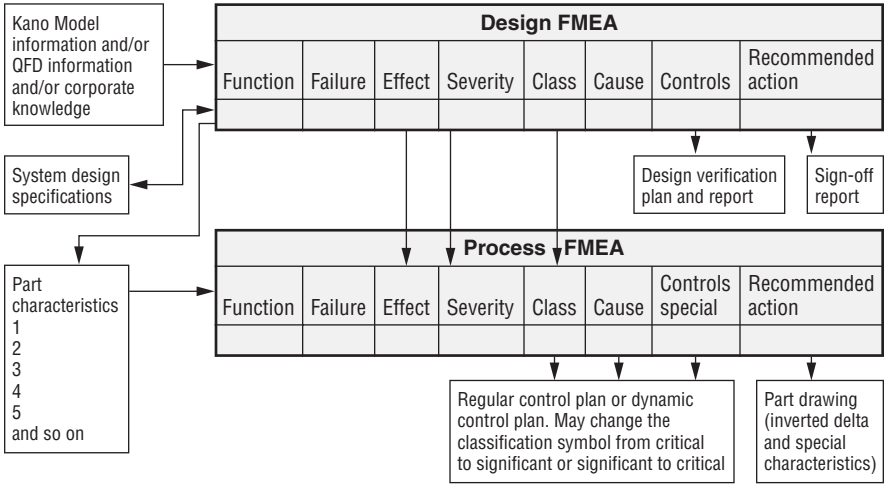


Figure 11.1 Linkage from DFMEA to PFMEA to CP.

- Misunderstanding of severity, occurrence, and detection on FMEAs.
- Failure mode is not identified in FMEA.
- Inadequate or no linkage between FMEA and CP exists.
- Ineffective control and or gauging strategies.
- Process parameter controls are not included or detailed in the CP.
- Ineffective and/or inappropriate sampling plans (size and frequency).
- Inadequate or no reaction plan.
- CP and/or reaction plan *not* followed.

TOOLS USED

- SPC charts
- Sampling
- Measurement systems analysis
- Jigs
- Process flowchart
- Inspection

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Linkages

It is imperative for the reader to understand that in generating any FMEA there have to be "inputs" and "outputs." The linkages between FMEAs and control plans, 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. They are 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 system design specifications (SDSs)
- Pre–product development targets for system performance
- SDSs for the system
- Corporate knowledge

PROCESS CONCEPT INPUT

- Customer requirements
- Regulatory requirements
- Historical performance information
- Benchmarking techniques
- Corporate knowledge

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, geometric dimensioning and tolerancing [GD&T] 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 → Design verification system (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, GD&T 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 GD&T
- 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 prelaunch control plans
- Prelaunch 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

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Tools

AN OVERVIEW OF SOME TYPICAL TOOLS USED IN FMEA

This chapter provides the reader with a quick reference to some typical and most often used tools in the problem-solving process and especially in the FMEA. We believe the most basic of all problem-solving methodologies is the eight-stage process, which of course is a derivative of the scientific approach. The individual stages are:

1. Identify
2. Scope
3. Define
4. Analyze
5. Implement

6. Evaluate
7. Follow-up
8. Continual improvement

Affinity Diagram

A number of small cards (1" × 3") each inscribed with an idea or solution. The affinity diagram is based on brainstorming and a cause-and-effect diagram.

What It Does: This tool 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 the appearance of a rectangle (the box) with a horizontal line, 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: Continual improvement

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 process. Yields information similar 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, and 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 that 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 their location (process average). The *X*-bar chart covers averages of values in small subgroups (sample taken)—known as *measure of location*. The *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 the chart considers standard deviation and is more complicated to calculate.

What It Does: Graphically displays stability of process *S* factor; it is a 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

Decision Tree

Decision trees are excellent tools for helping you to choose between several courses of action. They provide a highly effective structure within which you can lay out options and investigate the possible outcomes of choosing those options. They also help you to form a balanced picture of the risks and rewards associated with each possible course of action.

What It Does: The decision tree lays out the problem so that all options can be challenged. It helps in the analysis of the possible consequences of a decision by providing the framework to quantify the values of outcomes and the probabilities of achieving them. It is an excellent tool to identify and make the best decisions on the basis of existing information and best guesses.

When to Use It:

Stage 4: Analyze

Stage 6: Evaluate

Design of Experiments (DOE)

Several methods are available, of which the following are examples: (1) Taguchi method, including signal-to-noise (S/N) ratios, (2) accelerated testing methods—not in the reliability sense but rather in maximizing the results of multiple testing rather than performing tests one at a time, (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 Plot

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 the 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: Continual improvement

Fault Tree Analysis

A graphical display similar to the shape of tree roots that permits one to identify multiple causes of failures and display interactions between causes.

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: Continual improvement

Function Tree

A graphical representation of functions to ensure clear, total team understanding of actionable and measurable items. From left to right, the question is "how is function achieved?" and from right to left, the question is "Why is function included?"

What It Does: Provides an organized brainstorm (verb/noun) approach to identify the essential

features of a product (or process sometimes). In addition, it helps to ensure that "unspoken" and "spoken" requirements are defined.

When to Use It:

Stage 1: Identify

Stage 3: Define

Stage 4: Analyze

Stage 6: Evaluate

Stage 7: Follow-up

Stage 8: Continual improvement

Gage Repeatability and Reproducibility (Gage R&R)

A measurement of the repeatability and reproducibility of a gage and the operator, respectively.

What It Does: Measures variations in gages 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 Chart

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 Chart

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. A 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 Chart

A 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. The area of the circle can be used to demonstrate a change or 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

Kano Model

The Kano model is a theory of product development and customer satisfaction developed in the 1980s by Professor Noriaki Kano. The model separates the delightful, performance, and basic requirements. The strength of the model lies in the fact that over time it recognizes that the delightful requirements eventually become basic.

What It Does: The model is used to prioritize the critical-to-quality characteristics, as defined by the voice of the customer. In essence, the model provides insights into the dynamics of customer preferences, and therefore it helps optimize the design and/or process with both "must have" and "want to have" items.

When to Use It: It is used primarily in concept and design FMEA. Quite often it is used as a complement to QFD.

Stage 1: Identify

Stage 4: Analyze

Stage 6: Evaluate

Operational Definitions

Terms necessary for the common understanding of a process.

What It Does: This tool contains three elements: (1) a set of criteria, (2) a test by which criteria are applied, and (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: Continual improvement

Pareto Diagram

An *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 the 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: Continual improvement

Program Evaluation and Review Technique (PERT) or Critical Path Analysis

Road map of interdependent elements within a process, 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 the order of sequential priority within a 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 Flowchart

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) the present situation, (2) differences between what should/is thought to be happening and the actual situation, (3) the 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

Process Decision Program Chart (PDPC)

A tree-type chart. It is a contingency plan to limit risks by emphasizing the consequential impact of failure on activity plans, and creating appropriate plans to mitigate that risk.

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 the problem or 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: This technique allows comparisons between the current concept/design, criteria required, and a number of alternative solutions. Each alternative is compared with the

current situation, requirement by requirement, and summarized in the 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 that enables a comparison of customer requirements against a number of design elements. Also allows areas of conflict to be plotted.

What It Does: QFD is a broad management system that assists in translating the voice of the customer into operational definitions that can be used to produce and deliver product/services 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: Continual improvement

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 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 Chart

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 Diagram

An *X*–*Y* graph that examines the possibility of a relationship between two variables.

What It Does: Checks for possible cause-and-effect relationships. It can not prove that one variable causes another, but makes clear whether or not a relationship exists and the strength of the relationship.

When to Use It:

Stage 4: Analyze

Stage 6: Evaluate

Shared and Interlocking Objectives Matrix

A chart that lists various departments on both the *X* axis 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 Plot

A vertical line with data to the left of the line being known as the *stem* and individual criteria as stem ends. Criteria to the right of the line are known as the *leaf*. An alternative to the histogram.

What It Does: Quicker to produce than a histogram and allows data used to be viewed in traditional column format.

When to Use It:

Stage 4: Analyze

Stage 6: Evaluate

Survey

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) the shape of the process, and so on.

When to Use It:

Stage 1: Identify

Stage 2: Scope

Stage 7: Follow-up

Stage 8: Continual improvement

Time Series Forecasting

A series of statistical formulae, tables, and graphs.

What It Does: A broad area of study that takes data measured at discrete, equispaced time intervals and 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: Continual improvement

Tree Analysis

Also called *systematic diagram*, *analytical tree*, and *hierarchy diagram*. It is a functional tool that helps in communicating details to others when analyzing processes in detail and/or evaluating several potential solutions.

What It Does: It helps the team to organize the discussion from generalities to specifics. In other

words, it is used to break down broad categories into finer and finer levels of detail. It is an excellent tool to be used as a follow-up to an affinity diagram or relations diagram in order to focus on the newly discovered key issues.

When to Use It:

Stage 1: Identify

Stage 4: Analyze

Stage 6: Evaluate

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Troubleshooting an FMEA

AFTER FMEA

1. Review the FMEA
2. Highlight the high-risk areas based on the RPN
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 that have C_{pk} or P_{pk} of less than or equal to 1.33
7. Work on processes that have C_{pk} or P_{pk} greater than 1.33 to reduce variation and reach a C_{pk} or P_{pk} of greater than or equal to 2.0

HEADER OF FMEA

- Use correct FMEA form
- Include accurate dates, including revisions
- Identify process step/component name/system name, and so on
- Identify all team members
- FMEA number
- Who prepared FMEA
- No blank fields

FUNCTION/PURPOSE

- Written as verb/noun measurable construction
- Include technical specifications and engineering requirements, process requirements stated
- Describe any special conditions
- Identify all functions

POTENTIAL FAILURE MODE

- Failure modes addressed: no, partial/over function/degraded over time, intermittent, and unintended failures
- PFMEA: describes failure mode as what product would be rejected for
- No causes or effects listed as failure modes
- Associate each failure with a function or special conditions identified for similar failure modes
- Question any function with only one failure mode

POTENTIAL FAILURE EFFECT(S)

- Are all effects considered, including customer, government, product?
- Does effect relate to failure mode?
- Any causes incorrectly listed?
- Note the severity behind each effect or behind the worst, for historic purposes
- "Correct" effect phrasing—clear, concise, accurate?

SEVERITY

- Government regulations or safety for 9 and 10
- Question any rating of 1
- Only highest severity ranking entered for each failure mode

CLASSIFICATION

- Classification marks for each special characteristic
  - Are they correct?
- DFMEA—YC and YS only
- PFMEA—confirm CCs, SCs, OSs, and HIs
- Verify special controls for each CC and SC

POTENTIAL CAUSE(S)/ MECHANISM(S) OF FAILURE

- Are causes with government/safety effects (9–10) at root level? Note part characteristic if appropriate.
- Failure modes have multiple causes listed.

- Both assumptions used in development of causes.
- Any effects incorrectly listed?
- DFMEA—no "operator error" or "machine malfunction" listed.
- PFMEA—no "operator error" or "machine malfunction" listed, especially for significant or critical characteristics or OS.
- Have noise factors been considered?

OCCURRENCE

- Question any rating of 1.
- Was occurrence table followed?
- Question any rating of 10. Does a rating of 10 have an action?
- Set controls to determine occurrence rating.
- One rating per cause.

PREVENTION CONTROLS

- Are there prevention controls in place?

APPROPRIATE CONTROLS APPLIED

- Are the prevention controls effective?
- Are there DFMEA and D-CFMEA controls up front? (Early test strategies, not downstream production controls.)
- No process controls on DFMEA.
- Detection and prevention mechanisms identified in correct columns.
- Careful consideration given to identifying specific controls.
- Actual, planned controls, not "wished for."
- Prevention methods not rated as detection.

DETECTION

- Question any rating of 1
- Verify that visual inspection is not rated less than 4
- Verify that sampling is not overrated
- Best detection rating used for more than one control
- One (best) rating per control set

RISK PRIORITY NUMBER (RPN)

- One RPN per cause.
- Some organizations do not recommend a threshold value for RPNs.

RECOMMENDED ACTION

- Recommended action taken in priority for each S, or S × O or RPN.
- DFMEA—Recommended actions are not process actions or controls.
- DFMEA—All recommended actions point at design itself.
- PFMEA—Recommended actions for special characteristics list the special controls to be put in place.
- Use of "none" or "none at this time"—no blanks. Only the classification column may be blank, *only* and *only if* there are no special characteristics identified.
- Recommended action on all "classified" items.

RESPONSIBILITY/TARGET COMPLETION DATE

- Name and date specified for each recommended action
- Not "TBD" or "ongoing"
- Should be assigned to team member

ACTIONS TAKEN/REVISED RATINGS

- Action taken listed only after the action is completed
- List the action results, not just "completed" or done
- Dates completed and document reference numbers may be helpful for historic purposes
- Enter revised ratings when actions taken are listed—even if there is no rating change
- Consider additional actions if the first action was not successful

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Typical Concerns When Conducting an FMEA

1. COMMON TEAM PROBLEMS

- Poor team composition (Not cross-functional or multidisciplinary)
  - Low expertise in FMEA
  - Not multilevel
  - Low experience/expertise in product
  - One-person FMEA
- 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 versus 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).
- Subgroup 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 the above 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 gained from 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 IN YOUR COMPANY

- Institutionalizing FMEA is challenging, and its success is largely dependent on the culture in the organization, as well as why it is being utilized. Following 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

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FMEAs Used in Selected Specific Industries

FMEAs were first introduced in the 1940s in the U.S. military. However, the methodology grew when the manned space missions started in the 1960s. After this introduction, the FMEA as a risk-mitigating methodology took hold in many industries to the point where special standards have been developed over the years to make sure the appropriate risks are defined and their control is appropriate and applicable.

In this section we are not going to address all applications in all industries. Instead, we are going to address selected industries with quite diverse needs as well as expectations. Our focus is to demonstrate the flexibility of the FMEA to be used in any industry no matter what the product or process is.

For the healthcare industry, please see Chapter 9.

AUTOMOTIVE

The auto industry did not widely adopt FMEAs until the late 1970s. Ford Motor Company introduced them for safety and regulatory items to improve automotive designs and manufacturing, specifically in response to the Pinto fuel tank issues. The success that the Ford Motor company had with the FMEA spread throughout the industry and now is part of the specific requirements of all automotive companies, both domestic and international. Typical FMEAs in the automotive world are the concept FMEA, DFMEA, and PFMEA. Because of the many original equipment manufacturers (OEMs) and their different requirements, the Automotive Industry Action Group (AIAG) was formed to standardize the FMEA. Today, the AIAG has published their 4th edition of generic guidelines for all to follow.

AEROSPACE

In the aerospace industry the risk factors are many and quite often catastrophic. As such, for automobile references the J1739 standard is used, and for all practices for non-automobile applications the standard ARP5580 is utilized.

Both standards recommend the FMEA, which encompasses functional, interface, and detailed FMEA, as well as certain pre-analysis activities (FMEA planning and functional requirements analysis), post-analysis activities (failure latency analysis, FMEA verification, and documentation), and applications to hardware, software, and process design.

The focus of the aerospace FMEA is on organizations assessing safety and reliability of system elements, or as part of their product improvement processes. The general approach is the traditional FMEA; however, quite often the FMECA is used to account for criticality. (http://topics.sae.org/fmea/standards/aerospace/?pg=2)

SOFTWARE

The focus of the software FMEA (SWFMEA) is to evaluate the individual risks by differentiating between high-risk and low-risk components, modules, and functions. This approach makes risk-oriented development of software-intensive systems possible.

The actual FMEA may be performed at different phases of the software development, such as analysis, design, coding, module test, system test, and final test (field test). The actual

approach is the same as the generic one. However, in most cases it follows the rationale of the DFMEA.

A typical SWFMEA is used for architecture or design review during development. This means before the implementation of the software. It may not be executed on software source code.

CHEMICAL/PHARMACEUTICAL

In both the chemical and pharmaceutical industries, risk management is of paramount concern. The risk is mitigated through a formal risk management methodology in the planning, design, and process of a particular project. This methodology is followed in order to avoid project failure due to anticipated or unanticipated events. Whereas the failure mode and effect analysis (FMEA) is indeed a flexible yet powerful tool and is used as a good option for identifying and controlling adverse risk, quite often in both industries the FMECA is followed because of it's criticality nature. Typical concerns in both industries are:

- Understanding the risk
- Defining the specific risk

- Forming the appropriate and applicable team
- Drawing a flowchart of the process
- Analyzing and evaluating the process
- Selecting the appropriate outcome
- Taking action on the most likely outcome
- Measuring the outcome and comparing with the original
- Instituting improvement in the process and similar processes

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ISO, Six Sigma, Lean, and FMEA

ISO

The International Organization for Standardization (ISO) has developed many standards that include risk assessment. Part of that assessment is the use of FMEA. One of the first standards that was devoted to identifying, evaluating, and mitigating risk was ISO 14971:2000, which dealt with medical devices. Unlike the EN 1441 standard, ISO 14971 covers significantly more details of the process and the full life cycle of the device. In other words, ISO 14971 provides a comprehensive approach to reducing risk to the lowest reasonable level. The recommended tool for such an endeavor is the FMEA, and specifically its application of the analysis, evaluation, and control of each risk.

In the United States, the standard has been recognized by FDA, and in Europe it is already

in use, having replaced the old EN 1441. The implication of this is that compliance with ISO 14971 is very crucial not only in assuring the safety of medical equipment, but in meeting regulatory requirements as well. Furthermore, FDA's Quality System Regulation, 21 CFR Part 820, and related standards like ISO 14971 and ISO 13485:2003 require that design validation shall include risk analysis. That is, some form of FMEA and/or FMECA.

Other ISO standards related to FMEA, hazard analysis, and FMECA are the ISO 26262 and IEC 61508 standards. However, the standard that is all-inclusive about risk is ISO 31000, with very detailed prescriptions of both FMEA and FMECA methodologies.

ISO/TS 16949

ISO/TS 16949 is an ISO Technical Specification that aligned the American (QS-9000), German (VDA6.1), French (EAQF), and Italian (AVSQ) automotive quality system standards within the global automotive industry, with the aim of eliminating the need for multiple certifications to satisfy customer requirements.

This technical specification is full of references to reliability, maintainability, failure

control, control plans, and even specific references to FMEA as a prevention methodology for both design and process. This specification is also direct in mentioning (a) the necessity of quality system requirements for the design/development, production, installation, and servicing of automotive-related products, and (b) that the customer-specific requirements pertaining to FMEA are valid and must be followed.

SIX SIGMA

FMEA represents a technique aimed at averting future issues in project processes and eliminating risks that may hamper a solution. Therefore, it fits the Six Sigma methodology in identifying and evaluating defects that could potentially result in reducing the quality of a product. Defects within the methodology are defined as anything that reduces the speed or quality at which a product or service is delivered to happy customers. While Six Sigma techniques are implemented to discover and reduce the variables in processes that cause nonrandom fluctuations, FMEA is used to discover and prioritize aspects of the process that demand improvement, and also to statistically analyze the success of a preemptive solution.

In the DMAIC model we use the FMEA in the *measure* and *control* phases. In the measure phase we make sure that the causes and customer impacts of potential process/product failure modes are considered and addressed. In the control phase we make sure that the appropriate controls are implemented so that failures can be stopped before they reach the customer.

In design for Six Sigma (DFSS), FMEA is used to anticipate problems in design, processes, and products in order to reduce costly and embarrassing risks. In other words, the FMEA is used to find areas that need design/process improvement and to measure the success of the implemented fix. Specifically, it is used in the *optimize* phase of the define, characterize, optimize, verify (DCOV) model.

LEAN

By definition, *lean* is a method of identifying and removing waste. Waste is defined as *variation*. Therefore, the FMEA is used in a variety of ways to identify failures and remove those failures from the system or process under consideration. Specifically, the FMEA in a lean environment acts as a proactive tool to prevent the solutions from going wrong.

AFTER IMPROVEMENTS ARE MADE

Whether the FMEA is used under the ISO, ISO/TS, Six Sigma, or lean criteria, when completed it is reviewed with the intention of making sure that (1) all failures have been identified, (2) actions have been recommended for the causes, and (3) appropriate strategies have been identified to control and monitor these actions to prevent recurrence.

In some cases lists are also made that provide step-by-step guidelines to follow when evaluating process maps and control plans as a result of the PFMEA, which may include the following:

- Key process stages
- Probable failure modes for each stage
- Effects of each failure mode
- Severity of effect on scale of 1–10
- Identification of failure mode causes
- Identification of controls being used to detect problems
- Statistical analysis of data collected
- Allocation of necessary actions to responsible individuals

- Reevaluation of the design and/or process

CONCERNS

One of the biggest complaints about conducting an FMEA when it is used to assess a design or a process is that it is stored away after completion and no longer referred to when additional problems occur in the course of developing supplementary projects. In other words, most of the time it ceases to be a dynamic (living) and useful document. Furthermore, the complaint of being too time-consuming discourages management from being serious about conducting an FMEA as it should be.

To be sure, the FMEA is considered both useful and dynamic in all areas of improvement in quality initiatives such as TQM, ISO, Six Sigma, and lean methodologies, and provides valuable information that contains beneficial implications regarding the design or process of the product. This explicit benefit should be further utilized when similar issues occur in future projects, which could save time, money, and useless expenditures of energy and manpower.

Indeed, all FMEAs and its derivatives take time. However, if the organization is committed to continual improvement and reduction in waste,

all FMEAs will contribute to this improvement. In order for this to happen, there are three fundamentals that must be followed:

1. *Evolve and adapt*. Use the *things gone wrong* (TGW) method to improve, but do not forget the *things gone right* (TGR). Both are important. TGW focuses on past failures and lessons learned, but TGR should emphasize and remind us of the good things that happened and need to be repeated.

2. *Nourish and grow*. Since the FMEA is a living document, it must always be remembered that it takes encouragement to identify problems without the fear of intimidation. It is appropriate to recall the famous words of Henry Ford here, who said, "Coming together is a beginning, keeping together is a process, working together is a success."

3. *Devote time*. Paul Masson, a famous American winemaker, advertises that "we will sell no wine before its time." The implication is that the wine under his name is taken care of with as much time as is necessary for color, taste, and bouquet. In order to accomplish this, storage in oak barrels and storage length

are very important. Consequently, the price is adjusted to reflect these parameters for higher quality. If it is good enough for Paul Masson, it should be good enough for everyone concerned with quality and reduction of risk to appropriate enough time to have the optimum result. Certainly, we can not know or control all the unknowns, but we can identify and mitigate the risk involved with some level of success by building a strong foundation to respond to potential failures. That response is the methodology of FMEA and its derivatives.

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Introduction

In the past 100 years or so, the United States has been the envy of the world. It has been the leader in almost every major innovation people have made. The historical trend has been positive indeed. However, what about the future? Can the status quo be retained? Is there anything to worry about? Can the leadership for tomorrow be guaranteed by following past successes?

Yes, 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 by those who will pursue technological and quality improvements for their products and/or services. In simple terms, this means that our attitude and behavior toward quality must change.

A good starting point is for organizations to start with 6S (sort, store [straighten], shine, standardize, sustain, and safety), emphasizing the areas of sustain and safety. Both of these focus on prevention and will lead to good designs as well as excellent processes.

As with any transformation, this change brings uncertainty and risk. However, this transformation may be successful if the organization has (1) vision, (2) mission, (3) strategy, (4) an action plan, and (5) an implementation strategy. 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. 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. In this booklet we will focus only on a small portion of this engineering responsibility, specifically, the FMEA methodology. Here we must emphasize that FMEA is only *one* methodology of many that can help in the strategy, action, and implementation strategy for improvement.

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