Web Source http://www.weibull.com/basics/fmea.htm

Failure Modes and Effects Analysis (FMEA) and Failure Modes, Effects and Criticality Analysis (FMECA)

An Overview of Basic Concepts

Failure Mode and Effects Analysis (FMEA) and Failure Modes, Effects and Criticality Analysis (FMECA) are methodologies designed to identify potential failure modes for a product or process, to assess the risk associated with those failure modes, to rank the issues in terms of importance and to identify and carry out corrective actions to address the most serious concerns.

Although the purpose, terminology and other details can vary according to type (*e.g.* Process FMEA - PFMEA, Design FMEA - DFMEA, System FMEA, Product FMEA, FMECA, etc.), the basic methodology is similar for all. This document presents a brief general overview of FMEA / FMECA analysis techniques and requirements.

FMEA / FMECA Overview

In general, Failure Modes, Effects and Criticality Analysis (FMEA / FMECA) requires the identification of the following basic information:

- Item(s)
- Function(s)
- Failure(s)
- Effect(s) of Failure
- Cause(s) of Failure
- Current Control(s)
- Recommended Action(s)
- Plus other relevant details

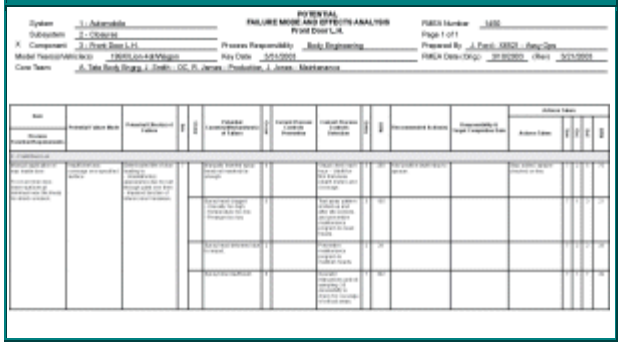
Most analyses of this type also include some method to assess the risk associated with the issues identified during the analysis and to prioritize corrective actions. Two common methods include:

- Risk Priority Numbers (RPNs)
- Criticality Analysis (FMEA with Criticality Analysis = FMECA)

Published Standards and Guidelines

There are a number of published guidelines and standards for the requirements and recommended reporting format of failure mode and effects analyses. Some of the main published standards for this type of analysis include SAE J1739, AIAG FMEA-3 and MIL-STD-1629A. In addition, many industries and companies have developed their own procedures to meet the specific requirements of their products/processes. Figure 1 shows a sample Process FMEA (PFMEA) in the Automotive Industry Action Group (AIAG) FMEA-3 format. Click to enlarge the image.

Figure 1 [Enlarge]



Basic Analysis Procedure for FMEA or FMECA

The basic steps for performing an Failure Mode and Effects Analysis (FMEA) or Failure Modes, Effects and Criticality Analysis (FMECA) include:

- Assemble the team.
- Establish the ground rules.
- Gather and review relevant information.
- Identify the item(s) or process(es) to be analyzed.
- Identify the function(s), failure(s), effect(s), cause(s) and control(s) for each item or process to be analyzed.
- Evaluate the risk associated with the issues identified by the analysis.
- Prioritize and assign corrective actions.
- Perform corrective actions and re-evaluate risk.
- Distribute, review and update the analysis, as appropriate.

Risk Evaluation Methods

A typical failure modes and effects analysis incorporates some method to evaluate the risk associated with the potential problems identified through the analysis. The two most common methods, Risk Priority Numbers and Criticality Analysis, are described next.

Risk Priority Numbers

To use the Risk Priority Number (RPN) method to assess risk, the analysis team must:

- Rate the **severity** of each effect of failure.
- Rate the likelihood of **occurrence** for each cause of failure.
- Rate the likelihood of prior **detection** for each cause of failure (*i.e.* the likelihood of detecting the problem before it reaches the end user or customer).
- Calculate the RPN by obtaining the product of the three ratings:

RPN = Severity x Occurrence x Detection

The RPN can then be used to compare issues within the analysis and to prioritize problems for corrective action. This risk assessment method is commonly associated with Failure Mode and Effects Analysis (FMEA).

Criticality Analysis

The MIL-STD-1629A document describes two types of criticality analysis: quantitative and qualitative. To use the quantitative criticality analysis method, the analysis team must:

- Define the reliability/unreliability for each item and use it to estimate the expected number of failures at a given operating time.
- Identify the portion of the item's unreliability that can be attributed to each potential failure mode.
- Rate the probability of loss (or severity) that will result from each failure mode that may occur.
- Calculate the criticality for each potential failure mode by obtaining the product of the three factors:

Mode Criticality = Expected Failures x Mode Ratio of Unreliability x Probability of Loss

- Calculate the criticality for each item by obtaining the sum of the criticalities for each failure mode that has been identified for the item.

Item Criticality = SUM of Mode Criticalities

To use the qualitative criticality analysis method to evaluate risk and prioritize corrective actions, the analysis team must:

- Rate the severity of the potential effects of failure.

- Rate the likelihood of occurrence for each potential failure mode.
- Compare failure modes via a Criticality Matrix, which identifies severity on the horizontal axis and occurrence on the vertical axis.

These risk assessment methods are commonly associated with Failure Modes, Effects and Criticality Analysis (FMECA).

Applications and Benefits for FMEA and FMECA

The Failure Modes, Effects and Criticality Analysis (FMEA / FMECA) procedure is a tool that has been adapted in many different ways for many different purposes. It can contribute to improved designs for products and processes, resulting in higher reliability, better quality, increased safety, enhanced customer satisfaction and reduced costs. The tool can also be used to establish and optimize maintenance plans for repairable systems and/or contribute to control plans and other quality assurance procedures. It provides a knowledge base of failure mode and corrective action information that can be used as a resource in future troubleshooting efforts and as a training tool for new engineers. In addition, an FMEA or FMECA is often required to comply with safety and quality requirements, such as ISO 9001, QS 9000, ISO/TS 16949, Six Sigma, FDA Good Manufacturing Practices (GMPs), Process Safety Management Act (PSM), etc.

You can use something as simple as a paper form or an Excel spreadsheet to record your FMEA / FMECA analyses. However, if you want to establish consistency among your organization's FMEAs, build a "knowledge base" of lessons learned from past FMEAs, generate other types of reports for FMEA data (*e.g.* Top 10 Failure Modes by RPN, Actions by Due Date, etc.) and/or track the progress and completion of recommended actions, you may want to use a software tool, such as ReliaSoft's **Xfmea**, to facilitate analysis, data management and reporting for your failure modes and effects analyses. More information on applications and benefits...

References

The following resources provide additional information on FMEA / FMECA.

Web Resources

- SAE International: The Society for Automotive Engineers provides the ability to purchase the J1739 and ARP5580 standards, as well as the AIR4845 document.
- AIAG: The Automotive Industry Action Group provides the ability to purchase the AIAG FMEA Third Edition (FMEA-3) guidelines.
- IEC: The International Electrotechnical Commission provides the ability to purchase the IEC 60812 standard.

- Reliability-Related Military Handbooks and Standards on weibull.com: This site provides access to U.S. Department of Defense standards and handbooks in PDF format, including the MIL-STD-1629A standard for Failure Modes, Effects and Criticality Analysis (FMECA) analysis.
- FMEA Info Center: This site provides information on books, publications, standards, software, consultants and other resources related to Failure Mode and Effects Analysis (FMEA). It also provides an online discussion list.
- NASA STI Special Bibliography for FMEA: NASA's Scientific and Technical Information (STI) program provides a "sampler bibliography" that contains abstracts for documents related to Failure Mode and Effects Analysis (FMEA) and Failure Modes, Effects and Criticality Analysis (FMECA) in the NASA STI Database.

Printed Resources

- Automotive Industry Action Group (AIAG), *Potential Failure Mode and Effects Analysis (FMEA Third Edition or Fourth Edition)*, July, 2001 or June, 2008.
- Automotive Industry Action Group (AIAG), *Advanced Product Quality Planning and Control Plan (APQP First Edition or Second Edition)*, June, 1994 or July 2008.
- International Electrotechnical Commission (IEC), *Analysis Techniques for System Reliability: Procedure for Failure Mode and Effects Analysis (FMEA)*, July 1985.
- Kececioglu, Dimitri, *Reliability Engineering Handbook Volume 2*. Prentice-Hall Inc., Englewood Cliffs, New Jersey, 1991. Pages 473-506.
- McDermott, Robin E., Raymond J. Mikulak and Michael R. Beauregard, *The Basics of FMEA*. Productivity Inc., United States, 1996.
- Stamatis, D.H., *Failure Mode and Effect Analysis: FMEA from Theory to Execution*. American Society for Quality (ASQ), Milwaukee, Wisconsin, 1995.
- Society of Automotive Engineers (SAE), *Aerospace Recommended Practice ARP5580: Recommended Failure Modes and Effects Analysis (FMEA) Practices for Non-Automobile Applications*, June 2000.
- Society of Automotive Engineers (SAE), *Surface Vehicle Recommended Practice J1739: (R) Potential Failure Mode and Effects Analysis in Design (Design FMEA), Potential Failure Mode and Effects Analysis in Manufacturing and Assembly Processes (Process FMEA), and Potential Failure Mode and Effects Analysis for Machinery (Machinery FMEA)*, June 2000.
- U.S. Department of Defense, *MIL-STD-1629A: Procedures for Performing a Failure Mode Effects and Criticality Analysis*, Cancelled in November, 1984.

Failure Modes, Effects and Criticality Analysis

[Editorial Note: In the online version of this article, we have updated the discussion of the Quantitative Criticality Analysis calculation method to be consistent with the latest research.]

Failure Modes and Effects Analysis (FMEA) and Failure Modes, Effects and Criticality Analysis (FMECA) are methodologies designed to identify potential failure modes for a product or process before the problems occur, to assess the risk associated with those failure modes and to identify and carry out measures to address the most serious concerns.

This article presents a brief general overview of FMEA and FMECA analysis techniques and applications. ReliaSoft's Xfmea software has been designed to automate and facilitate the FMEA/FMECA process and provide flexible data management and reporting capabilities.

FMEA/FMECA Analysis Overview

There is a great variety within industry as to the specific implementation details for individual FMEA/FMECA analyses. A number of standards and guidelines have been developed to set the requirements for the analysis and each organization may have a unique approach to the analysis. Some common FMEA/FMECA guidelines/standards include the U.S. Department of Defense's MIL-STD-1629A, SAE International's J1739 and ARP5580 documents (for automotive and non-automotive applications, respectively) and the Automotive Industry Action Group's (AIAG) FMEA-3. In addition, some practitioners distinguish various types of FMEA/FMECA analysis based on the item or process that is analyzed, the stage in the manufacturing/development process when the analysis is performed and/or whether the analysis is performed on the hardware or the functions that the item is expected to perform. Some commonly acknowledged FMEA types include, but are not limited to, Design FMEA (DFMEA), Process FMEA (PFMEA), Functional FMEA and System FMEA.

Even though there are many different types and standards, most FMEAs/FMECAs consist of a common set of procedures. In general, FMEA analysis is conducted by a cross-functional team at various stages of the design, development and manufacturing process and typically consists of the following:

- **Item/Process:** Identify the item or process that will be the subject of the analysis, including some investigation into the design and reliability characteristics. For FMEA analysis of a product or system, the analysis could be performed at the system, subsystem, component or other level of the system configuration.
- **Functions:** Identify the functions that the item or process is expected to perform.
- **Failures:** Identify the known and potential failures that could prevent or degrade the ability of the item/process to perform its designated functions.

- **Failure Effects:** Identify the known and potential effects that would result from the occurrence of each failure. It may be desirable to consider the effects at the item level (Local Effects), at the next higher level assembly (Next Higher Level Effects) and/or at the system level (End Effects).
- **Failure Causes:** Identify the known and potential causes for each failure.
- **Current Controls:** Examine the control mechanisms that will be in place to eliminate or mitigate the likelihood that the potential failures will occur (*e.g.* end of line inspections, design reviews, etc.).
- **Recommended Actions:** Identify the corrective actions that need to be taken in order to eliminate or mitigate the risk and then follow up on the completion of those recommended actions.
- **Prioritize Issues:** Prioritize issues for corrective action according to a consistent standard that has been established by the organization. Risk Priority Number (RPN) ratings and Criticality Analysis are common methods of prioritization and they are described in more detail later in this article.
- **Other Details:** Depending on the particular situation and on the analysis guidelines adopted by the organization, other details may be considered during the analysis, such as the operational mode when the failure occurs or the system's intended mission.
- **Report:** Generate a report of the analysis in the standard format that has been established by the organization. This is generally a tabular format similar to the one shown in Figure 1. In addition, the report may include block diagrams and/or process flow diagrams to illustrate the item or process that is the subject of the analysis. If applicable, the criticality analysis may be included in a separate table and various plots/graphs can be included to display statistics on the modes and rankings.

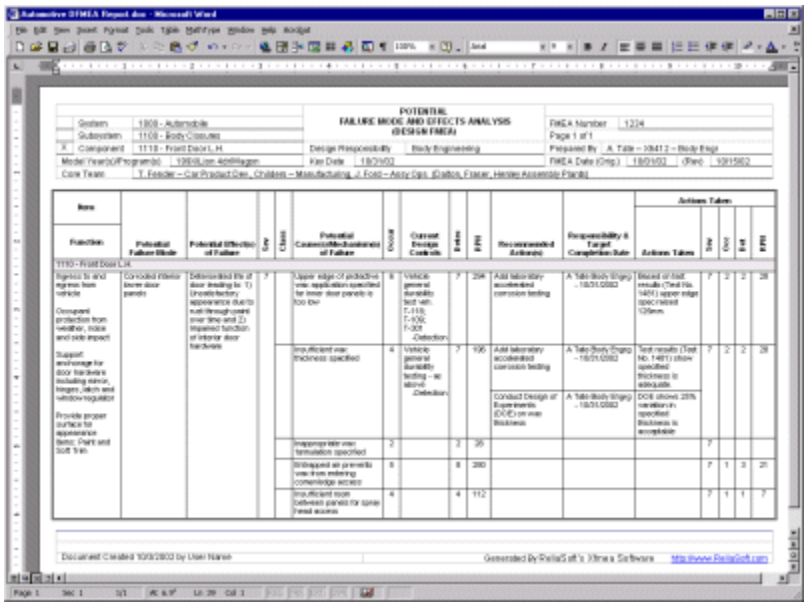


Figure 1: Sample FMEA report from the Xfmea software [Click to Enlarge]

Figure 2 shows ReliaSoft's Xfmea interface with the functions, failures, effects and causes displayed in a hierarchical fashion. The software also provides a "Worksheet View" of the analysis, which is similar to the tabular report output. Figure 3 shows the properties window for the Failure Cause, which can be used for data entry and display.

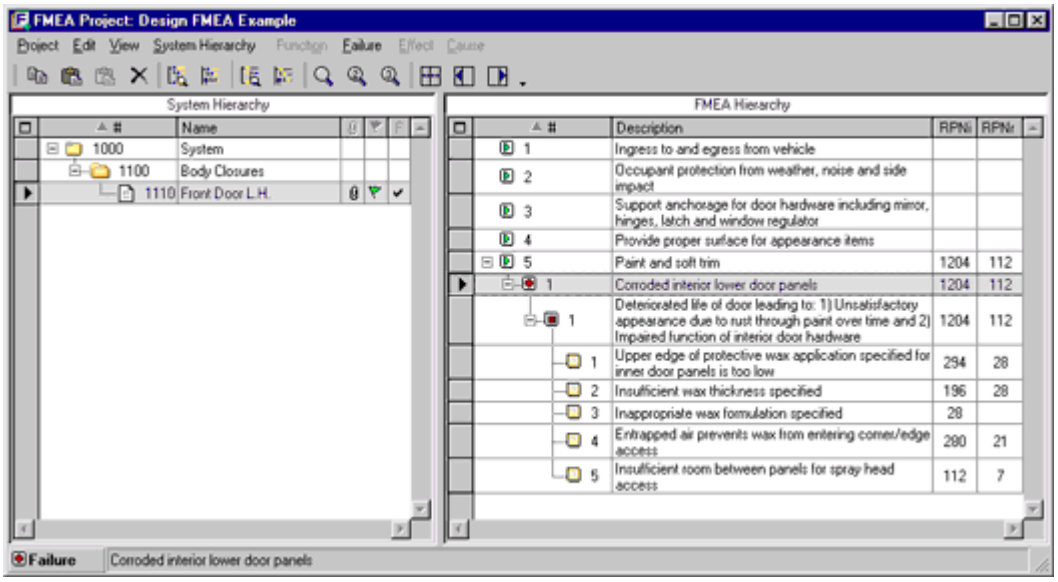


Figure 2: Xfmea interface with item and FMEA hierarchies [Click to Enlarge]

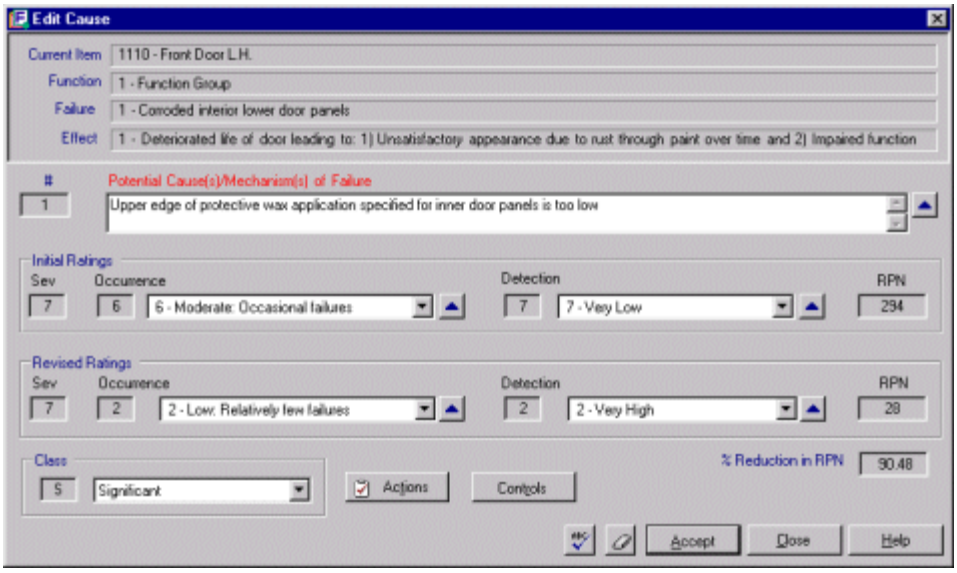


Figure 3: Xfmea Failure Cause Properties window [Click to Enlarge]

Prioritize Issues Based on RPN and/or Criticality

As mentioned previously, most FMEA/FMECA analyses include some effort to prioritize issues in

order to determine the sequence and time-frame for the corrective actions that will be performed. Although the methods used to set this priority may vary by organization, two commonly used methods are described next: Risk Priority Numbers and Criticality Analysis.

Risk Priority Numbers: The risk priority number (RPN) system is a relative rating system that assigns a numerical value to the issue in each of three different categories: Severity (S), Occurrence (O) and Detection (D). The three ratings are multiplied together to determine the overall RPN for the issue. The rating scales typically range from 1 to 5 or from 1 to 10 and the criteria used in each rating scale will be determined based on the particular circumstances for the product/process that is being analyzed. Because all issues are rated according to the same set of rating scales, this number can be used to compare and rank issues within the analysis. However, because the ratings are assigned relative to a particular analysis, it is generally not appropriate to compare RPN numbers among different analyses. The RPN is calculated as follows:

$$RPN = (S)(O)(D)$$

Where:

- **Severity (S):** A rating of the severity or seriousness of each potential failure effect.
- **Occurrence (O):** A rating of the likelihood of occurrence for each potential failure cause.
- **Detection (D):** A rating of the likelihood of detecting the failure cause.

For example, consider the following partial FMEA for a battery, which uses ten point rating scales to rank the severity, occurrence and detection:

Item	Function	Failure	Effect	S	Cause	O	D	RPN
Battery	Provide adequate relay voltage	Fails to provide adequate power	System fails to operate	8	Battery plates are shorted	5	1	40

The following rating criteria are applicable to the battery failure mode:

- **Severity:** 8 - Extreme Effect. Product inoperable but safe. Customer very dissatisfied.
- **Occurrence:** 5 - Low. Occasional number of failures likely; expect about 2.7 failures per 1000 due to this cause.
- **Detection:** 1 - Almost Certain. The operator will almost certainly be able to detect the failure.

The RPN for the issue is (8)(5)(1) = 40. This risk priority number is then compared with the ratings for other issues to help determine which areas to focus on for improvement.

Criticality Analysis: The Criticality Analysis method is similar to the RPN rating system except that it calculates the rankings in a different way. Criticality Analysis takes into account the probability of failure for the item and the portion of the failure likelihood that can be attributed to a particular failure mode. The Criticality is calculated for each failure mode as follows:

Mode Criticality = Expected Failures x Mode Ratio of Unreliability x Probability of Loss

Where:

- **Expected Failures:** The expected number of failures at a given operating time, calculated based on the reliability characteristics that have been defined for the item (*i.e.* statistical lifetime distribution and parameters or fixed probability that does not vary with time).
- **Failure Mode Ratio of Unreliability (FMFR):** The ratio of the item unreliability that can be attributed to the particular failure mode. For example, if an item has four failure modes, then one mode may account for 40% of the failures, a second mode may account for 30% and the two remaining modes may account for 15% each.
- **Probability of Loss (P_L):** The probability that the failure mode will cause a system failure (or will cause a significant loss). This is an indication of the severity of the failure effect and may be set according to the following scale:
  - Actual Loss = 100%
  - Probable Loss = 50%
  - Possible Loss = 10%
  - No Loss = 10%

For example, consider a criticality analysis for the partial FMEA on the battery. The reliability of the battery can be described with a 2 parameter Weibull distribution (beta = 1.3 and eta = 22291.83) and therefore the expected failures at the operating time of interest (t = 2000) can be estimated as .0435. The portion of the item unreliability that can be attributed to the given failure mode is 25% (or 25% of the item failures are likely to be due to this particular failure mode). The probability of loss is 100% because the occurrence of the failure mode will cause a system failure. The Criticality for the failure mode is then calculated as (.0435)(.25)(1.00) = .010875. As with the RPN method, this Criticality value can be compared with the Criticalities for other failure modes to help rank the issues that must be addressed.

Item	Expected Failures	Function	Failure	FMFR	Effect	PL	Cause	Cr
Battery	.0435	Provide adequate relay voltage	Fails to provide adequate power	.25	System fails to operate	1.00	Battery plates are shorted	.010875

Figure 4 displays the Xfmea Criticality Analysis utility, which can also be used to generate FMECA charts and reports.

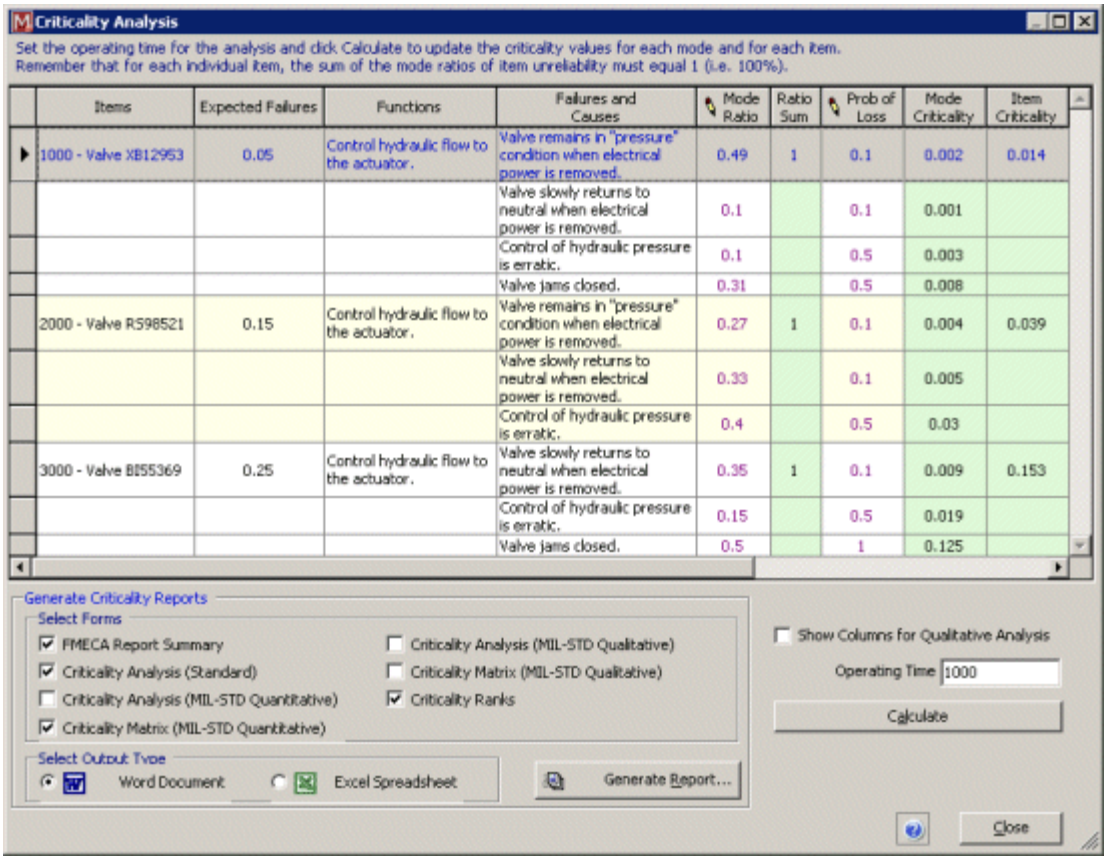


Figure 4: Xfmea Criticality Analysis utility [Click to Enlarge]

Applications and Related Analyses

FMEA/FMECA techniques are used throughout industry for a variety of applications and the flexible analysis method can be performed at various stages in the product life cycle. FMEA/FMECA analysis can be employed to support design, development, manufacturing, service and other activities to improve reliability and increase efficiency. For example, there is widespread use of both design and process FMEAs within the automotive industry and documentation of this analysis is a common requirement for automotive suppliers. This methodology is also widely used in the aerospace, medical and other manufacturing industries.

The MSG-3 procedures used by the airline industry incorporate FMEA techniques into the analysis procedure. (Reliability Edge Volume 3, Issue 1 contains an article on MSG-3 and ReliaSoft's MPC 3, software designed to automate the process.) Likewise, Reliability Centered Maintenance (RCM) procedures incorporate FMEA as a primary component of the analysis.

In addition, the FMEA reporting structure can be used to provide a centralized location for reliability-related information for the system/process. For example, the FMEA can be incorporated into an effective Reliability Growth management policy by providing a structure to organize information about product failures and assisting with efforts to identify the failure modes that have been observed during reliability growth testing and the failure modes that may still yet be observed.

Conclusion

FMEA/FMECA analysis is a flexible process that can be adapted to meet the particular needs of the industry and/or the organization. However, most analyses include the basic procedures and data requirements described in this article. ReliaSoft's Xfmea software supports these basic procedures, the major published industry standards (*e.g.* J1739, MIL-STD-1629A, etc.) and also provides the flexibility to customize the analysis and reports to meet the user's needs for a particular application. On the Web at http://www.ReliaSoft.com/xfmea.

FMEA/FMECA References

Many references for FMEA/FMECA analysis are available in print and on the Web. Some useful references include:

- Kececioglu, Dimitri, *Reliability Engineering Handbook Volume 2*. Prentice-Hall Inc., Englewood Cliffs, New Jersey, 1991. Pages 473-506.
- *MIL-STD-1629A: Procedures for Performing a Failure Mode Effects and Criticality Analysis*. U.S. Department of Defense, Washington, D.C., November 28, 1984. *Note: This standard was cancelled by the DoD in August 1998.*
- *SAE Aerospace Recommended Practice ARP5580: Recommended Failure Modes and Effects Analysis (FMEA) Practices for Non-Automobile Applications*. SAE International, Warrendale, PA, 2001.
- *SAE Surface Vehicle Recommended Practice J1739: Potential Failure Mode and Effects Analysis in Design (Design FMEA), Potential Failure Modes and Effects Analysis in Manufacturing and Assembly Processes (Process FMEA), and Potential Failure Mode and Effects Analysis for Machinery (Machinery FMEA)*. SAE International, Warrendale, PA, June, 2000.
- Stamatis, D.H., *Failure Mode and Effect Analysis: FMEA from Theory to Execution*. American Society for Quality (ASQ), Milwaukee, Wisconsin, 1995.

Key Factors for Effective FMEAs

Carl S. Carlson
Senior Reliability Engineer, ReliaSoft Corporation

Today's organizations face unprecedented worldwide competition as a result of three continuing challenges: the mandate to reduce costs, faster development times and high customer expectations for the reliability of products and processes. The necessity for reliability assurance will not abate; however, there is increasing emphasis on Design for Reliability as an organizational strategy.

One of the tools that show up on almost every "short list" of Design for Reliability tools is Failure Mode & Effects Analysis. Most corporate and military applications require some form of FMEA or FMECA. Yet questions remain about the overall effectiveness of FMEA as applied in many companies and organizations today. Frankly, there are mixed results with FMEA applications.

The prerequisite for effective FMEAs is a sound knowledge of the basics of FMEA. There is no substitute for learning these fundamentals. Interested readers are encouraged to take ReliaSoft's two day training course that covers the FMEA basics and supporting software (RS 470: Failure Modes Effects and Criticality Analysis and Xfmea). Once these basics are well understood, it is possible to capture and apply certain lessons learned that make FMEAs highly effective.

There are a number of success factors that are critical to uniformity of success in the application of FMEA in any company. In the previous issue of Reliability Edge, the focus was on an effective FMEA process. This article will outline the lessons learned and quality objectives that make for effective FMEAs.

The FMEA lessons learned presented here are the result of personally supervising or participating in over a thousand FMEA projects, and collaboration with many corporations and organizations on the FMEA process and its shortcomings.

There is a maxim that says, "Good judgment comes from experience and experience comes from poor judgment." Based on this maxim, the following lessons learned are based on considerable experience. Each of these lessons is from direct experience of how FMEAs were done wrong and how to improve the overall effectiveness.

FMEA Lessons Learned

So here we go. What are the primary ways that FMEAs can be done wrong (Mistakes) and the key factors that make for effective FMEAs (Quality Objectives)?

Mistake # 1

Based on empirical review of many FMEAs, some FMEAs do not drive any action at all; some FMEAs drive mostly testing while others drive ineffective action. The mistake is:

Failure of the FMEA to drive design or process improvements

Quality Objective # 1

The FMEA drives product design or process improvements as the primary objective

Note: Reliability Engineering has a multitude of tools to choose from in driving design or process improvements. The key is to use the FMEA "Recommended Actions" field to identify and execute best practice tools that can optimize designs. This is one of the reasons that Reliability Engineers need to participate on FMEAs.

Mistake # 2

There are various methods that the FMEA team can use to identify which failure modes and their causes require follow up action. Some companies set pre-determined risk thresholds; others review RPNs or Criticality using Pareto or other techniques. Whatever method is used, failure to address all high-risk failure modes (including high severity) can result in potentially catastrophic problems or lower customer satisfaction. The mistake is:

Failure of the FMEA to address all high-risk failure modes

Quality Objective # 2

The FMEA addresses all high-risk failure modes, as identified by the FMEA Team, with effective and executable action plans

Note: The emphasis on this Quality Objective is to ensure that all of the high-risk failure mode/causes are adequately addressed with effective actions. The key is effective action that reduces or eliminates the risk.

Mistake # 3

Some companies miss the opportunity to improve Design Verification Plan and Reports (DVP&Rs) or Process Control Plans based on the failure modes/causes from the FMEA. Some FMEA teams do not include knowledgeable representatives from the test or analysis department. The result is inadequate product testing or process control plans. The mistake is:

Failure of the FMEA to improve test/control plans

Quality Objective # 3

The Design Verification Plan & Report (DVP&R) or the Process Control Plan (PCP) considers the failure modes from the FMEA

Note: The FMEA team will often discover failure modes/causes that were not part of the design controls or test procedures. The key is to ensure that the test plan (DVP&R) or Control Plan is impacted by the results of the FMEA. This can be done by including test/control membership on the FMEA team or through well-written actions.

Mistake # 4

Empirical data shows that at least 50% of field problems can occur at interfaces or integration with the system. Some companies focus on part or subsystem failures and miss the interfaces. The mistake is:

Not including interfaces or integration in FMEA

Quality Objective # 4

The FMEA scope includes integration and interface failure modes in both block diagram and analysis

Note: Interfaces can be included as part of the item by item analysis or as a separate analysis. It is recommended that the FMEA Block Diagram clearly show the interfaces that are part of the FMEA scope.

Mistake # 5

Some companies provide no linkage between FMEAs and field data. It takes concerted effort to integrate problem resolution databases with FMEA. Otherwise, serious problems can repeat. The mistake is:

Disconnect between FMEA and information from the field

Quality Objective # 5

The FMEA considers all major "lessons learned" (such as high warranty, campaigns, etc.) as input to failure mode identification

Note: Field failure data can be brought into generic FMEAs on a regular basis. Then, when new program-specific FMEAs are started, they benefit from field lessons learned. If generic FMEAs are not used, new FMEAs should be seeded with potential field problems and required to show how they will not repeat in the new design/process. The key is to hold the FMEA team responsible to ensure that major field problems do not repeat.

Mistake # 6

Many companies have a Key Characteristics policy. The Design FMEA can identify Key Product Characteristics and the Process FMEA can identify Key Process Characteristics for special controls in manufacturing. Some companies miss this opportunity. The mistake is:

FMEA omits Key Characteristics

Quality Objective # 6

The FMEA identifies appropriate Key Characteristics candidates, if applicable according to company policy

Note: This is an underutilized element of FMEAs. Both the SAE J1739 and AIAG FMEA-3 guidelines for FMEA use the "Classification" column.

Mistake # 7

Many companies do FMEAs late, and this reduces their effectiveness. FMEAs should be completed by design or

process freeze dates, concurrent with the design process. This is a very common problem and greatly reduces the effectiveness of the FMEAs. The mistake is:

Doing FMEAs late

Quality Objective # 7
The FMEA is completed during the "window of opportunity" where it can most effectively impact the product or process design

Note: The key to getting FMEAs done on time is to start the FMEAs on time. FMEAs should be started as soon as the design or process concept has been determined. The exception is FMEAs done during trade-off studies, which should, of course, be started earlier.

Mistake # 8
Some FMEA teams do not have the right experts on the core team. Some FMEA teams do not have good attendance. Some FMEA team members just sit in their chairs and don't contribute to team synergy. The mistake is:

FMEAs with inadequate team composition

Quality Objective # 8
The right people participate on the FMEA team throughout the analysis and are adequately trained in the procedure

Note: Based on an actual survey of Reliability Engineering internal customers on FMEAs: FMEAs are too important not to do, but too time consuming to participate in. The FMEA facilitator must value the time of team members and not waste time. People have blind spots (scotomas). The key is to get the people who are knowledgeable and experienced about potential failures and their resolutions to actually show up at the meetings. Attendance often takes management support. Team size is best between four to eight people. If the team gets too large, consider breaking into additional limited-scope FMEAs.

Mistake # 9
There are hundreds of ways to do FMEAs wrong. Some companies do not encourage or control proper FMEA methodology. Training, coaching and reviews are all necessary to success. The mistake is:

FMEAs with improper procedure

Quality Objective # 9
The FMEA document is completely filled out "by the book," including "Action Taken" and final risk assessment

Note: One common problem is the failure to get to root cause. Expert input is necessary. Follow-up actions based on poorly defined causes will not work and the FMEA will not be successful. Another common problem is lack of

follow-up to ensure that the FMEA Recommended Actions are executed and the resulting risk is reduced to an acceptable level.

Mistake # 10

Some companies mandate FMEAs, and then do not ensure that the time is well spent. Pre-work must be completed, meetings must be well run and there must be efficient follow-up of high-risk issues. Ask the FMEA team if their time has been well spent and take action to address shortcomings. The mistake is:

Lack of efficient use of time

Quality Objective # 10

The time spent by the FMEA team, as early as possible, is an effective and efficient use of time with a value added result

Note: If this Quality Objective is met, then future FMEAs will be well attended and supported by subject matter experts and management.

FMEA Quality Surveys/Audits

Each FMEA team (and internal customer of FMEA) can be surveyed for FMEA effectiveness. Surveys are based on the FMEA Quality Objectives. Surveys are in writing, 1 or 2 pages. Individual content can be confidential. This provides valuable feedback to improve future FMEAs.

In-person audits of completed (or nearly completed) FMEAs should be done. They are performed by supervisors and managers over the FMEA process, with the FMEA facilitator and core team. An in-person interview format is recommended, on a pre-scheduled or random basis. Typically they take one hour maximum per audit, which amounts to about five minutes for each of the ten FMEA Quality Objectives.

FMEA audits provide valuable feedback to improve future FMEAs, in the form of action items identified for follow up. Focus needs to be on improving the FMEA process, not on the person/team doing the FMEA. Don't expect to instantly achieve all ten objectives; work to maintain steady improvement. Management audits demonstrate commitment. In the words of W. Edwards Deming, "Quality cannot be delegated."

Summary

FMEA/FMECA is a powerful reliability tool to improve product or process designs early in the development process. This not only increases the initial reliability, but saves considerable cost of future testing and field warranty. It is worth the effort to get the tool implemented in an effective manner.

Achieve the FMEA Quality Objectives and your result will be more effective FMEAs for your company or organization.

References

Automotive Industry Action Group (AIAG), *Potential Failure Mode and Effects Analysis (FMEA Third Edition)*, July, 2001.

ReliaSoft Training Course: *RS 470 - Failure Modes, Effects and Criticality Analysis.* On the Web at http://www.ReliaSoft.com/seminars/gencourses/rs470.htm.

Society of Automotive Engineers, *SAE J1739: Potential Failure Mode and Effects Analysis in Design (Design FMEA), Potential Failure Modes and Effects Analysis in Manufacturing and Assembly Processes (Process FMEA), and Potential Failure Mode and Effects Analysis for Machinery (Machinery FMEA).* SAE International, Warrendale, PA, June, 2000.

NOTE: The author participated in the development of the SAE J1739 guidelines for Design, Process and Machinery FMEAs. The Quality Objectives presented in this article are also reflected in Appendix A and Appendix B of that document, which is available for purchase from the Society of Automotive Engineers (http://www.sae.org).

About the Author

Carl S. Carlson is a consultant and instructor in the areas of FMEA, reliability program planning and other reliability engineering and management disciplines. He has 20 years of experience in reliability engineering and management positions at General Motors, most recently Senior Manager for the Advanced Reliability Group. Mr. Carlson co-chaired the cross-industry team to develop the Society of Automotive Engineers (SAE) J1739 for Design/Process/Machinery FMEA and participated in the development of the SAE JA 1000/1 Reliability Program Standard Implementation Guide. He has also chaired technical sessions for the Annual SAE RMSL Symposium, was a four-year member of the RAMS Advisory Board and served for five years as Vice Chair for the SAE's G-11 Reliability Division. He is an ASQ Certified Reliability Engineer.

FMEA Success Factors: An Effective FMEA Process

Carl S. Carlson
Senior Reliability Engineer, ReliaSoft Corporation

Few reliability tools elicit stronger responses from quality and reliability professionals than Failure Mode and Effects Analysis (FMEA). Reactions around the virtual "water cooler" range from "waste of time, lack of support" and "don't want anything to do with it" all the way to "powerful tool, effective way to prevent problems" and "needs to be done across the board."

Why is there so much variation in the application of a tool that has been around for many decades? What can be done to help achieve more uniformly successful results?

There are four broad success factors that are critical to uniformity of success in the application of FMEA in any company: an effective FMEA process, strong management sponsorship, best-practice FMEA application and adequate FMEA resources. In this article, the first success factor (an effective FMEA process) will be discussed. The remainder of the success factors will be addressed in subsequent articles.

Effective FMEA Process

Without an effective FMEA process, actual FMEA results will be dependent on individual personalities and the whims of varying company priorities. If participants happen to be knowledgeable in the application of FMEA and have the time to invest in FMEA team meetings, then it may be successful. If not, then the FMEA project may not be as successful.

This article outlines eleven tasks that must be established within any organization that aspires to achieving uniformly positive results in its application of FMEA. The entire process is presented graphically in Figure 1.

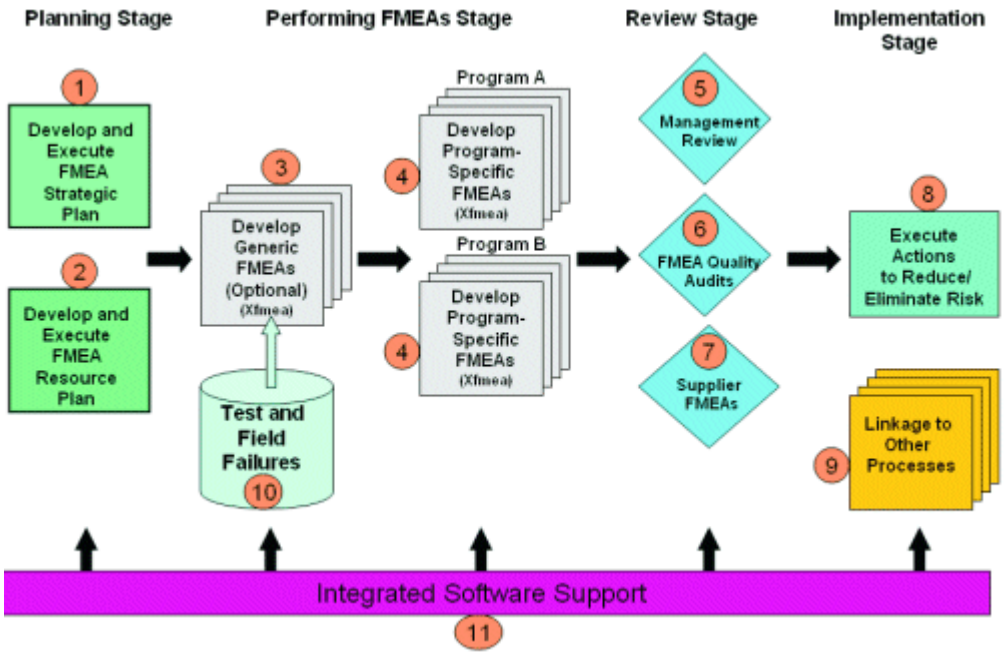


Figure 1: Effective FMEA Process Diagram

Task 1: FMEA Strategic Plan

As with any significant project, it is important to develop and follow a strategic plan that will guide the organization's efforts. Some of the key decisions that management must make regarding FMEA policy include the type of FMEAs to be performed (such as Design, Process, Equipment, etc.), the timing of FMEAs (for example, prior to design freeze) and the selection criteria (such as new technology, new applications, etc.).

Additional strategic management decisions related to other aspects of an effective FMEA process will be described in the following sections.

Task 2: FMEA Resource Plan

Together with the development of the FMEA Strategic Plan, management must also make decisions to ensure that the required resources will be available to all FMEA teams. Along with decisions about FMEA software and meeting facilities, key questions include the use and staffing of FMEA facilitators, ownership of FMEA documents and FMEA process, and FMEA training.

The strong support of management is vital to the short- and long-term success of FMEAs in any organization. I would go so far as to say that without solid management support, FMEAs will fall far short of their potential as an effective problem prevention tool.

Such support is often led by an FMEA champion at the executive level who helps to generate support at the staff level, advocates for FMEA budget and process and sees to the staffing, training, business process, standards, management reviews and quality audits.

Task 3: Generic FMEAs (Optional)

The development of generic FMEAs may be part of the organization's FMEA Strategic Plan. They contain both

historic (empirical) and potential failure modes, effects, causes and controls, and are done at the generic level of the system, subsystem or component. It is important to keep them updated based on test and field data and/or new technology.

Once accomplished, generic FMEAs can save considerable time in the performance of program-specific FMEAs. They are also useful in support of concept trade-off studies.

To perform each generic FMEA, it will be necessary to complete Steps 1 to 4 of the "Basic FMEA Steps" outlined in Table 1. Note that Step 4 is only completed up to design or process controls for generic FMEAs.

#	Analysis Step
1	Assign FMEA facilitator and team.
2	Establish FMEA timing and scope.
3	Gather relevant documentation (generic FMEAs if available, past FMEAs from archive, and all other needed pre-work).
4	Perform FMEA analysis (according to FMEA standard) up through Recommended Actions.
5	Provide input to DVP&R or Process Control Plan.
6	Review risk and recommended actions with management (per FMEA Strategic Planning).
7	Update FMEA project tracking (per FMEA Strategic Planning).
8	Execute recommended actions, and do new risk assessment.
9	Review and approve all critical Supplier FMEAs (per FMEA Quality Objectives).
10	Ensure risk reduced to acceptable level and FMEA is completed "by the book"; then forward to archive.

Table 1: Basic FMEA Analysis Steps

Task 4: Program-Specific FMEAs

Program-specific FMEAs are where the bulk of the FMEA work is performed. They focus on specific applications and can either be done right from the beginning or tailored from a generic FMEA. They should be performed by a team made up of the right experts to examine the design or process and follow the directions from FMEA strategic planning.

To be successful, FMEA teams should be well staffed (anywhere from 4 to 8 members are recommended, depending on FMEA scope and complexity), trained, facilitated and executed. Their work should be done during the "window of opportunity" that maximizes the impact of the analysis to improve the design or process.

To perform each program-specific FMEA, it will be necessary to complete all ten steps of the "Basic FMEA Steps" in Table 1.

Task 5: Management Reviews

Most organizations have a Failure Review Board established to review and address high risk issues discovered during test or field phases. High risk issues identified from FMEAs should be included in the review format. This ensures management understanding, buy-in, support and adequacy. In addition, FMEA reports and charts can be generated to provide valuable status, per the FMEA Strategic Plan.

I have found that it is useful to have the design owner present the high risk issue from the FMEA to the Failure Review Board in order to bring proper context and ownership to the issue.

Task 6: Quality Audits

Effective process models inevitably include a feedback loop to improve the process by incorporating both positive and negative feedback. An effective FMEA process includes both FMEA quality surveys (of the internal customer of the FMEA) and FMEA quality audits (in-person audits of completed or nearly completed FMEAs, done by the FMEA manager).

FMEA quality surveys and audits are based on FMEA Quality Objectives, such as the ones outlined in "Design FMEA Quality Objectives." They provide valuable information to strengthen what works and address shortfalls.

Having personally done hundreds of FMEA quality audits, I believe this is one of the most important steps to achieving uniformly successful FMEA application. Each audit takes about one hour and I always learned ways to improve the FMEA process.

Task 7: Supplier FMEAs

Potential higher risk system- or subsystem-level failures can have their root causes in components provided by independent suppliers. FMEA strategic planning should determine how to address supplier FMEAs, and how to identify which suppliers require formal FMEA review. For suppliers of parts that are identified as higher risk (critical parts), it is recommended that the supplier be required to perform and submit an FMEA for review and approval by a qualified company representative.

Reviewing supplier FMEAs should be based on the FMEA Quality Objectives. I suggest returning inadequate FMEAs to be redone by the supplier until they meet the Quality Objectives.

Task 8: Execution of Recommended Actions

FMEAs have little value unless the recommended actions are fully executed. Each recommended action must be followed up to ensure completion to the satisfaction of the FMEA team and the risk has been eliminated or mitigated to an acceptable level. The Failure Review Board must ensure that all high risk actions are successfully executed.

It is my experience that the FMEA team should stay intact during the execution stage. Many companies want to disband the team once the FMEA has been completed up to the Recommended Actions step (Step #4 of the "Basic FMEA Steps" in Table 1). The FMEA team needs to be responsible for and empowered to reduce the risk to an acceptable level. The execution stage is fraught with variables that can derail the important work of reducing risk.

Task 9: Linkage to Other Processes

FMEAs can and should be linked to other important processes to leverage their effectiveness. For example, ReliaSoft's Xfmea software for FMEA analysis, data management and reporting integrates with requirements from Advanced Product Quality Planning (APQP) guidelines, and has the potential to generate new Process FMEAs based on existing Design FMEAs. Xfmea can also be used to create integrated Design Verification Plan and Reports (DVP&Rs), Process Control Plans (PCPs) and Process Flow Diagrams (PFDs).

FMEAs can provide important input to other processes, such as Design Reviews, Design Trade Studies, Reliability Growth Analysis, etc. The FMEA Process should be integrated with the overall Product Development Process.

Linking the FMEA with other key processes improves quality, and saves time and money.

Task 10: Test and Field Failures

One of the common mistakes when implementing an FMEA process is to omit subsequent test and field failures. If generic FMEAs are used, they can be updated with information from the organization's Failure Reporting, Analysis and Corrective Action System (FRACAS). This is invaluable when FMEA documents become input to future design programs. When feedback from subsequent test and field failures is omitted from the FMEA process, future designs are at risk for repeating past failure modes.

Task 11: Software Support

To be most effective, the FMEA process should utilize software that provides database functionality, such as ReliaSoft's Xfmea (http://www.ReliaSoft.com/xfmea). The Xfmea software does an excellent job of managing multiple FMEA projects and databases, and also provides the plots/reports and linkage to other processes that are essential to successful FMEA outcomes.

Summary

One of the most important factors for the success of FMEA in any organization is an effective FMEA Process. It takes a focused strategy to bring about the infrastructure that is necessary to support effective FMEAs, but it is well worth the time and effort.

Companies are faced with intense global competition, and must shorten product development times and reduce costs. Preventing problems with an effective FMEA process is essential to success in reducing warranty and increasing customer satisfaction.