The Quality of FMEAs

By Carl S. Carlson

Across the globe, product development times are becoming shorter, cost concerns more acute, and customers are demanding and expecting absolute safety and high reliability. In order to stay competitive, companies need to rethink how they achieve these objectives. There are a myriad of quality and reliability tools available to corporations worldwide, but the one that shows up consistently in company after company is Failure Mode and Effects Analysis (FMEA).

The plain truth is FMEA has the potential to anticipate and prevent problems, reduce costs, shorten product development times, and achieve safe and highly reliable products and processes. However, there’s a caveat, and it’s a big one. Not everyone gets uniformly great results from FMEAs. They have to be done properly, with the right preparation, the right team composition, and the right procedure. In addition, they have to be done in such a way that they don’t consume excessive time and money. Done correctly, FMEAs will save money, speed up product development, increase safety, and achieve high reliability in products and processes. However, done improperly, they can waste time and not add value.

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? In other words, what are the essential ingredients for success in implementing FMEAs, and how can these best be achieved?

Based on experience from thousands of FMEAs from hundreds of companies, there are four broad success factors that are critical to uniformity of success in the application of FMEA in any company.

**Success Factor One: Understanding the Fundamentals and Procedure of FMEAs**

There are many courses and tutorials covering the basics of FMEAs. It is essential to the success of FMEA applications that the FMEA facilitator and team thoroughly understand and apply the fundamental concepts and definitions of FMEA.

In addition to understanding the fundamentals of FMEA, it is important to follow the right procedure. Figure 1 shows the high-level FMEA “Roadmap” for doing FMEAs. Each of the boxes in this illustration represents an important step in the FMEA procedure.

![Figure 1. FMEA Roadmap – High Level](image-url)
The Quality of FMEAs, cont.

Success Factor Two: Applying Lessons Learned
Understanding FMEA fundamentals and procedure is not enough to be a successful FMEA practitioner. Performing successful FMEAs requires avoiding common mistakes and implementing key factors for effective FMEAs. What are the primary ways that FMEA can be done wrong? (Mistakes) What are the key factors that make for effective FMEAs? (Quality Objectives)

The following are the 10 most common FMEA mistakes and the corresponding quality objectives:

1. Based on empirical review of many FMEAs, some of them do not drive any action at all; some drive mostly testing; others drive ineffective action.
   **Mistake**: failure of the FMEA to drive design or process improvements.
   **Quality Objective**: the Design FMEA drives product design or process improvements as the primary objective.

2. Failure to address all high risk failure modes (including high severity) can result in potentially catastrophic problems or lower customer satisfaction.
   **Mistake**: failure of the FMEA to address all high risk failure modes.
   **Quality Objective**: the FMEA addresses all high risk failure modes, as identified by the FMEA team, with effective and executable action plans.

3. Some companies miss the opportunity to improve Design Verification Plans 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 manufacturing department.
   **Mistake**: failure of the FMEA to improve test/control plans.
   **Quality Objective**: the Design Verification Plan of the Process Control Plan considers the failure modes from the FMEA.

4. Empirical data show that at least 50 percent of field problems can occur at interfaces or integration with the system.
   **Mistake**: not including interfaces or integration in FMEA.
   **Quality Objective**: the FMEA scope includes integration and interface failure modes in both block diagram and analysis.

5. Some companies provide no linkage between FMEAs and field data. This can allow serious problems to repeat.
   **Mistake**: disconnect between FMEA and information from the field.
   **Quality Objective**: the FMEA considers all major lessons learned (such as high warranty and campaigns) as input to failure mode identification.

6. Some FMEAs go into too much detail, making it difficult to focus on areas of higher risk, “missing the forest for the trees.” Some FMEAs go into too little detail, making it difficult to determine root causes and effective corrective actions.
   **Mistake**: wrong level of detail in the analysis.
   **Quality Objective**: the FMEA provides the correct level of detail in order to get to root causes and effective actions.
The Quality of FMEAs, cont.

7. Many companies are late to perform FMEAs late, reducing their effectiveness. FMEAs should be completed by design or process freeze dates, concurrent with the design process.

   **Mistake:** performing FMEAs late.

   **Quality Objective:** the FMEA is completed during the “window of opportunity” from where it can most effectively impact the product or process design.

8. Some FMEA teams do not have the right experts on the core team. Some FMEA teams do not have good attendance.

   **Mistake:** FMEAs with inadequate team composition and lack of participation.

   **Quality Objective:** the right people, adequately trained in the procedure, participate in the FMEA team throughout the analysis.

9. There are hundreds of ways to do FMEAs wrong. Some companies do not encourage or control proper FMEA methodology.

   **Mistake:** FMEAs with improper procedure.

   **Quality Objective:** the FMEA document is completed “by the book,” including “Action Taken” and final risk assessment.

10. Some companies mandate FMEAs and then do not ensure the expert’s time is well spent.

    **Mistake:** inefficient use of time.

    **Quality Objective:** the time spent by the FMEA team is an effective and efficient use of time with a value-added result.

Figure 2 summarizes the 10 FMEA Quality Objectives. These objectives should be integrated into FMEA team training and reviewed at each stage of FMEA project completion. FMEAs should not be considered complete until the quality objectives have been met. And they are an essential part of quality audits.

1. **DESIGN IMPROVEMENTS**  The FMEA drives product design or process improvements as the primary objective.

2. **HIGH RISK FAILURE MODES**  The FMEA addresses all high-risk failure modes with effective and executable action plans.

3. **DVP/CONTROL PLAN**  The Design Verification Plan (DVP) or the Process Control Plan (PCP) considers the failure modes from the FMEA.

4. **INTERFACES**  The FMEA scope includes integration and interface failure modes in both block diagram and analysis.

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

6. **LEVEL OF DETAIL**  The FMEA provides the correct level of detail in order to get to root causes and effective actions.

7. **TIMING**  The FMEA is completed during the "window of opportunity" whence it can most effectively influence the product or process design.

8. **TEAM**  The right people are adequately trained in the procedure and participate on the FMEA team throughout the analysis.

9. **DOCUMENTATION**  The FMEA document is completely filled out "by the book," including "Action Taken" and final risk assessment.

10. **TIME USAGE**  Time spent by the FMEA team is an effective and efficient use of time with a value added result.

Figure 2. FMEA Quality Objectives
The Quality of FMEAs, cont.

Success Factor Three: Providing Excellent Facilitation
FMEA facilitation is a different subject than FMEA methodology. To be successful, FMEA leaders need to develop expert facilitation skills, and apply those skills to achieve the objective of FMEAs. Good facilitation is critical to prevention of high-risk problems without wasting time. FMEA teams led by someone with poor facilitation skills will not accomplish the objectives of FMEAs and will waste valuable time of subject matter experts.

The primary FMEA facilitation skills include brainstorming, asking probing questions, encouraging participation, active listening, controlling discussion, making decisions, conflict management, and managing time. Mastering these skills will help ensure success in facilitating effective FMEAs.

Success Factor Four: Implementing an Effective FMEA Process
In order to be fully effective, FMEAs require an infrastructure and coordinated approach from many different departments and organizational functions. A company-wide FMEA process is the entire set of systems and tasks essential to support development of high-reliability products and processes through timely accomplishment of well-done FMEAs. This fourth success factor will be the subject of another article in the next edition of the newsletter.

In summary, to obtain the best possible results from FMEA, companies need to focus on key success factors: understanding the fundamentals and procedure of FMEAs, applying lessons learned, providing excellent facilitation, and implementing an effective company-wide FMEA process. Doing this will ensure FMEAs achieve safe, reliable and economical products and processes.

Carl S. Carlson is a consultant and instructor in the areas of FMEA, reliability program planning and other reliability engineering disciplines, currently supporting clients of ReliaSoft Corporation. He has 30 years experience in reliability testing, engineering, and management positions, including manager of product reliability at General Motors. He co-chaired the cross-industry team that developed the commercial FMEA standard (SAE J1739, 2002 version) and was a past member of the Reliability and Maintainability Symposium (RAMS) Advisory Board. He holds a B.S. in Mechanical Engineering from the University of Michigan and is a Certified Reliability Engineer. Information about his book, Effective FMEAs, can be found at www.effectivefmeas.com. He can be reached at Carl.Carlson@EffectiveFMEAs.com

For more information on FMEA, check out this new course from the RMC!

FMEA’S AND R&M
(Failure Mode and Effects Analysis)

Process
Product
FMEA
R&M
Improvements

Learn the basics of performing a FMEA and participate in class exercises, with a focus on Reliability and Maintainability! Topics include: “The Who, What, Where, and When of FMEA’s”, “History of the FMEA Technique”, “How to use a FMEA to Develop R&M Strategies,” and more.

DON’T WAIT ANY LONGER!
Provide your R&M team with the ability to identify potential failures and perform a successful FMEA.

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