Implementing an Effective FMEA Process
By Carl S. Carlson

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In the article "The Quality of FMEAs" (RMC Newsletter, October 2012), four broad FMEA success factors were discussed:

- Understanding the Fundamentals and Procedure of FMEAs
- Applying Lessons Learned
- Providing Excellent Facilitation
- Implementing an Effective FMEA Process

This article will focus on the fourth success factor: 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.

Why is this important? The simple fact is management has key roles and responsibilities that enable successful FMEAs. Without these specific actions, FMEAs can flounder and become unsuccessful. FMEA practitioners need to know the key elements of an effective FMEA process so they can work with management to bring them about.

"Leadership is the capacity to translate vision into reality." Warren G. Bennis

The importance of broad support from management in implementing a company-wide effective FMEA process cannot be overstated. Here is a short list of key management responsibilities.

a. Champion the subject of FMEA with management and employees.
b. Provide agreement on FMEA strategy and support needed resources.
c. Implement an effective FMEA training program.
d. Vigorously implement each of the steps of the FMEA process, as covered in this article.
e. Define roles and responsibilities for all FMEA participants, and integrate with employee work instructions.
f. Assist in integrating FMEA with other business processes, including Design Reviews, Design Verification Plans, Process Control Plans and others.
g. Provide effective reviews of high-risk failure modes and recommended actions.
h. Support attendance of expert FMEA team members.
i. Help ensure FMEAs are fully executed.
j. Establish an FMEA audit process to continuously improve the quality of FMEAs.

Figure 1 is a graphic illustration of an effective company-wide FMEA process, and how an entire company works together to support FMEAs that get results. This process is based on experience working with hundreds of companies and epitomizes the vital steps that are needed to support high-quality and uniformly effective FMEAs. Each of these steps will be discussed below.

[Insert Figure 1]

"Good things only happen when planned; bad things happen on their own." Philip B. Crosby

Step 1A Develop and execute an FMEA strategic plan

The essence of FMEA strategic planning is to discuss and decide the specific business-related tasks that are needed before beginning actual FMEA projects. Strategic decisions include the types of FMEAs that will be done (System, Design, Process, Hazard Analysis, Maintenance, Software, etc.), the selection criteria that will be used to identify new FMEAs, the appropriate FMEA timing, the FMEA standard that will be used, how quality audits will be implemented, how FMEA projects will be tracked including closure of all recommended actions, how supplier FMEAs will be handled, and other planning tasks.

Step 1B Develop and execute an FMEA resource plan

Management must also make resource decisions, such as what FMEA software is needed, who will perform FMEA facilitation and administration, the FMEA training plan for facilitators and teams, the specific FMEA procedure, how the procedure will it be documented and adhered to, the composition of the FMEA core team, the content and frequency of management reviews, the approval system for FMEA recommended actions, and other resource tasks.

Step 2 Develop generic FMEAs (optional)

The use of generic FMEAs can greatly reduce the overall time and effort in performing FMEAs. Generic FMEAs contain both *historical* (empirical) and *potential* failure modes, causes, controls, etc. They are done at the generic level of the system, subsystem or component, not at the program-specific level. Most often, they are done once; and updated when needed from test and field data and/or new technology. The purpose is to support a learning organization, retain the lessons learned from test and field, and make it easier to generate program-specific FMEAs in the future.

Step 3 Develop program-specific FMEAs

Program-specific FMEAs focus on specific applications or projects. They are tailored from generic FMEAs or are done newly. They are completed through the entire FMEA worksheet and must meet the FMEA Quality Objectives. All of the information from the previous article entitled "The Quality of FMEAs" is applicable when performing program-specific FMEAs: understanding and applying the proper FMEA fundamentals, avoiding the most common FMEA mistakes, and providing excellent facilitation.

Once FMEAs are completed up through recommended actions, there are three types of reviews that should be done.

Step 4 Conduct management reviews of high-risk FMEA Issues

Management must regularly review the high-risk issues and recommended actions from FMEAs until the FMEA is fully implemented and risk reduced to an acceptable level. This is essential to ensure understanding, agreement, support, adequacy and execution. The management review of FMEAs should focus on high-severity issues (regardless of RPN) and high-RPN issues, including failure modes, causes, recommended actions and execution progress.

Step 5 Conduct FMEA quality audits

FMEA quality audits are in-person audits of FMEAs, done with the FMEA facilitator and the FMEA core team present. Someone, usually from management, who is experienced with the content and quality of good FMEAs, performs these quality audits. Done in an interview format, on a pre-scheduled or random basis, they are based on the ten FMEA Quality Objectives as covered in the previous RMC article. FMEA quality audits take about one hour per audit, or about five minutes per individual quality objective. They provide valuable feedback to improve future FMEAs.

Step 6 Review supplier FMEAs

Potential high-risk system or subsystem level failures may have their root causes in supplier components. It is a good reliability management practice to ensure all suppliers demonstrate due care in their product designs and manufacturing processes. For suppliers of *critical* parts, they should be required to submit completed FMEAs for review *and approval*, prior to part shipment. Reviews based on the FMEA Quality Objectives should be conducted either by the FMEA team or by a qualified representative. The supplier continues working on their FMEAs until they meet all quality objectives.

Step 7 Execute actions to reduce or eliminate risk

FMEA has little value unless the recommended actions are fully executed. It is vital to follow up each recommended action to ensure completion to the satisfaction of the FMEA team so that risk is eliminated or mitigated to an acceptable level. Successful FMEA recommended actions should be effective, detailed and executable. They must have management support and their primary focus should drive design improvements. FMEA teams should use the full range of reliability tools. The FMEA team must bring problems with execution back to management.

Step 8 Link FMEAs to other processes

There are many important quality, reliability, design, manufacturing, and maintenance processes that can seamlessly link to FMEAs, greatly leveraging their value and usefulness. Examples of these include developing Design Verification Plans (linked to System and Design FMEAs), developing manufacturing Process Control Plans (linked to Process FMEAs), conducting Design Reviews (linked to all types of FMEAs), and developing Preventive Maintenance Plans (linked to Equipment FMEAs). Many of these processes are detailed in the Advanced Product Quality Planning (APQP) guidelines. Consider using FMEA software that integrates all of these processes, in order to maximize the value of FMEAs.

Step 9 Incorporate test and field failures

One of the most important elements of a successful FMEA program is to ensure FMEAs include test and field history. By so doing, the FMEA team can ensure problems that have occurred in the past do not

show up in new or modified products. Unfortunately, it is quite common that many product or manufacturing issues that result in expensive recalls and warranty payments have occurred before. Future FMEA projects must be aware of problems that have occurred in the past (lessons learned) and ensure that previously seen failures do not repeat. Care must be taken to avoid inaccurate data from the warranty system, which is often "noisy," due to focus on dealer costs and reimbursements, not failure modes and causes.

Step 10 Support FMEA Process with fully integrated software

An effective FMEA process needs to be supported by integrated relational database software. The characteristics of good FMEA software include accessibility to all previous and current FMEA projects, configurability of FMEA standards to organization needs, maintenance of generic and program-specific FMEAs, ability to easily import and export FMEA data and attach files, seamless linkage to other processes, easy tracking of execution of risk reduction actions, easy generation of plots and reports for management reviews, and allowing users simultaneous access to FMEA database. Xfmea software from ReliaSoft Corporation is one such relational database that has been effective in accomplishing all of the above objectives.

In summary, FMEA can be a powerful tool to achieve high reliability and safety in products and processes. Properly done, FMEAs harness the inherent passion and energy that employees have for helping consumers and users receive safe and reliable products. The four FMEA success factors can go a long way to achieving these goals.

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