FMEA Success Factors

Few reliability tools elicit stronger responses from quality and reliability professionals than Failure Mode and Effects Analysis. 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 boards."

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 FMEA success factor (an effective FMEA process) will be discussed. In subsequent articles, the remainder of the success factors will be addressed.

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, it may not be as successful.

In this article, eleven tasks are outlined that need to be established and operational within any company that aspires to achieving uniformly positive results in their application of FMEA. The entire process is presented graphically in Figure 1.

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.

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 decision 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.

Vital to the short and long term success of FMEAs in any company is the strong support of management. 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 executive level, who helps to generate support at staff level, advocates for FMEA budget and process and sees to the staffing, training, business process, standards, management reviews, and quality audits.

3. Generic FMEAs (optional)

The development of Generic FMEAs may be part of the organization's 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 from test & 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 Figure 2. (Note: step 4 is only completed up to design or process controls.)

4. Program-Specific FMEAs

This is where the bulk of the FMEA work is performed. Program-specific FMEAs 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 (recommend anywhere from 4 to 8 members, 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 steps 1 to 10 of the "Basic FMEA Steps" outlined in Figure 2.

5. **Management Reviews** (sometimes called Failure Review Board)

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 FMEA high risk item to the Failure Review Board in order to bring proper context and ownership to the issue.

6. Quality Audits

[Reference Figure 3, "Design FMEA Quality Objectives"]

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 the FMEA Quality Objectives outlined in Figure 3. They provide valuable information to strengthen what works and address shortfalls.

Having personally done 100s of FMEA Quality Audits, I believe this is one of the most important steps to achieving uniformly successful FMEA application. They take about one hour each and I always learned ways to improve the FMEA process.

7. Supplier FMEAs

Potential higher risk system or subsystem level failures can have their root cause in Supplier components. 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 supplier until they meet the Quality Objectives.

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 risk 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 is completed up to the Recommended Actions step (step # 4 of the "Basic FMEA Steps"). 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.

9. Linkage to other processes

FMEAs can and should be linked to other important processes to leverage their effectiveness. Xfmea 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 also has the potential 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 FMEA with other key processes improves quality, and saves time and money.

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 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.

11. Integrated Software Support

To be most effective, the FMEA process should utilize software that provides database functionality. The best software to integrate the steps of the FMEA process is Xfmea. It 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.

Figure 1

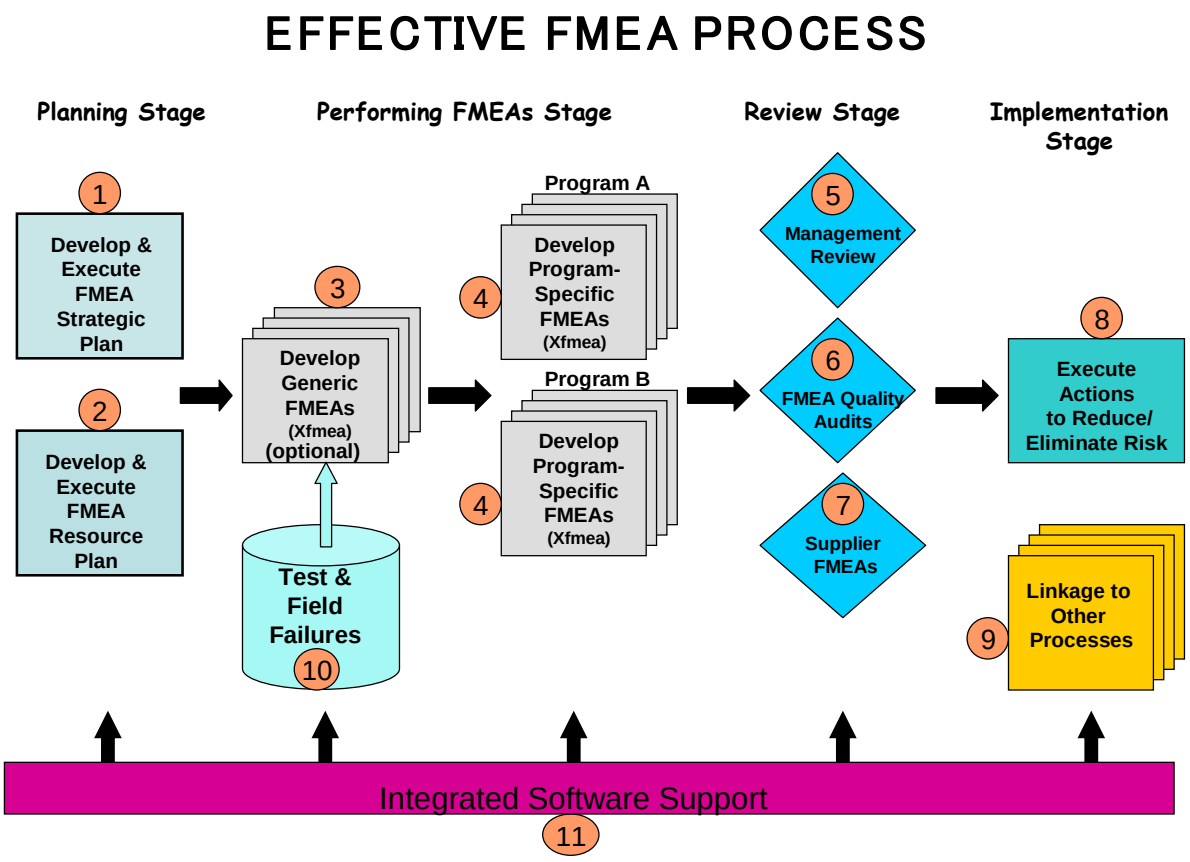
EFFECTIVE FMEA PROCESS
Planning Stage
Performing FMEAs Stage
Review Stage
Implementation Stage
1
Develop & Execute FMEA Strategic Plan
2
Develop & Execute FMEA Resource Plan
3
Develop Generic FMEAs (Xfmea) (optional)
Test & Field Failures
10
Program A
4
Develop Program-Specific FMEAs (Xfmea)
Program B
4
Develop Program-Specific FMEAs (Xfmea)
5
Management Review
6
FMEA Quality Audits
7
Supplier FMEAs
8
Execute Actions to Reduce/ Eliminate Risk
9
Linkage to Other Processes
Integrated Software Support
11

Figure 2

Basic FMEA Steps

For each Generic FMEA *(complete 4 steps; 4th step up to design or process controls)*
For each Program-Specific FMEA *(complete 10 steps)*

1. Assign FMEA facilitator & 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

Figure 3
(Note: similar page exists for Process FMEA)

DESIGN FMEA QUALITY OBJECTIVES

SAE J1739 Revised JUN2000, Appendix A

1. DESIGN IMPROVEMENTS

The FMEA drives Design Improvements as the primary objective.

2. HIGH RISK FAILURE MODES

The FMEA addresses all high risk Failure Modes, as identified by the FMEA team, with executable Action Plans. All other failure modes are considered.

3. DVP&R PLANS

The Design Verification Plan and Report (DVD&R) considers the failure modes from the Design 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. SPECIAL OR KEY CHARACTERISTICS

The FMEA identifies appropriate Key Characteristics candidates, as input to the Key Characteristics selection process, if applicable due to company policy.

7. TIMING

The FMEA is completed during the “Window of opportunity” where it could most efficiently impact the product design.

8. TEAM

The right people participate as part of the FMEA team throughout the analysis, and are adequately trained in the procedure. As appropriate, a facilitator should be utilized.

9. DOCUMENTATION

The FMEA document is completely filled out “by the book”, including “Action Taken” and new RPN values.

10. TIME USAGE

Time spent by the FMEA team, as early as possible, is an effective and efficient use of time, with a value-added result. This assumes Recommended Actions are identified as required and the actions are implemented.

(NOTE: SPECIFIC PROGRAM REQUIREMENTS TAKE PRECEDENCE)