Key Factors for Effective FMEAs

Today’s corporations are facing 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 a corporate strategy.

One of the tools that show up on most 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 on 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. Readers are encouraged to take the two day course that covers the FMEA basics and supporting software (RS 470, FMEA 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 are the result of personally supervising or participating in over a thousand FMEA projects, and collaboration with many corporations and organizations on 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 (Lessons Learned) and the key factors that make for effective FMEAs (Quality Objectives)?

Lesson Learned # 1

Based on empirical review of many FMEAs, some FMEAs do not drive any action at all; some FMEAs drive mostly testing; others drive ineffective action. The lesson learned 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.

Lesson Learned # 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 lesson learned 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 higher risk failure mode/causes are adequately addressed with effective actions. The key is effective action that reduces or eliminates the risk.

Lesson Learned # 3

Some companies miss the opportunity to improve DVP&R Plan 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 lesson learned 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 FMEA team or through well written actions.

Lesson Learned # 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 lesson learned 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 FMEA scope.

Lesson Learned # 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 lesson learned is:

*Disconnect between FMEA and field Lessons Learned*

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.

Lesson Learned # 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 lesson learned is:

*FMEA omitted 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. SAE J1739 or the AIAG FMEA standard uses the “Classification” column.

**Lesson Learned # 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 lesson learned is:

*Doing FMEAs late reduces effectiveness*

**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 design or process concept is determined. The exception is FMEAs done during trade-off studies, which should, of course, be started earlier.

**Lesson Learned # 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 lesson learned 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. 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 actually showing up at the meetings. Attendance often takes management support. Team size is best between 4 to 8 people. If team gets too large, consider breaking into additional limited scope FMEAs.

Lesson Learned # 9

There are 100s of ways to do FMEAs wrong. Some companies do not encourage or control proper FMEA methodology. Training, coaching, reviews are all necessary to success. The lesson learned 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 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.

Lesson Learned # 10

Some companies mandate FMEAs, and then do not ensure the time is well spent. Pre-work must be completed, meetings well run, efficient follow up of high risk issues. Ask FMEA team if their time is well spent, and take action to address shortcomings. The lesson learned 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 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 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 5 minutes for each of the 10 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 10 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.
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)
1. PROCESS IMPROVEMENTS
The FMEA drives Process Improvements as the primary objective, with an emphasis on Error/Mistake Proofing solutions.

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 Process Control Plan considers the failure modes from the Process FMEA.

4. INTEGRATION
The Process FMEA is integrated and consistent with the Process Flow Diagram and the Process Control Plan. The Process FMEA considers the Design FMEA as part of its 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.

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.

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)