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Lessons Learned for Effective FMEAs

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SUMMARY & PURPOSE

Many companies are faced with intense global competition and must shorten product development times and reduce costs. Failure Mode and Effects Analysis (FMEA) is one of the most effective techniques to achieve high reliability during shorter product development timelines and budget constraints. Using the four broad success factors for effective FMEAs (understanding the basics of FMEAs and Risk Assessment, applying key factors for effective FMEAs, providing excellent FMEA facilitation and implementing a "best practice" FMEA process) will help to assure success in FMEA applications.

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Carl Carlson is a consultant and instructor in the areas of FMEA, reliability program planning and other reliability engineering and management disciplines. He has 25 years experience in reliability engineering and management positions, most recently conducting reliability consulting with dozens of commercial companies and military organizations, and previously as Senior Manager for the Advanced Reliability Group of General Motors. Previous to General Motors, he worked as a Research and Development Engineer for Litton Systems, Inertial Navigation Division.

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1. INTRODUCTION

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

Today's corporations are facing unprecedented worldwide competition as a result of three ongoing 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 continue to be important; 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 (Failure Mode Effects and Criticality Analysis).

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.

Four broad success factors are critical to uniformity of success in the application of FMEA in any company or organization. They are:

1. Understanding the basics of FMEAs and Risk Assessment
2. Applying key factors for effective FMEAs
3. Providing excellent FMEA facilitation
4. Implementing a "best practice" FMEA process

2. UNDERSTANDING THE BASICS OF FMEAS AND RISK ASSESSMENT

The prerequisite for effective FMEAs is a sound knowledge of the basics of FMEA. There is no substitute for learning these fundamentals. Once these basics have been well learned, it is possible to understand and apply certain lessons learned that make FMEAs highly effective.

Risk assessment is helpful to identify which FMEAs will be done as part of product and process development. Risk assessment is also an integral part of the FMEA procedure. FMEA costs money to perform and should be used where the highest risk is anticipated.

In order to identify the highest risk areas that are candidates for FMEA, the following criteria can be examined. It is suggested that FMEAs be done when risk is associated with one or more of the following areas:

- New technology
- New designs where risk is a concern
- New applications of existing technology
- Potential for safety issues
- History of significant field problems
- Potential for important regulation issues
- Mission Critical applications
- Supplier Capability

Avoid excessive time on lower risk systems.

Every part of the FMEA procedure can have too much or too little detail. It is up to the FMEA Team and Facilitator to navigate the challenges of detail. Too little detail can result in not identifying root causes, ineffective actions, and other problems. Too much detail bogs down the FMEA team and can result in "missing the forest for the trees."

The Key is to be "Risk Conscious" and to consistently keep the team focused on risk; the higher the risk, the higher the level of detail that is needed throughout the analysis.

3. APPLYING KEY FACTORS FOR EFFECTIVE FMEAS

The following 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 the FMEA process and its shortcomings.

There is a maxim that says, "Good judgment comes from experience and experience comes from poor judgment." 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 their overall effectiveness.

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

3.1 Mistake # 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 mistake is:

Failure of the FMEA to drive design or process improvements

3.1.1 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 in FMEAs.

3.2 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

3.2.1 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.

3.3 Mistake # 3

Some companies miss the opportunity to improve the Design Verification Plan & Report (DVP&R) or Process Control Plans (PCP) 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

3.3.1 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.

3.4 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 system and subsystem interfaces or subsystem integration in the FMEA

3.4.1 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.

3.5 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 be repeated. The mistake is:

Disconnect between FMEA and field lessons learned

3.5.1 Quality Objective # 5

The FMEA considers all major "lessons learned" (such as high warranty, campaigns, etc.) as input for 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 be repeated in the new design/process. The key is to hold the FMEA team responsible to ensure that major field problems are not repeated.

3.6 Mistake # 6

A Key Characteristic is a feature of a material, process or part (including assemblies) whose variation within the specified tolerance has a significant influence on product fit, performance, service life or manufacture. 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

3.6.1 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 and the AIAG FMEA standard use the "Classification" column to identify key product and process characteristics.

3.7 Mistake # 7

Many companies do FMEAs late, and this reduces their effectiveness. FMEAs should be done concurrently with the design process and completed by design or process freeze dates. This is a very common problem and greatly reduces the effectiveness of FMEAs. The mistake is:

Doing FMEAs late

3.7.1 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 is determined, with the exception of FMEAs done during trade-off studies, which should, of course, be started earlier.

3.8 Mistake # 8

Some FMEA teams do not have the right experts on the core team and some 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

3.8.1 Quality Objective # 8

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

Note: An actual survey of Reliability Engineering internal customers on FMEAs showed that they thought 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. Additionally, people have blind spots (scotomas) and a diverse team will mitigate this issue. 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 kept between 4 and 8 people. If the team gets too large, consider breaking up the FMEA into additional limited scope FMEAs.

3.9 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

3.9.1 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 the root causes of a failure. 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 a lack of follow-up to ensure that the FMEA Recommended Actions are executed and the resulting risk is reduced to an acceptable level.

3.10 Mistake # 10

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

Lack of Efficient Use of Time

3.10.1 Quality Objective # 10

The time spent by the FMEA team is an effective and efficient use of time with a value-added result

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

Reference the following Figures 1 and 2, which are taken from SAE J1739 Revised JUN2000, Appendix A and B.

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 for failure mode identification.

6. SPECIAL OR KEY CHARACTERISTICS: The FMEA identifies appropriate Key Characteristics candidates, as input for 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. A facilitator should be utilized, as appropriate.

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 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)

Figure 1. Design FMEA Quality Objectives

(from SAE J1739 Revised JUN2000, Appendix A)

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. Process Control 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 for failure mode identification.

6. SPECIAL OR KEY CHARACTERISTICS: The FMEA identifies appropriate Key Characteristics candidates, as input for 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 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)

Figure 2. Process FMEA Quality Objectives
(from SAE J1739 Revised JUN2000, Appendix B).

4. FMEA CASE STUDIES

4.1 FMEA Case Study # 1

A vehicle system integrator performs a System FMEA to address safety and field concerns. The FMEA was started on time, but progress was very slow due to inadequate FMEA software (not user friendly, not supporting best practice, etc.). The FMEA document grew to hundreds of pages. However, due to the resulting lateness of the FMEA the Test Plans, Control Plans, Design Reviews and Design modifications were not driven by a completed FMEA.

Analysis of this case study shows that the majority of FMEA Quality Objectives were not achieved: the FMEA did not drive Design Improvements, or Test/ Control Plans; it was too late to be effective; and the risk rankings were assigned by one person instead of the team.

Lessons learned include the following: FMEA software should be easy to use and support FMEA best practices; FMEAs need to be completed early; program teams need to focus on the highest risk items; and FMEAs that are too long may become ineffective.

4.2 FMEA Case Study # 2

A product development team performed a Design FMEA in order to reduce the reliability risk of an optical system featuring new technology. In general, there were good results from the FMEA. However, there was one major failure mode that was not adequately addressed because it had "no solution." The team did not know what to do, so the issue was not resolved.

Analysis of this case study shows that there was at least one FMEA Quality Objective that was not achieved: the FMEA did not address all high risk failure modes.

The lesson learned from this case study is that an FMEA team must ensure that all high risk failure modes have effective actions regardless of whether or not a solution is envisioned by the team. Further studies can be commissioned, outside help can be solicited or management support can be brought in. The FMEA facilitator should be on the alert for failure modes that have "no solution."

4.3 FMEA Case Study # 3

A medical company routinely performs Process FMEAs in order to meet ISO compliance.

Analysis of the quality of the Process FMEAs shows that overall, they were not value-added. Process FMEAs were performed regardless of whether or not a preliminary risk assessment revealed any risk in the process at all. RPNs used to assess the risk were uniformly low. No follow-up actions were identified; no process improvements were sought or driven. In effect, the FMEA team was only focused on meeting compliance instead of improving the design of either the product or the process. As a result, the majority of the FMEA Quality Objectives were not achieved: there were no recommended actions; the resultant RPNs indicated mostly high severity, low occurrence failure modes; and the FMEA document was very long and of little value.

The lesson learned from this case study is that the overall objective of an FMEA should be design or process improvement, and this objective needs to be identified and supported by both the FMEA team and management. Compliance with standards will follow if the FMEA meets Quality Objectives.

5. PROVIDING EXCELLENT FMEA FACILITATION

A facilitator is "one who contributes structure and process to interactions so groups are able to function effectively and make high quality decisions." Another definition is "a helper and enabler whose goal is to support others as they achieve exceptional performance." Basically, a facilitator's job is to support team members to do their best thinking.

An FMEA facilitator is a person who is trained in both FMEA procedures and facilitation techniques. The facilitator leads an FMEA team to successful completion of an FMEA project, with associated risk reduced to an acceptable level.

The primary FMEA facilitation skills are:

- Brainstorming and Probing Questions
- Encouraging Participation
- Active Listening
- Controlling Discussion
- Making Decisions
- Conflict Management
- Managing Level of Detail
- Managing Time

The importance of expert facilitation to effective results of FMEAs cannot be overstated.

Good FMEA facilitators drive the team through the process, saving valuable time and ensuring effective results. They help sort the insignificant input from those inputs that affect product and process reliability and safety.

6. IMPLEMENTING A "BEST PRACTICE" FMEA PROCESS

Without an effective FMEA process, actual FMEA results will depend 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.

Ten 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 3.

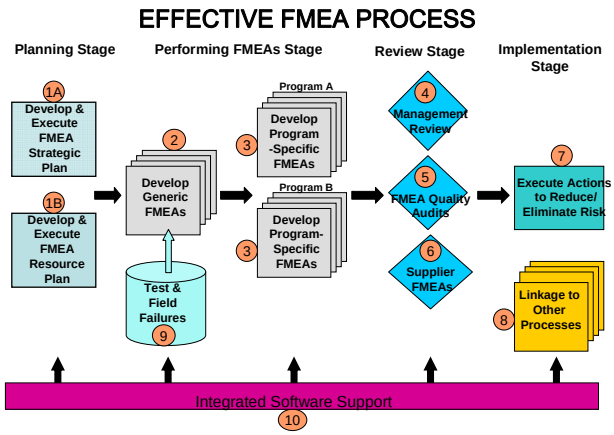

Figure 3. Effective FMEA Process.

6.1A 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 (*e.g.* Design, Process, Equipment, etc.), the timing of FMEAs (*e.g.* prior to design freeze) and the selection criteria (*e.g.* new technology, new applications, etc.).

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

6.1B 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 the FMEA process and FMEA training.

Strong support of management is vital to both short- and long-term success of FMEAs in any company. I would go so far as to say that without solid management support, FMEAs will fall far short of their potential as effective problem prevention tools.

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

6.2 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 with test and field data and for 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 through 4 of the "Basic FMEA Steps" outlined in Figure 4. (Note: Step 4 of Figure 4 is only completed up to design or process controls.)

6.3 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 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 (between 4 to 8 members are recommended, depending on FMEA scope and complexity) and trained. Their work should be well facilitated and executed 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 through 10 of the "Basic FMEA Steps" outlined in Figure 4.

For each Generic FMEA *(complete 4 steps -- the 4th step up to design or process controls)*

For each Program-Specific FMEA *(complete 10 steps)*

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 preliminary 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."

Figure 4. Basic FMEA Steps.

6.4 Management Reviews (sometimes called Failure Review Board)

Many 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 also 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.

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.

6.5 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 the FMEA Quality Objectives outlined in Figures 1 and 2. They provide valuable information to strengthen what works and address shortcomings.

Having personally done hundreds of FMEA Quality Audits, I believe this is one of the most important steps to achieving a uniformly successful FMEA application. Audits take about one hour each and provide valuable ways to improve the FMEA process.

6.6 Supplier FMEAs

Potential high risk system or subsystem level failures can have their root causes 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 high 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.

6.7 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 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 through the Recommended Actions step (step # 4 of the "Basic FMEA Steps" in Figure 4). 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. New failure modes introduced by changes in the design to mitigate one risk may also need to be reviewed by the team.

6.8 Linkage to Other Processes

FMEAs can and should be linked to other important processes to leverage their effectiveness. FMEA software that is based on a relational database can integrate requirements from Advanced Product Quality Planning (APQP) guidelines and has the potential to generate the beginning of new Process FMEAs based on existing Design FMEAs. Such software 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 for other processes, such as Design Reviews, Design Trade Studies, Reliability Growth Analyses, etc. The FMEA Process should be integrated with the overall Product Development Process.

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

6.9 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 for 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.

6.10 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 based on a relational database. Such software can do an excellent job of managing multiple FMEA projects and databases and also provide the plots/reports and linkages to other processes that are essential to successful FMEA outcomes.

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

7. CONCLUSION

It is not enough to learn and perform FMEAs by "filling out the form". In order to ensure FMEAs are fully effective in supporting high product and process reliability there are four broad success factors: understanding the basics of FMEAs and Risk Assessment, applying key factors for effective FMEAs, providing excellent FMEA facilitation and implementing a "best practice" FMEA process. Individual practitioners and management will succeed in FMEA strategies by learning and applying these four factors.