



Which FMEA Mistakes Are *You* Making?

Turn 10 common **FMEA missteps** into an effective audit process

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In 50 Words Or Less

- Failure mode and effects analysis (FMEA) can achieve safe, reliable and economical products and processes.
- Certain FMEA mistakes are repeated, however, with many organizations getting little value for the time and resources expended.
- Focusing on achieving quality objectives and using an FMEA audit process will greatly enhance the tool's effectiveness.

“Experience is the name everyone gives to their mistakes.”¹
—Oscar Wilde

FAILURE MODE AND EFFECTS analysis (FMEA) can be used to anticipate and prevent problems, reduce costs, shorten product development times, and achieve safe and reliable products and processes. It must, however, be performed on the correct parts, by the correct team, during the correct timeframe and with the correct procedure.

Frankly, there are mixed results with FMEA applications. Consider these questions: Why is there so much variation in applying





a tool that has been around for decades? What can be done to help achieve uniformly successful results?

Six important elements are critical to uniform success in applying FMEA:

1. Understanding the fundamentals, definitions and procedures of FMEAs.
2. Selecting the right FMEA projects.
3. Preparation steps for each FMEA project.
4. Applying lessons learned and quality objectives.
5. Providing excellent facilitation.
6. Implementing an effective organization-wide FMEA process.

This article focuses on the fourth element.

There is a maxim that says, “Good judgment comes from experience and experience comes from poor judgment.” This article presents lessons learned from experience with more than 2,000 FMEAs in more than 100 organizations and can serve as the foundation for an effective FMEA audit process.

Readers will learn the top 10 FMEA mistakes and their associated design and process FMEA quality objectives (Table 1, p. 38). You will learn how to avoid these FMEA pitfalls and how to audit FMEAs² against quality objectives (read the sidebars “FMEA Defined,” p. 39, “Using Quality Objectives,” p. 40, and “FMEA Audit Procedure,” p. 41.

Mistake No. 1: design/process improvements

A review of FMEA applications across industries shows some FMEAs drive ineffective actions or no action at all. Some design FMEAs drive mostly testing, while some process FMEAs drive mostly controls. FMEA's failure to drive product or process improvements is mistake No. 1.

Associated quality objective

The FMEA drives design improvements (design FMEA) or manufacturing or assembly process improvements (process FMEA) as the primary objective.

Effective application: The quality and reliability fields have many tools to choose from in driving design or process improvements. The key is using the recom-

mended actions worksheet column of the FMEA to identify and execute tools that can optimize designs and processes. This is one of the reasons quality or reliability engineers should participate in FMEAs.

How to audit: Review the FMEA recommended actions and observe whether most of them drive design improvements (for a system or design FMEA) or process improvements (for a process FMEA). Talk with team members to ensure their focus was on improving the design or process.

Mistake No. 2: high-risk failure modes

Although organizations define risk using different criteria, failure to address all high-risk failure modes can result in potentially catastrophic problems or lower customer satisfaction. Failure of FMEA to address all high-risk failure modes is mistake No. 2.

Associated quality objective

The FMEA addresses all high-risk failure modes, with effective and executable action plans.

Effective application: The team first addresses all high-severity issues, regardless of risk priority number (RPN). After high-severity issues are addressed, the team can prioritize and address high-RPN issues (or high severity x occurrence if severity and occurrence are used rather than RPN). The key is effective actions that reduce or eliminate risk. Most high-risk problems require multiple corrective actions.

How to audit: Review high-severity and high-RPN issues to determine whether the corresponding recommended actions are adequate to reduce risk to an acceptable level. Talk with the team members to ensure they are satisfied that all high risks were addressed and no important concerns were left unaddressed.

Mistake No. 3: design verification or process control plans

Some organizations miss the opportunity to improve their design verification plan (DVP) or process control plan (PCP) based on the failure modes or causes from the FMEA. The result is inadequate product testing or PCPs. Failure of the FMEA to improve test and control plans is mistake No. 3.

Associated quality objective

The DVP considers the failure modes from the design FMEA. The PCP considers the failure modes from the process FMEA.

FMEA quality objectives / TABLE 1

- 1. Design/process improvements.** The failure mode and effects analysis (FMEA) drives design improvements (design FMEA) or manufacturing or assembly process improvements (process FMEA) as the primary objective.
- 2. High-risk failure modes.** The FMEA addresses all high-risk failure modes, with effective and executable action plans.
- 3. Design verification or process control plans.** The design verification plan considers the failure modes from the design FMEA. The process control plan considers the failure modes from the process FMEA.
- 4. Interfaces.** The scope of the design FMEA includes interface failure modes in both FMEA block diagram and analysis. The scope of the process FMEA includes inter-operation failure modes, such as transfer devices, as well as incoming parts and shipping, in both process flow diagram and analysis.
- 5. Lessons learned.** The FMEA considers all major lessons learned (from in-service warranties, customer service databases, recall campaigns, prior manufacturing or assembly problems and others) as inputs to failure mode identification.
- 6. Level of detail.** The FMEA provides the correct level of detail to get to root causes and effective actions.
- 7. Timing.** The FMEA is completed during the window of opportunity from where it can most effectively affect the product design or manufacturing process.
- 8. Team.** The right people, adequately trained in the procedure, 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 use.** Time spent by members of the FMEA team is an effective and efficient use of time with a value added result.

Effective application: The FMEA team will often discover failure modes or causes that were not part of the design controls, process controls or corresponding procedures. The key is to ensure the DVP or PCP is affected by the results of the FMEA. This can be done by including test or control personnel on the FMEA team, and through well-written recommended actions.

How to audit: Review the recommended actions to determine whether there are improvements to the DVPs, PCPs or corresponding procedures based on risk associated with current design or process controls. Talk with the team members to determine whether they had adequate representation from test or controls groups, benefited from their input, and whether test and control procedures were improved.

Mistake No. 4: interfaces

Empirical data show at least 50% of field problems can occur at interfaces between parts and subsystems or between the system and environment. Similarly, many manufacturing or assembly problems occur at the interface between operations or beyond operations, such as while transporting materials, receiving incoming parts or shipping. Some practitioners miss these interfaces. Not including interfaces in design or process FMEAs is mistake No. 4.

Associated quality objective

The scope of the design FMEA includes interface failure modes in both FMEA block diagram and analysis. The scope of the process FMEA includes inter-operation failure modes, such as transfer devices, and incoming parts and shipping, in both process flow diagram and analysis.³

Effective application: Product design interfaces can include physical connections, material exchanges, energy transfers or data exchanges. The FMEA block diagram should clearly show the interfaces that are part of the design FMEA scope. Similarly, the process flow diagram should show inter-operation connections and exchanges, such as with materials transport, and receipt of incoming parts and shipping.

How to audit: Review items, functions, failure modes and other portions of the FMEA to ensure interface issues were addressed within the design FMEA scope. Ensure connections and exchanges between operations were addressed within the process FMEA scope. Review the FMEA block diagram and process

FMEA DEFINED

Failure mode and effects analysis (FMEA) is a method designed to:

- Identify and fully understand potential failure modes and their causes, and the effects of failure on the system or end users, for a given product or process.
- Assess the risk associated with the identified failure modes, effects and causes, and prioritize issues for corrective action.
- Identify and carry out corrective actions to address the most serious concerns.

FMEA is an engineering analysis done by a cross-functional team of subject matter experts that thoroughly analyzes product designs or manufacturing processes, early in the product development process. Its purpose is to find and correct weaknesses before the product gets into the hands of the customer. The primary objective of an FMEA is to improve the design of the product or process being analyzed.

Design FMEA focuses on design-related deficiencies, with emphasis on improving the design and ensuring product operation is safe and reliable during the useful life of the equipment.

Process FMEA focuses on manufacturing or assembly-related deficiencies, emphasizing how the manufacturing process can be improved to ensure that a product is built to design requirements safely with minimal downtime, scrap and rework. —C.S.C.

flow diagram to verify. Ask the team how it determined no interface issues were missed.

Mistake No. 5: lessons learned

Some organizations do not provide links between FMEAs and field data (in design FMEAs) or manufacturing data (in process FMEAs). It takes concerted effort to integrate problem resolution databases with the FMEA. A lack of integration can cause serious problems to be repeated. Disconnect between the FMEA and information from the field or plant is mistake No. 5.

Associated quality objective

The FMEA considers all major lessons learned (from in-service warranties, customer service databases, recall campaigns, prior manufacturing or assembly problems and others) as inputs to failure mode identification.

Effective application: Field and manufacturing failure databases often have noise. Effort is needed to filter the correct input information to FMEAs. New FMEAs should be seeded with potential field and manufacturing problems, and should show how the problems will be avoided in the new or modified design or process. Hold FMEA teams accountable to ensure

known problems are not repeated.

How to audit: Review failure modes and causes to ensure they contain supplemental field failure data (for system and design FMEAs) and manufacturing failure data (for process FMEAs). Talk with the FMEA team to ensure the FMEA benefited from lessons learned and that high-risk issues will not recur.

Mistake No. 6: level of detail

Some FMEAs are too detailed in their analysis, which makes it difficult to focus on areas of higher risk. Some FMEAs aren't detailed enough, which makes it difficult to determine the root cause and effective corrective actions. Having the wrong level of detail in the analysis is mistake No. 6.

Associated quality objective

The FMEA provides the correct level of detail to get to root causes and effective actions.

Effective application: Good FMEA facilitation keeps a team focused on areas of risk that lead to root causes and effective corrective actions. FMEA discussions should be limited to areas of concern noted by at least one member of a properly constituted FMEA team. Avoid lengthy discussions about low-risk issues. The higher the risk, the more important and in-depth the discussion should be. Low-risk issues should receive less, but appropriate, discussion.

How to audit: Verify that the level of detail on high-risk issues is adequate to fully understand root causes and develop effective corrective actions. Review the different worksheet columns of the FMEA to ensure the overall level of detail is proper and adequate.

Too much detail may appear in the form of endless pages of FMEAs covering issues no one on the team is concerned about. Too little detail shows up as underdefined functions, failure modes, effects, causes or controls, or as areas of unaddressed concern from one or

more FMEA team members. Talk with the FMEA team members to determine how they addressed the level of detail and ensured all concerns were included in the scope of the FMEA project.

Mistake No. 7: timing

Many organizations conduct FMEAs late, and this reduces their effectiveness. FMEAs should be completed according to design or process freeze dates in line with the product development process. Performing FMEAs late is mistake No. 7.

Associated quality objective

The FMEA is completed during the window of opportunity from where it can most effectively affect the product design or manufacturing process.

Effective application: The key to completing FMEAs on time is to start the FMEAs on time. Design or process FMEAs should begin soon after the design or process concept is determined and be completed before design or process freeze dates. Starting and completing FMEAs on schedule requires proactive management support throughout the FMEA process.

How to audit: Review the timing of the FMEA against the product development process timeline. Verify the FMEA was started and completed in the proper timeframe to maximize the value of the FMEA results.

Mistake No. 8: team

Some FMEA teams do not have the right experts on their core teams. Some FMEA team members just sit in their chairs if they show up at all and don't contribute to team synergy. FMEAs having inadequate team composition and participation is mistake No. 8.

Associated quality objective

The right people, adequately trained in the procedure, participate on the FMEA team throughout the analysis.

Effective application: People have blind spots. A well-defined, cross-functional team minimizes errors due to blind spots. FMEA analysis requires SMEs from a variety of disciplines to ensure all necessary inputs are incorporated into the exercise. The cross-talk and synergy among SMEs that occurs during FMEA meetings is essential, because well-defined groups can discover what individuals miss. Attendance is influenced by management support. A team size of four to eight people works best.

How to audit: Review the FMEA team member ros-

USING QUALITY OBJECTIVES

Failure mode and effects analysis (FMEA) quality objectives should be integrated into FMEA team training and reviewed at each stage of FMEA project completion. They can be used to assess the quality and effectiveness of original equipment manufacturer and supplier FMEAs. FMEAs should not be considered complete until all of the quality objectives are met. They are important ingredients for an FMEA quality audit process and are essential to ensuring effective FMEAs. —C.S.C.

ter to ensure there was adequate representation from the various disciplines based on the type of FMEA and the project scope. Check FMEA team meeting records to ensure attendance was adequate at each meeting. Talk with individual team members to learn whether their input was elicited in decisions.

Mistake No. 9: documentation

There are hundreds of ways to do FMEAs wrong. Some organizations do not encourage or control proper FMEA methods. Or, they copy old FMEAs and don't adequately address changes, such as new technology or new applications. Training, coaching and reviews are necessary for success. Use of improper FMEA procedures is mistake No. 9.

Associated quality objective

The FMEA document is completely filled out by the book, including action taken and final risk assessment.

Effective application: The FMEA team must have a solid understanding of FMEA fundamentals, definitions and concepts. There is no substitute for properly applying FMEA fundamentals. This is a broad quality objective to ensure the FMEA worksheet is filled out completely and properly.

How to audit: Verify that the FMEA worksheet columns were correctly filled out and that FMEA procedure was properly followed. Talk with the FMEA team members to ensure they rigorously followed FMEA guidelines and practices.

Mistake No. 10: time use

Some organizations mandate FMEAs, but that doesn't ensure the time spent on them is productive. Pework must be completed, meetings must be productive and high-risk issues must be resolved. Ask the FMEA team whether their time was well spent, and take action to address shortcomings. Inefficient use of time is mistake No. 10.

Associated quality objective

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

Effective application: If this quality objective is met, future FMEA meetings will be well attended and supported by SMEs and management. Conversely, if subject matter expert time is wasted, it will be difficult to generate attendance at future meetings.

How to audit: Talk with the FMEA team to learn whether each member believes his or her time was well spent and whether a value-added result was achieved. If not, find out why.

FMEA AUDIT PROCEDURE

Failure mode and effects analysis (FMEA) quality audits are in-person audits of completed or nearly completed FMEAs, performed with the FMEA facilitator and core team present. Perform the audit on a prescheduled or random basis. The auditor must be skilled and experienced with the content and quality of good FMEAs. The auditor can be from management or be an FMEA expert.

Each of the 10 FMEA quality objectives has a corresponding "how to audit" recommendation. In a nutshell, an FMEA SME or manager reviews the FMEA results with the FMEA team against each of the FMEA quality objectives, one by one, using the audit recommendation. Each quality objective is evaluated for how well it is achieved. This evaluation can be assigned a variable representation, such as high (3), medium (2) or low (1), or another scale. The numerical output represents the quality of the FMEA.

Allocate one hour for the audit, or about five minutes per FMEA quality objective. In addition to the numerical output, the results of the audit provide valuable information to improve future FMEAs. The focus is on improving the FMEA process, not on the person or team doing the FMEA. The auditor is looking for specific process-related issues that underlie deficiencies in achieving the quality objectives, such as lack of training, procedures, facilitation skills, standards, resources or support. Action items from the FMEA quality audit should be documented and pursued to improve the overall FMEA process. Do not expect to achieve all 10 FMEA quality objectives instantly. Rather, work to maintain steady improvement. —C.S.C.

Increase FMEA value

FMEA has the potential to be a powerful reliability tool to reduce product design and manufacturing risk in a cost-effective manner. Yet in practice, FMEA does not always live up to its potential. Using an audit process based on the FMEA quality objectives will increase the value of FMEAs in your organization. **QP**

REFERENCE AND NOTES

1. Oscar Wilde, Act III, *Lady Windermere's Fan*, 1892.
2. For more information about FMEA auditing, including examples from an FMEA audit, view a webinar from the ASQ Reliability Division, "How to Audit FMEAs Using Quality Objectives," <https://asq.org/reliability/110170/web.html?shl=110170>.
3. An FMEA block diagram is a visual depiction of the entire system or design to clearly show the boundaries of the FMEA analysis (what is included and not included), the interfaces between items and other information that can help depict the scope of the FMEA. Definitions for basic FMEA terms used in this article are available at www.effectivefmeas.com/uploads/Glossary_of_FMEA_Terms.pdf. (case sensitive).

BIBLIOGRAPHY

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