FMEAs consistently remain one of the most used tools for failure and risk assessment; however, the way they are done also consistently remains the most variable. Because FMEAs are more fluid in implementation and structure than other failure risk assessment tools and methodologies, they pose unique challenges in practice. This paper explores some of the most common challenges and suggestions for meeting those challenges to get the most out of your FMEA efforts.
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FMEA: Failure Mode & Effects Analysis

FMEA, or Failure Mode and Effects Analysis, is an organized, systematic approach for assessing potential failures and their resulting consequences on a product, system, or process. The primary objective of a FMEA is two-fold: to evaluate the risks associated with failure effects and develop a plan to detect, prevent, or mitigate those effects deemed most critical. FMEAs have been long used throughout a wide range of industries as a proven technique for failure control and mitigation. It is one of the reasons FMEAs consistently remain one of the most used methodologies in corporate reliability and quality efforts.
The Variability of FMEAs in Practice

There are many ways to perform FMEAs, and even with a number of standards available describing FMEA methodologies, it does not make the task an easy process. For example, many FMEA standards are based on a best-practices approach, and allow for flexibility to enable you to adapt FMEAs to best suit your needs. Therefore, FMEAs can widely vary in application. Also, there are also several FMEA and FMECA standards, and you may find value in aspects of more than one standard. In this case, you may want to combine facets of multiple standards for an approach that meets your requirements. Additionally, many organizations have developed their own methods for assessing failure risk; so the standards may be employed as a starting point with individualized adaptations added on.

Consequently, while FMEAs consistently remain one of the most used tools for failure and risk assessment, the way they are done also consistently remains the most variable. In contrast, other reliability and quality techniques, such as Reliability Prediction, Reliability Block Diagram (RBD), and Fault Tree Analysis (FTA), have a defined structure and remain fairly consistent in application. FMEAs are more fluid in implementation and structure.

Because of the adaptability of FMEAs and its use in a wide range of industries, it comes with its own unique set of challenges. In this article, we’ll delve further into some of the challenges we have come across in our many years of supporting FMEA efforts by our customers, as well as in performing FMEAs ourselves. It is not meant to be an all-inclusive list, but highlights some of the more common challenges we observe. We also offer our insights in to ways to overcome these challenges.
While there are many challenges associated with performing FMEAs efficiently and effectively, we will highlight 5 that stand out. Considering this list upfront and tackling these challenges early on in your FMEA process will help you to get the most out of your FMEA efforts.

Five common challenges to explore include:

1. Communicating the importance of FMEA
2. Assembling an effective team
3. Creating an organized and clear FMEA document
4. Creating a useful FMEA document
5. Ensuring you don’t repeat past mistakes

Understanding these issues and then discussing how you can best address them will greatly enhance the benefits you achieve from your FMEAs.
Challenge #1: Communicating the Importance of FMEA

In some cases, FMEAs are a compliance requirement. In other cases, FMEAs are driven from management as part of reliability and quality continuous improvement objectives. Other times, a reliability or quality team tasked with measurable quality goals drives the FMEA process. Or, FMEAs may be a newly adopted approach to help address quality issues. In any and all cases, the ability to communicate the importance of FMEA is vital to its success.

In the case of compliance-based FMEAs, team members may view the effort as a checklist item, and, therefore, do not appreciate its importance. In the situations where an outside group, such as management or a quality team, drives the FMEA it may be difficult for analysts to grasp the reasoning for its use. Lastly, analysts new to FMEA may simply feel overwhelmed and not even know where to begin.

Communicating the importance of the FMEA process is important because it results in all team members understanding why FMEAs are useful – essentially ensuring team member “buy-in”.

One way to do this is to designate a team leader or team member who has positive experience with FMEAs, or simply has experience in dealing with the results of poor failure effect planning. A key way for team members to understand the how and why of FMEA is to learn about how it has helped in the past – whether internally or externally. There may be specific instances that a team member or members can relate about how an action plan avoided a critical situation, or how the lack of one created a “fire” that had to be dealt with. If not internally, look up some external news items as examples: Toyota brake failures, the airbag fiasco that touched so many, hover boards catching fire, and Samsung Galaxy battery explosions.
Challenge #2: Assembling an Effective Team

FMEA, perhaps more than any other quality related tool, requires strong communication and a team-centered approach. FMEAs cannot be “someone else’s” responsibility, but must be a team effort with full support of everyone in the organization. FMEAs remain one technique that spans the product lifecycle – from early design stage, to development, to manufacturing, to deployment – failures occur at any point and need to be addressed and their effects minimized.

One way to help overcome this challenge is to create a FMEA team that consists of members from all parts of the product or process lifecycle. This includes a representative from management, design engineering, the manufacturing floor, and customer service to name a few. Without the cross team communication, information does not flow and knowledge sharing is lost. For example, something as simple as a customer service representative explaining the number of times they have had to deal with a particular customer issue may be unrecognized by the design engineer. Once the issue is communicated, the design engineer may be able to discover a resolution that could be implemented in future product revisions.

The added benefit of creating a cross-team group is that it naturally improves communication – even outside the formal FMEA team meetings. The value of this type of team building is immeasurable.
Challenge #3: Creating an Organized and Clear FMEA Document

While it tempting to quickly get a FMEA completed, it is important to take some time to consider that the end result should be something that is easy to read and update. Too often, we see FMEA Worksheets that are inconsistent and disorganized. Trying to update these documents can be frustrating. Sometimes, even going back just to review your past work is problematic if the data is not organized. There are two key components to create clear and organized FMEA documents.

First, use phrase sets. Phrase sets are words, terms, or groups of words that are reused. Because FMEAs are collaborative documents, and can be performed between teams in various locations, terminology consensus is very helpful. This can range from the simple agreement to always use “No effect” versus “None” when filling out the FMEA Worksheet, to agreement on complex sentences for reuse when entering recommended actions. The resulting FMEA Worksheet is then easily readable by all team members, and can be easily searched for common terms.

Second, the team should agree on a template for all FMEA Worksheets. FMEA Worksheets are customizable, which is an advantage, but can also be problematic if it leads to disorganized FMEAs across your organization. Agreement on the layout and data to capture makes the FMEA task streamlined and keeps everyone on the team on the same page. Plan a team meeting to come to a consensus for your team.

Software FMEA tools can be beneficial in providing these useful features and in helping to create organized, structured FMEA Worksheets.
Challenge #4: Creating a Useful FMEA Document

Due to the substantial amount of textual data included, FMEA documents can become unmanageable and disorganized. There should not be an effort to minimize data capture; however, you want to make sure your FMEA is useful for your quality improvement efforts.

Overcoming this challenge involves focusing in on the main objectives of your FMEA: to assess risk in order to detect, eliminate, or mitigate those items deemed most critical. To do this, spend time prior to performing your FMEA to plan the process. Answer these crucial questions:

1. **How do you plan to assess risk?**

   Risk criteria approaches are defined in FMEA standards, such as RPN (Risk Priority Numbers). RPNs take into account severity, occurrence, and detection. Criticality metrics can also be computed based on projected failure rates. It usually is not difficult for organizations to come up with how they plan to assess risk when doing FMEAs. Some organizations prefer numeric scales, sometimes tied to metrics. Other organizations prefer a simpler risk scale: Minor, Marginal, Critical, and Catastrophic with descriptions of those terms defined. Define a standard set of risk level terms and criteria the team will use. In general, for consistency and usability, the more these are based on objective measures, the better. The main goal is to discuss your needs and come up with a plan everyone agrees with.
How do you determine which risks are most critical and need to be addressed?

Once risk levels can be assessed in some way, you then look at how to delineate those most critical to those that are minor. What you need to determine is what effects you will address with an action plan. Though your FMEA will include all potential effects, you want to prioritize your efforts in eliminating or mitigating those that are most detrimental to your system. Define your risk level grading system and then employ it across all your FMEAs.
3 How do you assign action items?

Your risk assessment guidelines will automatically determine which failures your team needs to focus on. At that point, you need to decide how you are going to assign action items. You need a way in your FMEA Worksheet to assign an action item to a team member, or a group of team members. You should also designate due dates for task completion. Even more helpful, it may be helpful to implement some type of notification system so that team members are notified of assignments and due dates.

4 How do you follow up on action items?

The final step is to determine your process for action item follow up. Who is responsible for following up on action items? How do you determine if an issue has been properly addressed? What is your process for dealing with overdue action items? Once again, define your process and communicate it to your team.

You want to make sure your FMEA document provides direction. Otherwise, the real advantages of your analysis will not be gained. For meaningful direction, you need to ensure that your FMEA focuses on items that are clearly critical, and also tracks the actions required to manage those items.

Having defined risk criteria, along with defined action plans with responsibility assignments ensures your FMEAs provide real value.
Challenge #5: Ensuring You Don’t Repeat Past Mistakes

Learning from past mistakes may be not only one of the most beneficial results of a FMEA, but at the same time one of the most overlooked. It is not that anyone disputes how advantageous building on past knowledge is - it is just that there is rarely a concerted effort, or an efficient way, to do it.

So how do you make your FMEA a living document – one that can be referred to, one that can be built on as you move forward?

One key item to remember is that teams will always change. Even with an attempt to keep team members intact for knowledge and expertise, we all know that personnel changes are a part of corporate life, for a multitude of reasons. So the best path is to accept this, and ensure that you capture the knowledge gleaned so it is not lost.

First, banking your FMEA knowledge in some way ensures FMEA efforts are not repeated. We have often heard someway say, “This seems familiar. I think we talked about this before.” Even looking back over archived FMEAs, you can see a pattern of repetition. The lack of efficiency becomes apparent.

Secondly, banking your FMEA data ensures that past mistakes are not repeated. For example, perhaps you overlooked a particular failure mode in your last analysis, but it was uncovered in the field. You then went back to the FMEA to add this newly discovered item in and completed your analysis. However, what happens when the next FMEA is done and once again that failure mode is overlooked? By having a data bank of past FMEAs, you can recover this information and have a starting point for your new FMEA that not only offers time savings, but also ensures your past mistake is not repeated.
Overcoming this challenge requires a bit more of an effort in selecting your method for completing your FMEAs. A choice for the easiest and least expensive option for performing FMEAs is often chosen without considering the consequences. For example, we see instances where FMEAs are done with basic Excel spreadsheets. While this may work fine for a one-off, simple FMEA, it cannot be expected to handle the complexities or have the depth of features required for complete FMEAs that a software package designed for FMEAs has. FMEA software built on databases offer a much more robust solution for your analyses. Plus, these packages often come with features meant for capturing lessons learned, archiving FMEAs for future reference, and searching abilities to automate FMEAs.

**Conclusion**

FMEAs are one of the most commonly used techniques for failure risk analysis due to their proven benefits. Their inherent variability in application and practice pose a unique set of challenges for analysts. Understanding what the challenges are prior to embarking on the details of the FMEA itself enables you to define an action plan to tackle them before they become problems for your team.

We’ve considered just five key challenges that are commonly encountered. Go through the action plans suggested for overcoming these challenges. Then open up a discussion with your team on other challenges that have been confronted and come up with action plans for those items. This upfront planning will ensure that you are getting optimal benefit from your FMEA efforts.