# Safety Bulletin
# Adding Value to the Design Process Through Failure Modes Effects Analysis (FMEA)

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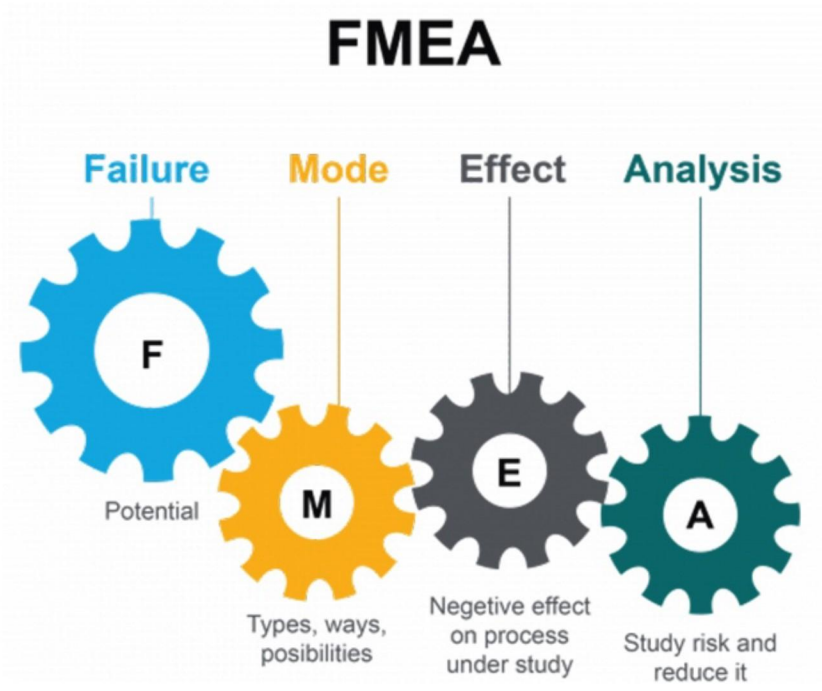
## Introduction

*Failure Modes Effects Analysis (FMEA) is a team methodology for evaluating potential failures for a design or process. First, failure modes are brainstormed by the team for not just the design or process as a whole, but also for assemblies and components within the design or process. After identifying these failure modes, specific causes are found, which could ultimately result in the occurrence of the failure mode. These failure modes/ causes are further assessed as scenarios. Scenarios are risk-ranked for consequence severity, likelihood of occurrence, and based upon the ability to detect. These risk-rankings are then multiplied to determine the Risk Prioritization Number (RPN). Recommendations are written if the scenario is above a pre-determined risk threshold, or if the team identifies further opportunities for improvement. The goal of the FMEA is to identify, assess, and document all known failure modes. This is done to develop robust follow-up plans for further risk mitigation.*

*For project teams, the FMEA can be an important springboard to further design improvement. If structured well, the study sessions can be value-add discussions that drive alignment on key project risks. In an ideal FMEA, the project team covers all aspects of the design. In essence, each team member is taking a step back from their day-to-day job and looking at the design from both a birds-eye view and detailed view at the component level. They are both brainstorming what could go wrong with the design and identifying opportunities for further improvement.*

*This Safety Bulletin provides three tips for improving the structure of the project FMEA work process. Implementing these tips can help improve the FMEA work process and result in FMEAs that are beneficial to the project team.*




## In This Issue

This Safety Bulletin provides three tips for improving the structure of Failure Mode Effects Analysis (FMEA) studies. Implementing these tips can help improve the FMEA work process and result in FMEAs that are beneficial to the project team.

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# Pre-Populating the FMEA Worksheet

Prior to conducting the FMEA study, the facilitator can pre-populate design information into the FMEA worksheets. This information can then be used and expanded-upon by the FMEA team.

**Tip #1: In order to brainstorm all the necessary scenarios in an efficient way, it is important to populate the FMEA worksheets with possible failure modes prior to the study sessions.**

This allows the Team to quickly begin brainstorming potential causes for these failure modes, resulting in more engagement and increased efficiency. The failure modes should be organized by system, assembly, and sub-system to the degree possible. For instance, all components of a sub-system may be listed as separate component failure modes. Then, the FMEA team can discuss what causes may result in component failure. After assessing each system, assembly, and sub-system in the FMEA study sessions, the facilitator should conduct further brainstorming for additional failure modes. This can be accomplished by asking the following questions:

- Are there any additional components in this system, assembly, or sub-system that we haven't discussed yet?

- Are there any additional failure modes present as a result of these components functioning as a working system, assembly, or sub-system that we haven't discussed yet?

Brainstorming additional failure modes in this way will help ensure a comprehensive FMEA assessment.

# FMEA Risk Matrix

There is no one-size-fits-all risk ranking matrix for conducting FMEAs; therefore, an FMEA matrix needs to be selected or developed prior to the study.

**Tip #2: The facilitator of the FMEA study should work with the project team to ensure the proposed risk matrix will adequately differentiate a wide range of risks for the project.**

If the risk matrix buckets are too broad (the matrix is too small), the risk-ranking may not be particularly meaningful to the project team. Remember, the goal of the FMEA is not only to identify failure modes, but also to differentiate the level of risk.

| Ranking | Severity of Effect on Product (S) | Likelihood of Failure (L) | Ability to Detect (D) |
|---|---|---|---|
| 10 | Potential failure mode affects safe operation or regulatory requirements, without warning | >1 in 2 | No known control(s) available to detect failure mode |
| 9 | Potential failure mode affects safe operation or regulatory requirements, with warning | 1 in 3 | Very remote likelihood current control(s) will detect failure mode |
| 8 | Loss of primary function | 1 in 8 | Remote likelihood current control(s) will detect failure mode |
| 7 | Degradation of primary function | 1 in 20 | Very low likelihood current control(s) will detect failure mode |
| 6 | Loss of secondary function | 1 in 80 | Low likelihood current control(s) will detect failure mode |
| 5 | Degradation of secondary function | 1 in 400 | Moderate likelihood current control(s) will detect failure mode |
| 4 | Item operable, but with annoyance noticed by >75% of customers | 1 in 2,000 | Moderately high likelihood current control(s) will detect failure mode |
| 3 | Item operable, but with annoyance noticed by >50% of customers | 1 in 15,000 | High likelihood current control(s) will detect failure mode |
| 2 | Item operable, but with annoyance noticed by >25% of customers | 1 in 150,000 | Very high likelihood current control(s) will detect failure mode |
| 1 | No noticeable effect | 1 in 1,500,000 | Current control(s) almost certain to detect failure mode. Reliable detection controls are known with similar processes. |

In selecting an appropriate risk matrix, it might be best to first consider a larger risk matrix that provides more differentiation for each risk-ranking category: consequence severity, likelihood of occurrence, and ability to detect. Then, if needed, the FMEA risk matrix can be adjusted to better fit the project objectives.

The 4 x 10 matrix provided on the previous page can be used as a starting point for developing a FMEA Matrix for design FMEAs. This matrix should be customized to differentiate risks specific to the design, as necessary. This can be accomplished by testing a few potential failure scenarios through the matrix in advance of the team sessions. The highest risks for the project team should yield a higher Risk Prioritization Number (RPN) than lower risks.

Some companies try to use a smaller matrix to make the risk-ranking process easier or to correlate with an existing company risk matrix that is used for other assessments. While it might make the FMEA risks a little easier to pinpoint on the FMEA matrix, making the FMEA matrix smaller can lead to a lack of risk differentiation, which can negatively impact the study. A preferred approach would be to use a larger matrix and for the facilitator to guide the team when ranking specific scenarios.

Once the FMEA matrix has been determined, the facilitator should share it with the FMEA team members. That way, the team members can be prepared to risk rank scenarios based on the parameters identified in the matrix.

# Pre-Established Criteria for Recommendations

A common pitfall for FMEA teams is that after completing the risk ranking for a specific scenario, it may not be clear when recommendations are required. Is the risk high enough to warrant follow-up work? However, this ambiguity can be avoided.

**Tip #3: Developing criteria for when FMEA recommendations are required should be done prior to the study.**

If recommendation criteria is pre-established, it is clear to all team members when a recommendation is required versus when a recommendation is optional. Then, the team can quickly align around the risk scenarios where there is a need for follow-up. The Risk Prioritization Number (RPN) can be used to trigger threshold criteria for when a recommendation must be made. Example threshold criteria is provided below, using a Green, Yellow, Orange, and Red scale based on the scenario RPN value. Recommendations should be written to reduce risk below a threshold level. For instance, implementation of an action item should shift the RPN such that the scenario risk shifts from Orange to Yellow or Green.

| Risk Prioritization Number (RPN) = S x L x D | |
|---|---|
| **RPN Range** | **Risk Rank Shading** |
| RPN > 400 | |
| 200 < RPN < 400 | |
| 100 < RPN < 200 | |
| RPN < 100 | |
| ***Recommendations will be written to mitigate all Orange and Red risks.*** | |

# Conclusion

FMEAs can be a value-add activity for a project team. With some prework to study sessions, the FMEA can be run in a focused and efficient manner.

Three tips for improving the structure of FMEAs are:

1. In order to brainstorm all the necessary scenarios in an efficient way, it is important to populate the FMEA worksheets with possible failure modes prior to the study.

2. The facilitator of the FMEA study should work with the project team to ensure the proposed risk matrix will adequately differentiate a wide range of risks for the project.

3. Developing criteria for when FMEA recommendations are required should be done prior to the study sessions.

References:

1. Severity of Effect on Product- "Effective FMEA" by Carl S. Carlson
2. Likelihood of Failure and Ability to Detect- sixsigmadsi.com
3. Risk Analysis – FMEA (Failure Mode Effect Analysis) (gminternational.com)

Nebula Safety and Environmental has experience in setting-up and facilitating FMEA studies. Please reach-out to the Nebula Safety and Environmental Team at NebulaSafety.com for additional information.