"Risk Mitigation and FMEA's: How to Determine What's Important and What's Not?"

Have you ever seen a design fail and wondered why they did it that way when it could have been easily prevented?

In most cases, you'll find that when a complicated, innovative project is started, the design team typically ends up going full speed. This is usually to get to where it's generating at least some revenue before running out of funds for the project. As production ramps up, the outcome is far from perfect.

This is where a failure modes and effects analysis (FMEA) can help. It's a method to let a team of experts take a step back and look for ways to mitigate issues before they come up.

But here's the conundrum: what risk assessments should be pursued and which should be low priority or even completely ignored?

This guide will help you decide the timing and method needed to get the most benefit for the least effort.

What Potential Risks Should Be Considered?

Most legacy standards mandate criticality be selected—-and most details are left to the user. This creates three scenarios:

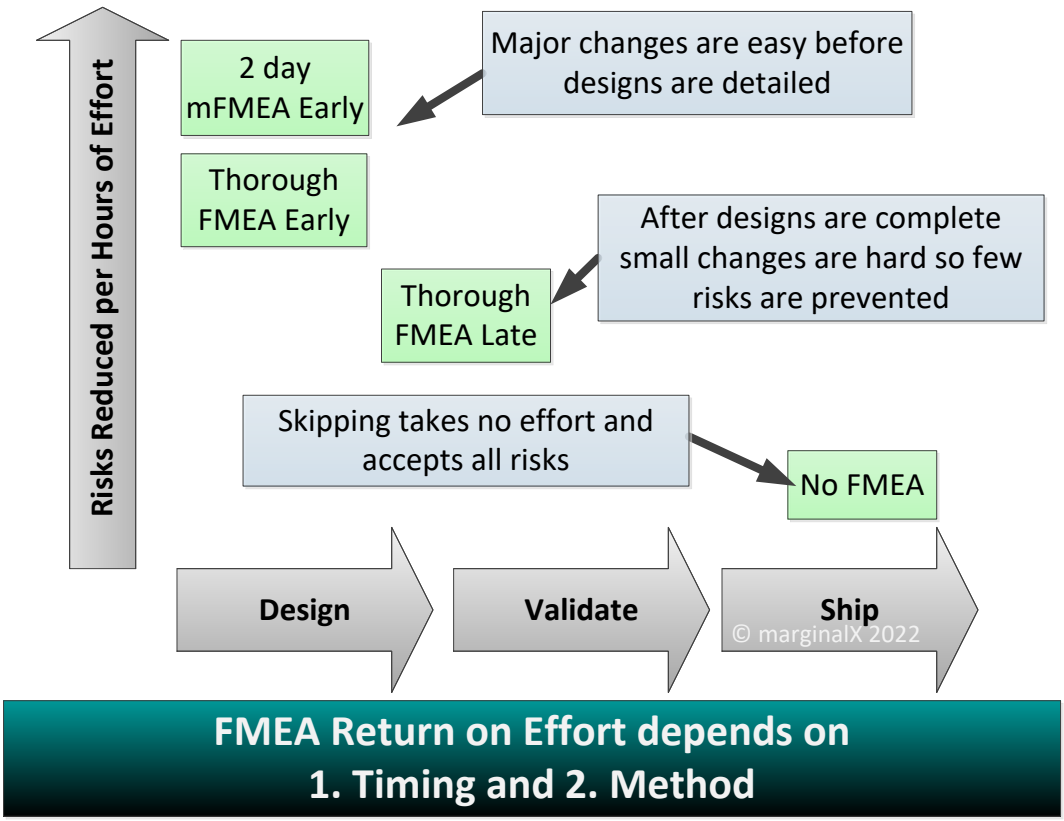
1. Little to no risk management is realized in spite of meeting the letter of the procedure.
2. A tremendous amount of work is done, yet few or no risks are mitigated.
3. There is a good balance of time and the serious risks are designed out. This is the desired scenario we want.

The glaring challenge with any FMEA is finding which risks need to be mitigated, which are trivial and which ones can be ignored.

Criticality

One challenge with an FMEA is many risks can be imagined prior to implementation, while many are either trivial or have a low possibility of happening. Attempting to mitigate everything has diminishing returns so the highest risks need to be identified and tackled first.

If your customer provides a scale and cites a specific method then, by all means, use those. If you don't have specific customer requirements and are being proactive, the charts below will help you decide the method and time to use.



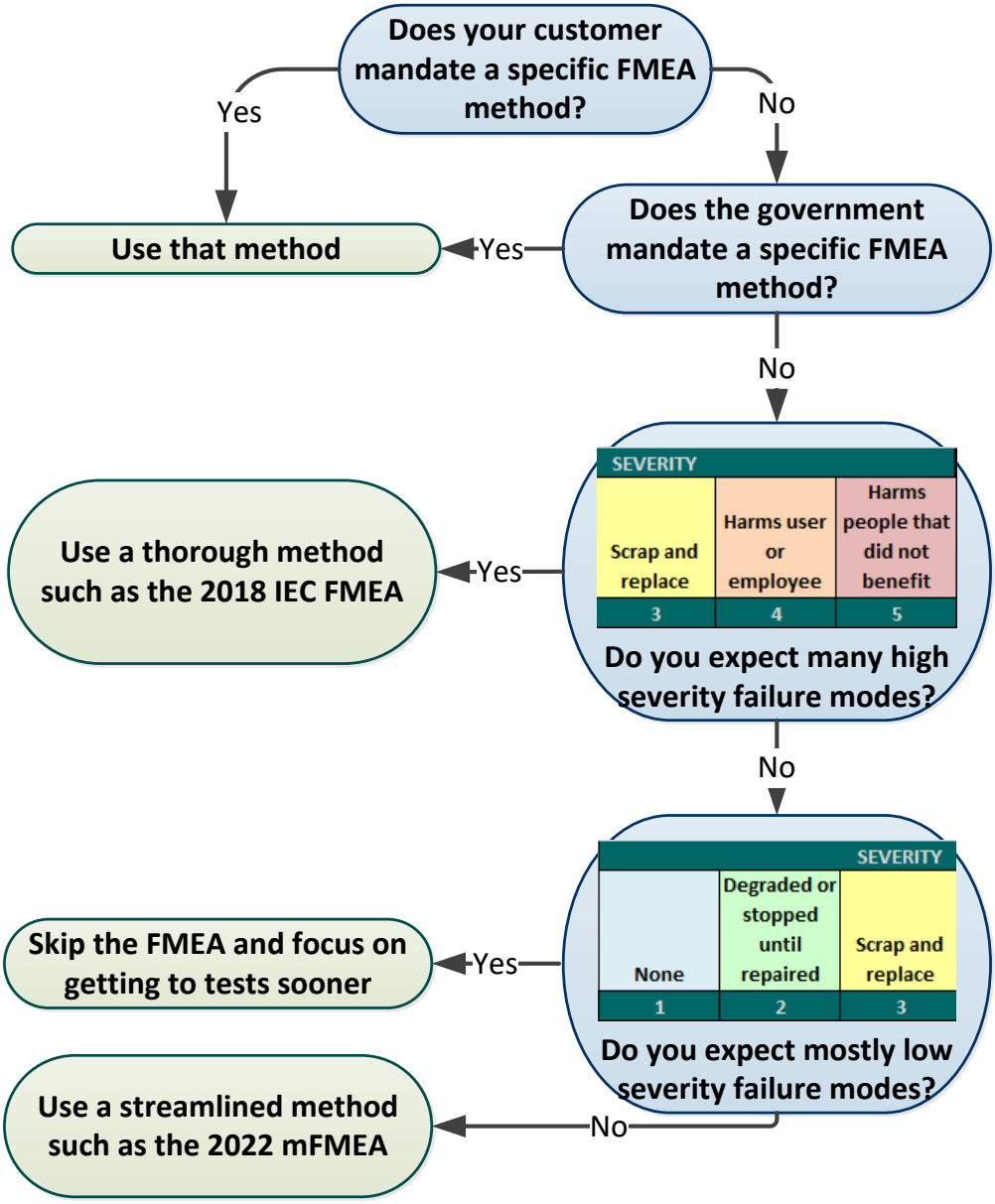
How Much Effort Is Required?

In the engineering space, time is money, so determining the level of effort required on a particular assessment should be considered.

Most guides require cutoffs and scales to be adjusted and tailored to fit every project. While this can maximize flexibility, it also means some teams may not be doing enough and others are doing too much. It takes time and attention to choose the correct scales and then building consensus can be challenging.

Using absolute scales puts risks in perspective across industries, customers, and systems. It saves the team time and effort from tailoring everything to adopt an existing solution to focus on completing the design sooner. All of the thorough methods use relative scales and the streamlined mFMEA method uses one universal scale for every project.

Decision Tree for Choosing When None, Thorough or a Balanced FMEA



You can now use this guide as a reference to provide a framework for prioritizing risk assessment on projects.

In conclusion there are three questions to make the best choice. First, when is the best time? Too soon and there isn't enough of a system defined to make brainstorming effective. Too late and changes become too hard. The best time is after functions have been defined and before too many details have been decided. The second choice is the level of effort to spend. Perhaps skip it completely, a meticulous method, or a balanced approach. The final question is if doing a comprehensive method which one? If balanced then the mFMEA is best.

Relative Vs Absolute Scales
Most FMEA guides require cutoffs and scales to be adjusted and tailored to fit every project.

These are relative scales. Another option would be universal scales that work without customizing.

Let me offer an example of each to explain:

For relative scales, let's take a high-risk application like designing oxygen gear for a Mount Everest climb. The team decides a single death to be bad and multiple deaths to be worse. So, they assign a level 5 to an explosion risk because it would hurt more than just the user, and a level 4 to an oxygen leak because it could cause just the user to run out of oxygen near the peak.

Meanwhile another team is doing an FMEA with a relative scale for a cooling pump and severities from 1 to 4. The team decides failures that can't be repaired is a total failure and assign that a 4. If it was a repairable failure, it may be assigned a 3. To simplify this example both used the same probability scale 1 to 5.

The tailored, relative, criticality scales and cutoffs to act on a failure mode may also be adjusted and defined by every team for every project and shown in this example. Every program chooses what scales to use and defines the criticality table, this makes them relative because severities like "2" or what criticality cell in the table is "Acceptable" is different for every case.

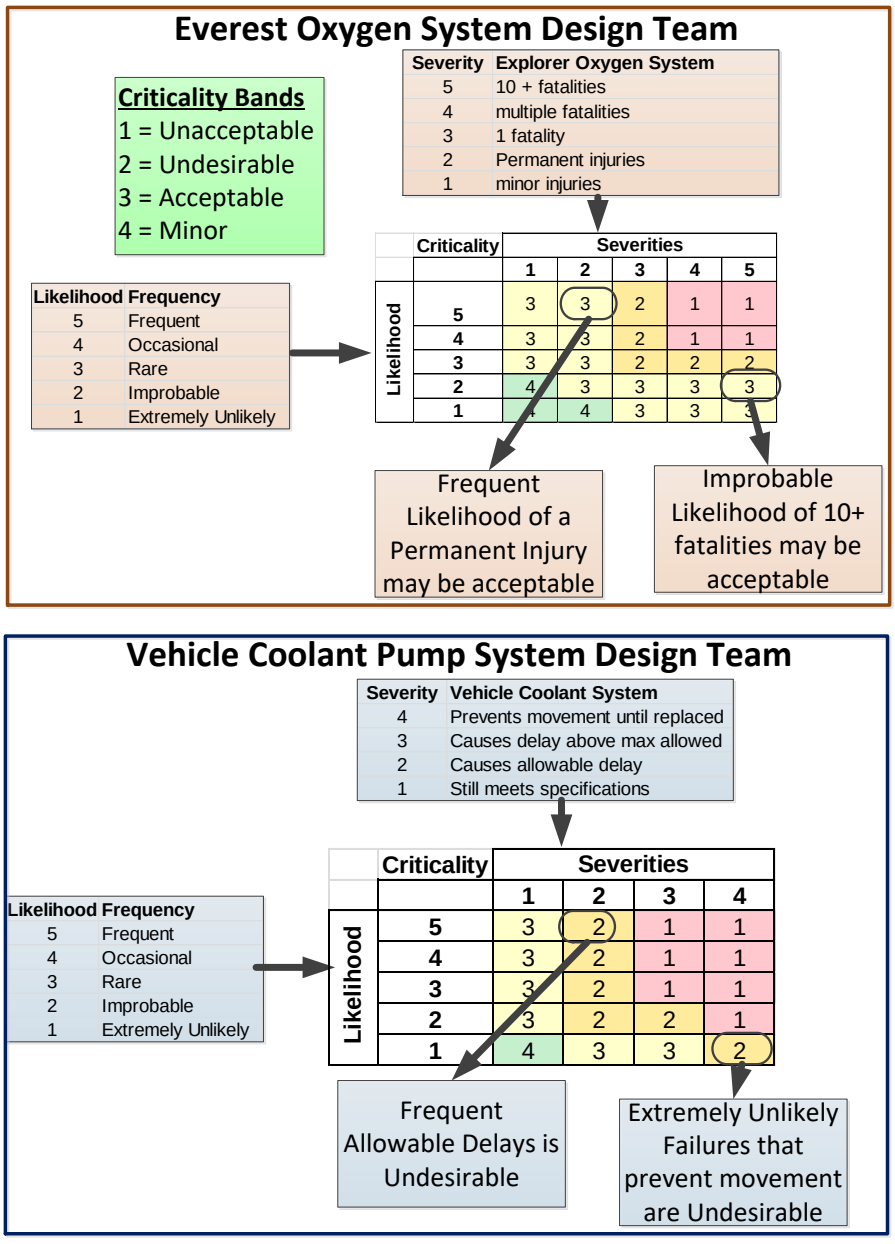


Fig1. Relative Scales and Criticality Example

You can see in Fig 1 how the two lead the riskier design to ignore issues that people might not tolerate, and how the pump team may be addressing more issues, all of which are much lower risk.

For contrast a universal scale acknowledges we live in the same world and have similar ideas about what low and high risks are regardless of engineering team discussions. In Fig 2 the universal scale would cause the pump manufacturer to focus more on process quality, if anything. The oxygen system design team using

this scale would be driven to improve the design to make it fail safer or eliminate risks completely. This is a better use of scarce engineering attention during and after the FMEA, for both companies!

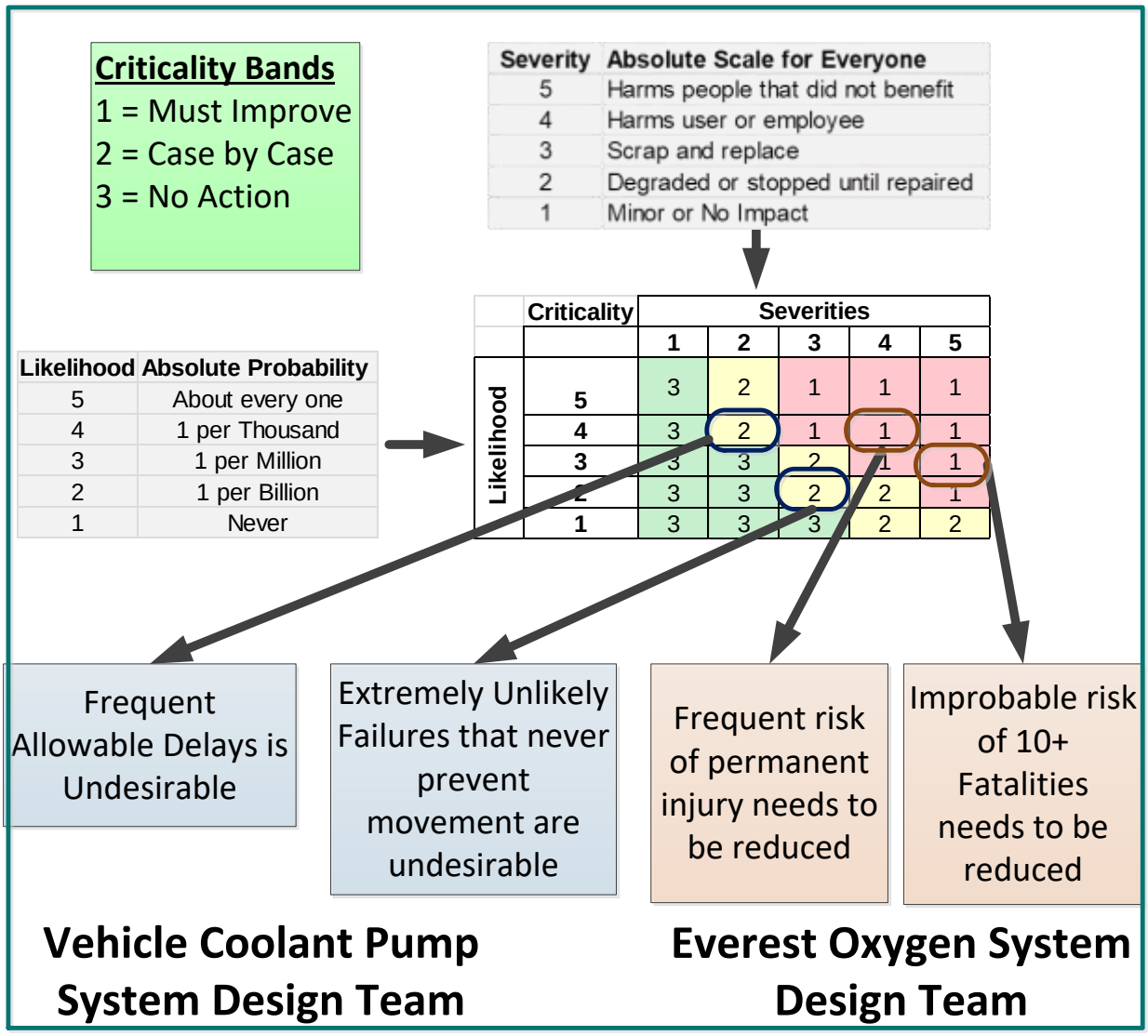


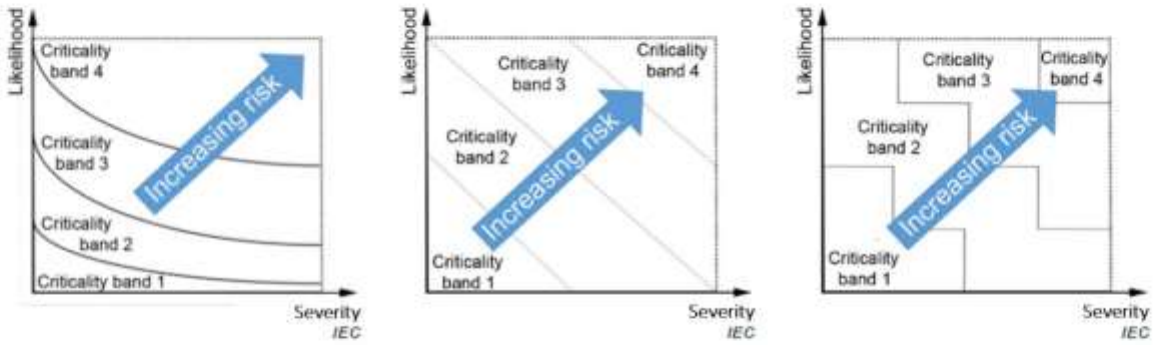
Fig 2. Universal Scales and Criticality Example

IEC 60812:2018 Relative Criticality Scales

	Criticality	Severities			
		1	2	3	4
Likelihood	5	3	2	1	1
	4	3	2	1	1
	3	3	2	1	1
	2	3	2	2	1
	1	4	3	3	2

Criticality Bands
1 = Unacceptable
2 = Undesirable
3 = Acceptable
4 = Minor

The International Electro technical Commission FMEA procedure allows any criticality table and suggests a few ways 4 criticality bands can be established



Example A **Example B** **Example C**

IEC60812:2018

The terms Likelihood, Probability, and Occurrence are used for estimating how often a failure mode may happen. Detectability may be scored but is not used for criticality.

mFMEA:2022 Universal Criticality Scales

This is intended to be a universal scale and not meant to be tailored for two reasons.

UNIVERSAL FMEA SCALES		SEVERITY				
		None	Degraded or stopped until repaired	Scrap and replace	Harms user or employee	Harms people that did not benefit
Probability	RANK	1	2	3	4	5
~ 1 per each	5	N	M	H	H	H
~1 per Thousand	4	N	M	H	H	H
~ 1 per Million	3	N	N	M	H	H
~ 1 per Billion	2	N	N	M	M	H
Never	1	N	N	N	M	M

1. This Severity scale can help decide what FMEA method to use

If you expect most failure modes in this range perhaps skip FMEA

If you expect many failure modes in this range please do a thorough FMEA

If you expect few harmful and otherwise a wide range of outcomes then a streamlined mFMEA is best

2. If the mFMEA method is chosen then universal scales accelerate decision making during the process

Criticality	Action
H	High: Must improve design or get better information
M	Marginal: consider case-by-case
N	No action: ok to consider removing a mitigation to save cost and schedule

FMEAs

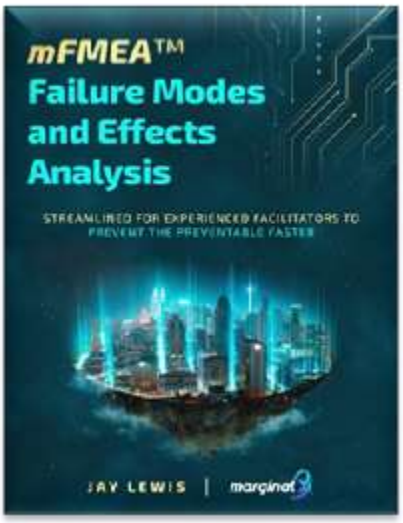
And when you determine that a FMEA needs to be implemented, there are a lot of options out there. There are almost too many to make an informed decision on the best one that's going to save you the most time and money. All things considered there are two I recommend.

1. **IEC 60812 Analysis Techniques For System Reliability – Procedure For FMEA.** This legacy methodology is designed to be thorough and flexible so that it can be tailored for every team to fit your particular situation. This is a comprehensive and thorough approach that leaves no stone unturned in risk mitigation.

$392.00 At the American National Standards Institute Webstore

2. **mFMEA 2 Day FMEA Procedure with template and handouts.** This is an 80/20 streamlined FMEA designed to capture most of what an exhaustive method would uncover. The distinction is that it helps teams save precious time and eliminate risks earlier in the design. This will help an experienced facilitator complete an FMEA within 2 days with 3 sessions. The link goes to a short phone call to answer any questions you have.

$97.00 Schedule a call by 18 November 2022 to get the extras: https://calendly.com/marginalx/reducerisk



Extras for Those Who Order by November 18

You Will Save Your Startup Over a Million Dollars in Two Days

The 2 Day mFMEA Procedure is a lean system FMEA to help smaller teams get results as good, or better, than companies with much larger staffs.

Ultimately what counts are changes that prevent preventable problems. By using this method your cross functional team can identify these faster and implement them sooner.

When you purchase the 2 Day mFMEA with template and handouts you will get the procedure, handouts, and a template with examples.

And those who purchase by 18 November 2022 also get 100% support to include:

- **Advance support to plan the FMEA sessions.**
- **A walk through in advance on using the method to ensure your success.**
- **Email and phone support throughout the process.**

* Normally this level of support would be charged at my consulting rate worth over $8000. This is why I'm limiting this. It's important to me that you are successful.

You get all this included free for the $97 price of the procedure.

Before making a decision I encourage you to book a 15-minute call so that I can answer any questions you have: https://calendly.com/marginalx/reducerisk

About Jay…

Jay Lewis is the principle consultant for Marginal X. As an electrical engineer, he has redesigned aircraft electronics systems using Value Engineering principles. He has also taught and coached dozens of engineers across many disciplines as a Design for Six Sigma Black Belt. He's used both innovations listed above when facilitating over 10,000 hours of FMEAs for Medical Devices, Spacecraft, Aircraft, and Renewable Energy. His 2 Day mFMEA with template and handouts is the first time all best practices and innovations are in one place.