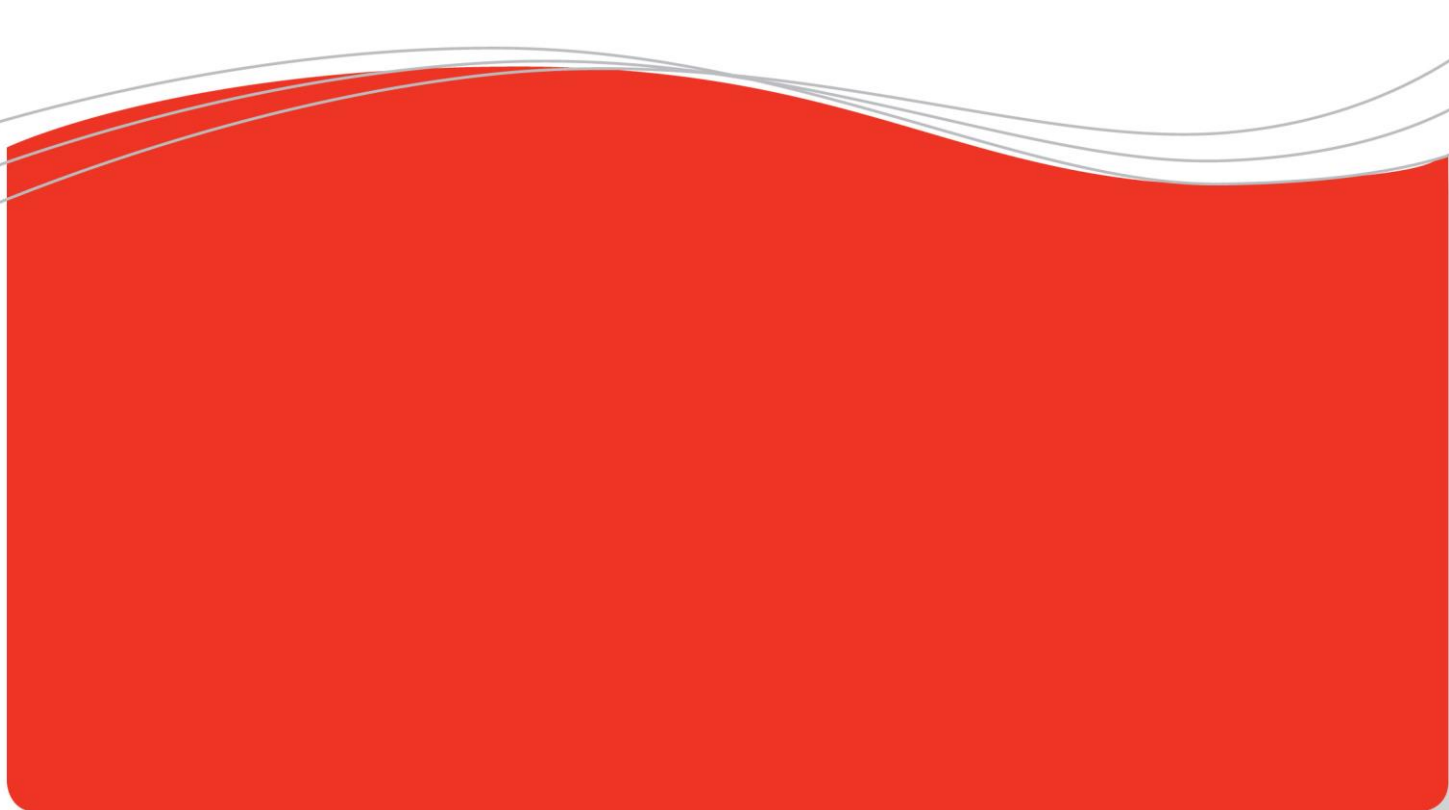




## Prioritizing risk in FMEA

By Charlaine Wijkniet





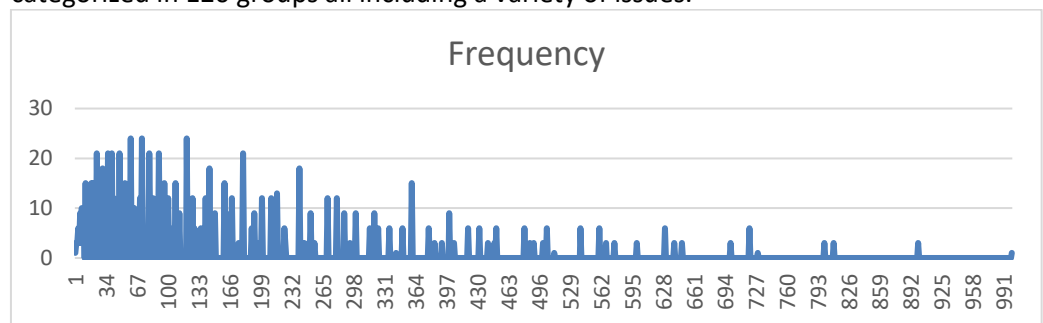
## Prioritizing risk in FMEA

### INTRODUCTION

The purpose of an FMEA process is to continuously improve the process to reduce risks. The FMEA is of course a living document and will be re-evaluated many times during its lifecycle, and each new revision will show changes in the risk analysis. But how do you determine which risks demand immediate action?

Risk Priority Numbers are, or better yet were, the most common way to assign priority in an FMEA. An RPN is calculated by multiplying the Severity with the Occurrence and the Detection, and as these three will get a number between 1 and 10 then the RPN would be a number between 1 and 1000. Over the years many concerns have come to light regarding the use of RPN numbers.

The first problem here is that the RPN will not be just any number between 1 and 1000, there are only 120 options. This means that 1000 potential issues will be categorized in 120 groups all including a variety of issues.



*Figure 1: Possible values of RPN and frequency of possible combinations of severity, occurrence and detection*

The second problem here is that the 120 groups are not evenly spread out on the 1-1000 X-axis.

The third and most important problem is that severity, occurrence and detection are treated similar in the RPN number and that should not be the case.

So, let us look at an example.

Situation 1: S=8 O=5 D=9 RPN= 360

Situation 2: S=10 O=6 D=6 RPN= 360

Situation 3: S=6 O=6 D=10 RPN= 360



Are these situations really that similar? In situation 2 we have a Severity of 10, which means there is a safety issue occurring without warning. Whereas in situation 3 it is not possible to detect the issue, but it is less severe. Therefore, they are not really comparable.

While RPN has been the most common way to evaluate and prioritize risks, because of the issues mentioned above, and several more, many new methods for prioritization have been introduced. The latest one being Action Priority introduced in the new harmonized FMEA VDA handbook. This article will highlight the positive features as well as the problems of the different new methods. Topics discussed are Risk Priority Matrixes, Action Priority, and the Criticality Matrix. This article will also present the benefits of using DataLyzer FMEA to prioritize risks.

### RISK MATRIXES

There are several ways to use risk matrixes to prioritize risk. Some companies use RPN combined with an SxO matrix. VDA (4<sup>th</sup> Edition) works with a risk matrix set of SxO, SxD, DxO and a Risk Matrix Ranking table. These matrixes use color coding, normally Red, Yellow and Green.

Some companies use a similar system where they use numbers (1,2,3) instead of colors, but the logic behind it is the same. Priority 1 is the highest and 3 is the lowest. Then the 27 possible combinations are categorized. If there is any "Red" or "1" in one of the matrixes, it's impossible to get a priority 3 or color "Green". This will ensure that you will take a critical look at any characteristics that have a high Severity, Occurrence or Detection associated with them. The problem with this approach is that you need to assign colors yourself, so you are going to assign colors based on combinations which you think are important. The rule that any red will lead to a red in the final matrix means it is hard to find the right combination and you might end up with no red in the matrix occurrence x detection. If you use default settings, you might get too many items that need attention. This is demonstrated in the picture below.

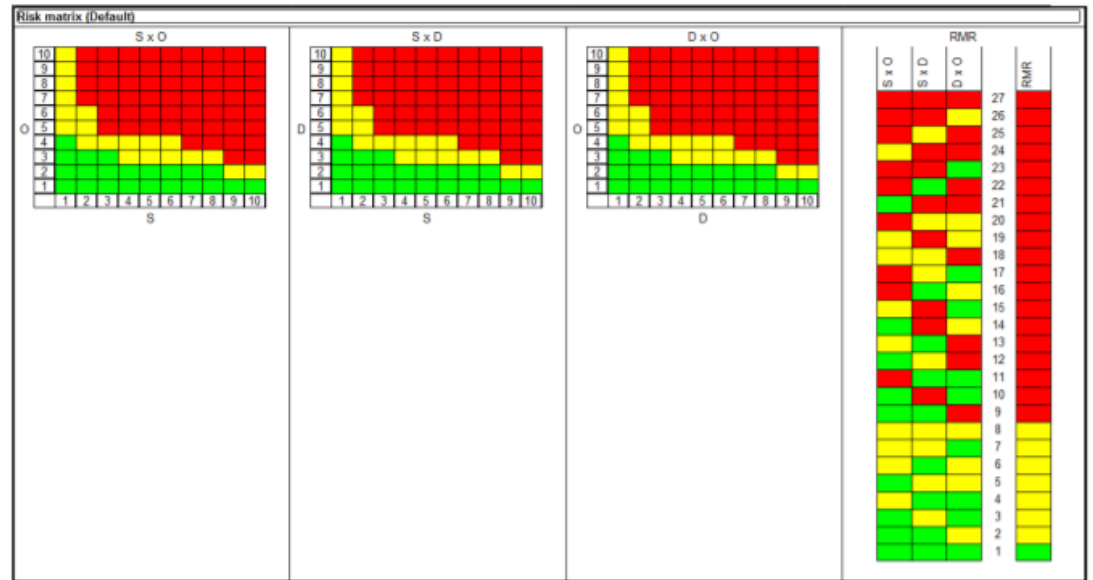


Figure 2: Example of a Risk matrix

### Action Priority

The new harmonized AIAG VDA (1<sup>st</sup> Edition) FMEA uses a table called Action Priority. It is basically the same approach as the risk matrix, except it does not look to the 3 matrixes but directly to the combination of Severity, Occurrence and Detection. AP sets the risk by weighing Severity the highest, then Occurrence and lastly Detection, according to a Justification Table (see figure 3).



Action Priority (AP) for DFMEA and PFMEA								
Effect	S	Prediction of Failure Cause...	O	Ability to Detect	D	ACTION PRIORIT...	Comments	
Product or Plant Effect Very high	9-10	Very high	8-10	Very high	1	H		
				Low - Very low	7-10	H		
		High	6-7	Moderate	5-6	H		
				High	2-4	H		
		Moderate	4-5	Very high	1	H		
				Low - Very low	7-10	H		
	7-8	Moderate	4-5	Moderate	5-6	H		
				High	2-4	H		
		Low	2-3	Very high	1	M		
				Low - Very low	7-10	H		
		Very low	1	Very high - Very low	Moderate	5-6	M	
					High	2-4	L	
Product or Plant Effect High	7-8	Very high	8-10	Very high	1	H		
				Low - Very low	7-10	H		
		High	6-7	Moderate	5-6	H		
				High	2-4	H		
		Moderate	4-5	Very high	1	M		
				Low - Very low	7-10	H		
		Moderate	5-6	M				

Figure 3: Action Priority Justification matrix in DataLyzer FMEA

The combination of Severity, Occurrence and Detection will give an Action Priority of High, Medium or Low. Because the Severity is weighed the highest, you will more likely get a High priority for any item that has a high Severity. As you can see, there is also a comment column, so when company specific guidelines have been discussed, they can be entered in the Action Priority table. This method also creates the necessary space to work on critical issues first.

The AIAG VDA FMEA (1<sup>st</sup> Edition) manual states about Action Priority:

“Priority High (H): Highest priority for review and action. The team needs to either identify an appropriate action to improve prevention and/ or detection controls or justify and document why current controls are adequate.

Priority Medium (M): Medium priority for review and action. The team should identify appropriate actions to improve prevention and/ or detection controls, or at the discretion of the company, justify and document why controls are adequate.

Priority Low (L): Low priority for review and action. The team could identify actions to improve prevention and detection controls.”

In figure 4 we show the relation between RPN and Action Priority:

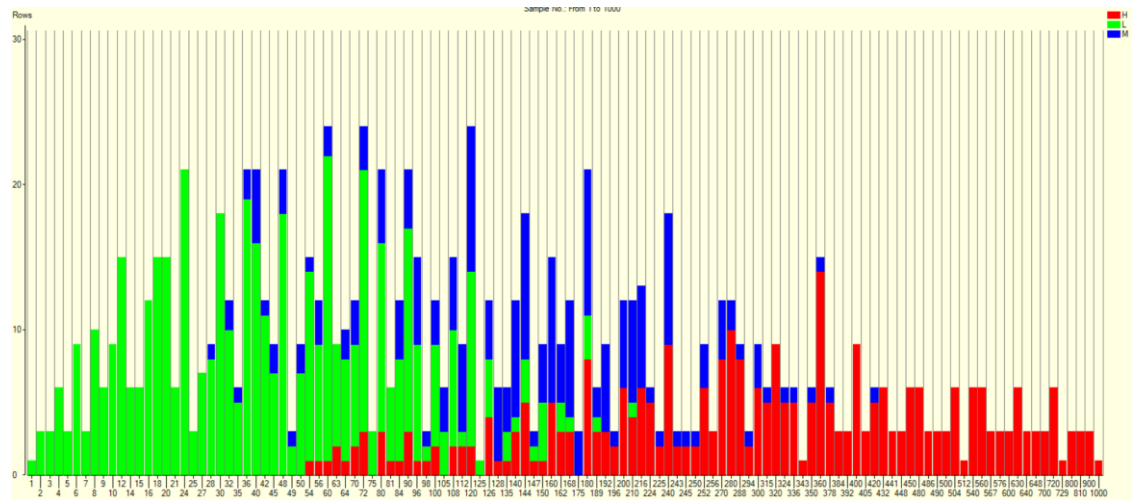


Figure 4: relation between RPN and Action priority, with 0 combinations excluded

Figure 4 clearly shows why RPN is not a good method to use. We see Action Priority items High with an RPN of 56 but also low priority items with an RPN of 210.

The problem with Action Priority as noted by first adopters, is that the categories are very broad. You might have a very large number of High-risk items, so how can you prioritize when you have a large number of items that require immediate action?

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### Classification Symbols

Another way to evaluate risks is by using Classification symbols. This can be done in multiple ways. Sometimes the critical characteristics are mentioned on the drawing or Design FMEA, or they can be internally determined.

It is also possible to use a criticality matrix. Using a criticality matrix means that a classification symbol will be entered based on Severity and Occurrence. Combinations of Severity and Occurrence can have a symbol attached to them. Normally the symbols will only be attached to characteristics with a high Severity or a combination of high Severity and Occurrence. The idea with this method is you prioritize on requirements that have a classification symbol associated with them.

Prioritizing on classification means that all predetermined items, e.g safety characteristics and critical characteristics will need extra attention. This, however, creates another problem. Which symbols have the highest priority? The





characteristics on the drawing/ DFMEA or the characteristics that have symbols attached because of the Criticality Matrix? Furthermore, how can you clearly state where the symbols came from on your PFMEA?

A clear advantage of using classification symbols is that you can standardize the usage on all documents including control plan and SPC control charts/data sheets on the shop floor, so it becomes obvious immediately that a specific characteristic/requirement is important.

### DataLyzer FMEA options

There is not one best recommendation which method should be used. For example, although it is becoming more and more obvious that RPN is not the best method, still more than 50% of customers are requiring RPN numbers to be reported, so you might be forced by customers to apply that method as well.

Different methods might also serve different purposes. The Action Priority will be used to establish priorities for engineering actions. Classification symbols partly serve the same purpose, but they will also be used to inform everybody involved clearly about the importance of a requirement.

So, in DataLyzer FMEA we offer different methods like RPN, Action priority, Criticality matrix and Classification Symbols which can be used in any combination and in different processes.

For example, in analyzing the FMEA you can group all failure modes, causes and actions according to Action Priority giving the process owner much more insight into priorities and the status of actions.

Drag a column header here to group by that column

Docume... Name	Step / Function	Require...	Failure Mode	Effect	Sev	Potential Cause of Failure	Controls Prevent...	Occ	Controls Detection	Det	Old AP	RPN	Recom... Action	Respons... /Target Comple... Date	Action taken / Comple... Date	Sev	Occ	Det	RPN	New AP
Beer brewi...	Process...	req 1	Equipment ...	[5%...	8	[Instructio...	Initial Stat...	7			7 H	392				0				0
Beer brewi...	Process...	req 1	Equipment ...	[5%...	8	[Instructio...	Initial Stat...	6			7 H	336				0				0
Beer brewi...	Process...	req 1	Equipment ...	[5%...	8	used to...	Instruction...	3	none		10 M	240				0				0
Beer brewi...	Process...	req 1	Equipment ...	[5%...	8	beforehand	Common...	3	none		10 M	240				0				0
Beer brewi...	Process...	req 1	Equipment ...	[5%...	8	organisms...	Controlled...	3	none		10 M	240				0				0
Beer brewi...	Step 4 /...	Characteri...	Wort is...	[5%...	7	beforehand	Common...	3	none		10 M	210				0				0
Beer brewi...	Step 4 /...	Characteri...	Wort is...	[5%...	7	organisms...	Controlled...	3	none		10 M	210				0				0
Beer brewi...	Function:...	requirement	Wort is...	[5%...	7	organisms...	Controlled...	3	none		10 M	210				0				0
Beer brewi...	step 6 /...	Characteri...	Wort is...	[5%...	7	beforehand	Common...	3	none		10 M	210				0				0
Beer brewi...	step 6 /...	Characteri...	Wort is...	[5%...	7	organisms...	Controlled...	3	none		10 M	210				0				0
Beer brewi...	Process...	Characteri...	Wort is...	[5%...	7	organisms...	Controlled...	3	none		10 M	210				0				0
Beer brewi...	Process...	Characteri...	Wort is...	[5%...	7	beforehand	Common...	3	none		10 M	210				0				0

Figure 5: FMEA before grouping



Docume... Name	Step / Function	Require...	Failure Mode	Effect	Potential Cause of Failure	Controls Prevent...	Occ	Controls Detection	Det	RPN	Recommended Action	Responsi... /Target Comple... Date	Action taken / Comple... Date	Sev	Occ	Det	RPN	New AP
Old AP: L																		
Old AP: M																		
Sev: 8																		
FMEA...	070 / Step...	Height	fail mode 70	Effect 70A	Action 70A		4			5	160			0				0
Old AP: H																		
Sev: 8																		
FMEA...	040 / Step...	Temperature	Failure mo...	Effect 10			6		6	288				1				0
FMEA...	050 / Step...	Temperatu...	Failure mo...	Effect 10		Poke Yoke	6	Datalyzer...	6	288	Implement PY device as instructed	n/s / ...	/ 29-08-2017	1				0
FMEA...	070 / Step...	Temperature	Failure mo...	Effect 10			6		6	288				1				0
FMEA...	010 / Step...	Temperatu...	Failure mo...	Effect 10 (8)		method A...	6	Camera (3)...	3	144				1				0

Figure 6: FMEA after grouping according to Action Priority and Severity

### Conclusion and future considerations

Prioritizing risk will always remain a discussion within the FMEA field, as not all options are suitable for every company, or even every industry. New factors come to light all the time. For example, environmental issues and the ecological footprint will have more impact on companies and will therefore somehow become part of the FMEA process.

Moreover, keeping in mind the COVID-19 pandemic; how has this been handled in regard to the FMEAs? Will we at some point need new classification symbols to indicate the ramifications of times when there are no more deliveries, or a sudden stop of production? Would it be possible to include contingencies if such a situation ever occurs again? Now is the time to consider how we can implement all these factors into the FMEA process.

Though there is no one method superior to the others, we can safely deduce that FMEAs are becoming more and more complex as time goes by. Using FMEA software with a database that allows you the flexibility to use multiple methods of prioritizing risk gives you an advantage, as you can manage information requirements for different type of users – Shop floor team, Engineers, Managers - in your company based on the same data source.





## ABOUT DATALYZER

Partners in continuous improvement for 40 years, DataLyzer provides a turnkey solution of training and software systems which includes:

- World-class Quality Management Systems consultancy
- Certificated, eLearning training - APQP, FMEA, Gage Management/MSA, Lean, OEE, Six Sigma and SPC etc.
- An integrated, modular suite of world-class software solutions
- Global installation and training services with continuing support and advice.

Software solutions include, Process Flow, FMEA, Control Plan; Ballooning, real-time SPC and OEE, with Gage Management/MSA, Mould Management, Certificate of Analysis (for reports like FAIR, ISIR and PPAP) and now developing CAPA.

We also provide integrated dashboards, providing advanced real-time/in-process, enterprise and supplier performance monitoring, analytics and reporting capability.

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