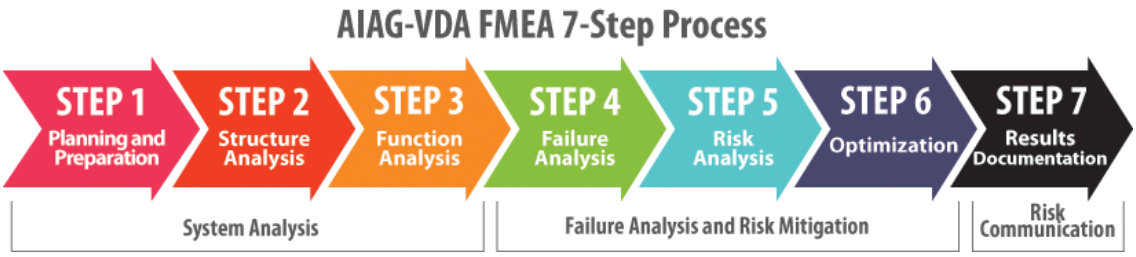
New Harmonised FMEA to be Released, June 2019

The final draft of the new handbook was approved by AIAG QSC on April 2nd, and is expected to be approved by VDA QMA on May 8th. The new FMEA manual will restructure the FMEA process. The manual is not yet released, but we know some of the proposed changes. In this article we will summarise the major changes and highlight those changes which are already available in DataLyzer FMEA software. When the new manual is released, DataLyzer is committed to implement any changes necessary to remain compliant to the new norm.

New Introduction Chapter

There is a new detailed introductory chapter, emphasizing and clarifying the foundations necessary to develop a robust FMEA. Here the use of 5Ts is added. In**T**ent-engaging the team by clarifying and defining the purpose and the scope of work, **T**iming-alignment with APQP Phases, **T**eam-defining typical roles and responsibilities, **T**ask-use of 7 Step Approach, **T**ool-FMEA examples, including software and traditional spreadsheets as a project planning approach for the development of FMEA's.

The new 7 step approach:

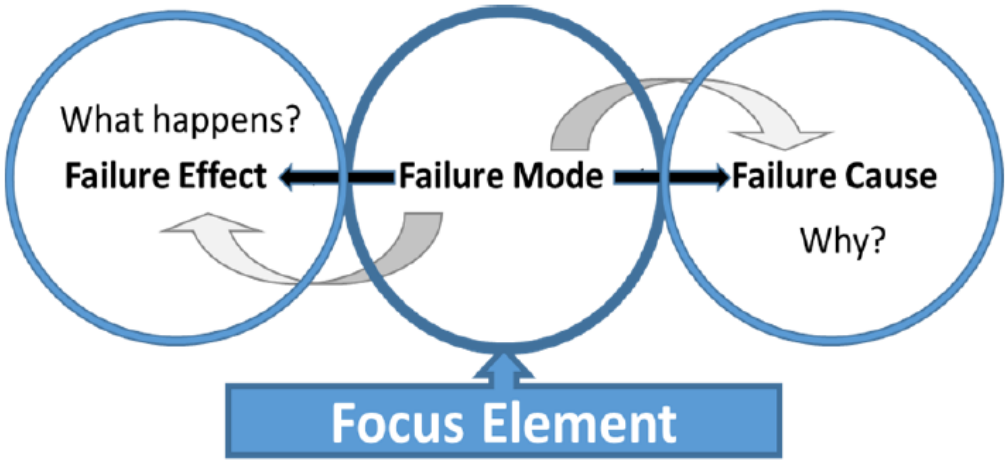


In the 4th edition manual, the steps were more along the lines of filling out the FMEA form, using the following steps:

- Identify the team
- Define the scope
- Define the customer
- Identify functions, requirements and specifications
- Identify potential Failure Modes
- Identify potential Effects
- Identify potential Causes
- Identify Controls
- Identifying and assessing Risk
- Recommended Action and Results.

For **DFMEA** the new 7-step method means:

- **Step 1** - Planning and Preparation: This is where the Header information is filled out and the scope of the FMEA is decided.
- **Step 2** - Structure Analysis: the DFMEA form starts with the understanding of the system structure. After the breakdown of the design into system, sub-system, and component level, the Focus Element, the Next Higher Level and Next Lower Level are described in the form. Additional clarification on tools to support the structure analysis before completing the DFMEA is provided (Block Diagram, Structure Tree).
- **Step 3** - Function Analysis: Deeper explanation on how to properly describe a function, including tools to support the function analysis (P-Diagram).
- **Step 4** - Failure Analysis: Concepts of types of failures and failure chain models are described to support a more comprehensive (more failures described) and more consistent (internal consistency between FE, FM, FC) failure description.
- **Step 5** - Risk Analysis: Further differentiation between Prevention Controls (PC) and Detection Controls (DC). The confirmation of PC and DC effectiveness needs to be considered before selecting the Occurrence and Detection ratings. More specificity in the criteria to determine levels for Severity, Occurrence and Detection ratings and the replacement of RPN to DFMEA Action Priority (AP). Low, Medium and High AP levels drive the determination of action priority.
- **Step 6** - Optimization: Recommended Action replaced with Preventive Action and Detection Action. Added the columns: Status (planned, decision/ implementation pending, completed, discarded) and Action Taken with pointer to evidence.
- **Step 7** - Results Documentation: Internal reporting to management and customer reporting.

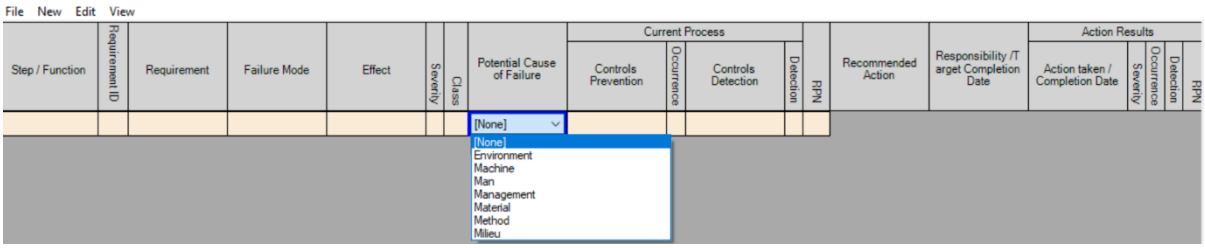


For **PFMEA** the 7 steps are as follows:

- **Step 1** - Planning and Preparation. In this step the Header information is filled out and the scope of the FMEA is decided.
- **Step 2** - Structure analysis. A more detailed breakdown of the manufacturing process is added. *Focus Element* of the PFMEA: the process step station number and name under review. *Next Higher Level*: process item system (the overall manufacturing process). *Next Lower Level process*: work element 4M type (based on Ishikawa approach). This encourages the users to consider the categories of Man, Machine, Material, Method, etc., leading to a more complete list of Failure Causes (FC.)
- **Step 3** - Function Analysis. Added the description of functions and requirements related to the Next Higher Level and Next Lower Level. This supports a clear and complete description of the Failure Effects (FE) and Failure Causes (FC).
- **Step 4** - Failure Analysis. Potential Failure Mode is replaced with Failure Mode (FM) of the Focus Element. Potential Effect(s) of Failure is replaced with Failure Effects (FE) to the Next Higher-Level Element and / or Vehicle End User. Potential Cause of Failure is replaced with Failure Cause (FC) of the Work Element.
- **Step 5** - Risk Analysis. Classification is replaced with Special Characteristics and Filter Code. Occurrence is replaced with Occurrence of the FC. The Occurrence rating now is based on "prediction of FC occurring", which leads to determining the actual robustness of the Prevention Controls (PC). Current Process Control – Prevention is replaced with Current Prevention Control (PC) of the Failure Cause (FC). Current Process Control – Detection is replaced with Current Detection Control (DC) of the Failure Cause (FC) or the Failure Mode (FM). Detection is replaced with Detection of the FC or FM. Detection is now based on three factors: detection method maturity, opportunity for detection, and ability to detect. RPN is replaced with AP.
- **Step 6** – Optimisation: Recommended Action replaced with Preventive Action and Detection Action. Added the columns: Status (planned, decision / implementation pending, completed, discarded), Action Taken with pointer to evidence, Special Characteristic, and Remarks.
- **Step 7** - Results Documentation: Internal reporting to management and customer reporting.

Failure Cause

In step 4, the Failure Analysis, it is now recommended to use the 4 Ms as a source for Failure Causes. In DataLyzer FMEA you can use Cause Categories to add the 4 Ms as source for the Failure Cause as follows:



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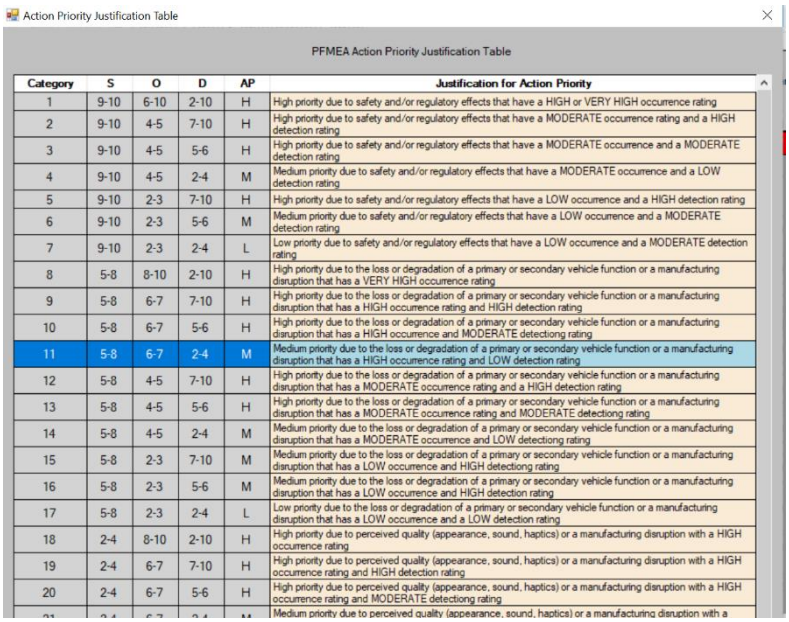
New Ranking Criteria

In step 5, Risk Analysis, the most important changes have been made to the Ranking Criteria. The new tables for Severity, Occurrence and Detection have not yet been released, however and in DataLyzer FMEA, you can already import/create multiple new Ranking Criteria and after the release of the new manual the new Ranking Criteria will be available in Excel upon request.

The known changes to the criteria are as follows: The Severity Tables will consist of three columns to rate the impact of an effect on "Your Plant," the "Ship-to Plant," and the "End-User." The Occurrence Tables will include a column on the "Type of Control" to differentiate between control approaches such as behavioural, technical and best practice controls. Two columns will be added to the Detection Tables called "Detection Method Maturity" and "Opportunity for Detection" to show the level of experience the organization has with this detection method.

Action Priority

RPN numbers will be replaced with Action Priority. Where RPN counts Severity, Occurrence and Detection equally, Action Priority puts most emphasis on Severity, then Occurrence and lastly Detection. In DataLyzer FMEA we have already implemented this. Please see this video for more information.


Action Priority Justification Table

PFMEA Action Priority Justification Table

Category	S	O	D	AP	Justification for Action Priority
1	9-10	6-10	2-10	H	High priority due to safety and/or regulatory effects that have a HIGH or VERY HIGH occurrence rating
2	9-10	4-5	7-10	H	High priority due to safety and/or regulatory effects that have a MODERATE occurrence rating and a HIGH detection rating
3	9-10	4-5	5-6	H	High priority due to safety and/or regulatory effects that have a MODERATE occurrence and a MODERATE detection rating
4	9-10	4-5	2-4	M	Medium priority due to safety and/or regulatory effects that have a MODERATE occurrence and a LOW detection rating
5	9-10	2-3	7-10	H	High priority due to safety and/or regulatory effects that have a LOW occurrence and a HIGH detection rating
6	9-10	2-3	5-6	M	Medium priority due to safety and/or regulatory effects that have a LOW occurrence and a MODERATE detection rating
7	9-10	2-3	2-4	L	Low priority due to safety and/or regulatory effects that have a LOW occurrence and a MODERATE detection rating
8	5-8	8-10	2-10	H	High priority due to the loss or degradation of a primary or secondary vehicle function or a manufacturing disruption that has a VERY HIGH occurrence rating
9	5-8	6-7	7-10	H	High priority due to the loss or degradation of a primary or secondary vehicle function or a manufacturing disruption that has a HIGH occurrence rating and HIGH detection rating
10	5-8	6-7	5-6	H	High priority due to the loss or degradation of a primary or secondary vehicle function or a manufacturing disruption that has a HIGH occurrence and MODERATE detectiong rating
11	5-8	6-7	2-4	M	Medium priority due to the loss or degradation of a primary or secondary vehicle function or a manufacturing disruption that has a HIGH occurrence rating and LOW detection rating
12	5-8	4-5	7-10	H	High priority due to the loss or degradation of a primary or secondary vehicle function or a manufacturing disruption that has a MODERATE occurrence rating and a HIGH detection rating
13	5-8	4-5	5-6	H	High priority due to the loss or degradation of a primary or secondary vehicle function or a manufacturing disruption that has a MODERATE occurrence rating and MODERATE detectiong rating
14	5-8	4-5	2-4	M	Medium priority due to the loss or degradation of a primary or secondary vehicle function or a manufacturing disruption that has a MODERATE occurrence and LOW detectiong rating
15	5-8	2-3	7-10	M	Medium priority due to the loss or degradation of a primary or secondary vehicle function or a manufacturing disruption that has a LOW occurrence and HIGH detectiong rating
16	5-8	2-3	5-6	M	Medium priority due to the loss or degradation of a primary or secondary vehicle function or a manufacturing disruption that has a LOW occurrence and HIGH detection rating
17	5-8	2-3	2-4	L	Low priority due to the loss or degradation of a primary or secondary vehicle function or a manufacturing disruption that has a LOW occurrence and a LOW detection rating
18	2-4	8-10	2-10	H	High priority due to perceived quality (appearance, sound, haptics) or a manufacturing disruption with a HIGH occurrence rating
19	2-4	6-7	7-10	H	High priority due to perceived quality (appearance, sound, haptics) or a manufacturing disruption with a HIGH occurrence rating and HIGH detection rating
20	2-4	6-7	5-6	H	High priority due to perceived quality (appearance, sound, haptics) or a manufacturing disruption with a HIGH occurrence rating and MODERATE detectiong rating
21	2-4	6-7	2-4	M	Medium priority due to perceived quality (appearance, sound, haptics) or a manufacturing disruption with a

Cost of Quality

There is also a new emphasis on the Cost of Quality as a measure of the effectiveness of your FMEA's. If there is no reduction in the cost of (poor) quality, the FMEA was not effective.

FMEA-MSR

The use of FMEA-MSR (Monitoring and System Response) as a supplement to Design FMEA's.

For more information about the new FMEA manual, please contact your DataLyzer Account Manager or email us at sales@datalyzer.com Thank you.