Introduction

'Failure Mode and Effect Analysis' (FMEA) is a structured risk analysis method that is used to identify potential failure modes in processes, products or services and to plan actions so that the negative effects will be minimized. It was one of the first systematic techniques of failure analysis. The FMEA is sometimes called PFMEA, meaning process-FMEA.

In today's competitive, modern workplace, Lean Six Sigma expertise can separate those students from their peers who lack this valuable skill set.

FMEA Content

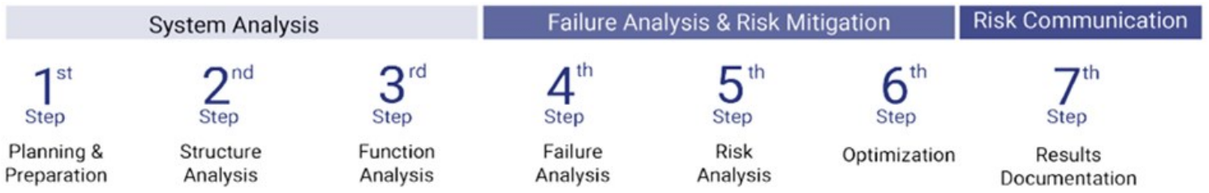
FMEA was initially developed in the 1950s to study problems that might arise from the malfunction of military systems. In 2019 the different standards were harmonized to one common standard. Nowadays, the FMEA methods are not only used in the Automotive, but are applied in many different industries, varying from the high-tech industry to the service industry. FMEA includes review of the following:

- **The process:** the consecutive activities
- **The objective**: what requirements must the result (product or service) meet?
- **Failure modes**: what could go wrong (deviation from the objective)?
- **Failure causes**: why would the deviation occur?
- **Failure effects**: what would be the consequences of the deviation?

Teams apply FMEA analysis to evaluate processes for possible failures and to prevent them by correcting the processes proactively, rather than reacting to adverse events after failures have occurred. FMEA is particularly useful in evaluating a new process prior to implementation and in assessing the impact of a proposed change to an existing process.

Setting up FMEA

1. **Planning & Preparation:**
   Defining the goal, scope, timeline, team, tasks and resources for the analyses
2. **Structure Analysis:**
   Reducing the product or process back to its system elements
3. **Function Analysis:**
   Defining the function and requirements of each element in the system
4. **Failure Analysis:**
   Defining possible failures, effects, causes and their relationship.
5. **Risk Analysis:**
   Assessing the risk of every possible failure by evaluating the severity, occurrence and detection.
6. **Optimization:**
   Defining the measures to control the important risks and evaluate the effectiveness of these measures.
7. **Results Documentation:**
   Summarize the results of the analyses and communicate to the stakeholders.



At step 5, the risk-level is calculated based on three factors, Severity, Occurrence and Detection. Every factor gets a score on the range of 1 to 10. Guidelines to determine the rating for Severity, Occurrence and Detection are defined by the AIAG in special tables.

1. Occurrence: the chance that the deviation occurs
2. Detection: the ability to detect the deviation before it occurs.
3. Severity: the severity of the effect, from a customer or process perspective

The risk-level is calculated by multiplying these three factors resulting in a 'Risk Priority Number' (RPN).

$$RPN = Severity \times Occurence \times Detection$$

Determining R.P.N.

The AIAG has introduced a number of tables for determining scores for Severity, Probability and Detection. These are very detailed and too extensive for most organizations. The Figure below provides a summary of these tables which is more practical to use.

Rating	Severity of Effect	Likelihood of Occurrence	Ability to Detect
10	Affects safety of user	Extremely high	Very Low
9	Noncompliance with regulations	Very High	
8	Loss of primary vehicle function		Low
7	Degradation of primary function	High	
6	Loss of convenience function		Moderate
5	Degradation of convenience function	Moderate	
4	Appearance, sound, vibration, harshness, or haptics		High
3		Low	
2		Very low	
1	No discernible effect	Extremely low	Very High

For most organizations, it is sufficient to calculate the RPN value using this table and thus determine the greatest risks. However, for those working in the automotive or high tech industry it is recommended to use the 2019-AIAG tables, as applying the FMEA properly in these sectors is very important. Since the integration of the AIAG standard and the VDA standard in 2019, the 'Action Priority' (AP) has been introduced within these sectors as an alternative to the RPN value. A disadvantage of the RPN value is that all three factors weigh equally heavily. When determining the AP value, the Occurrence score is weighted more heavily than the Detection score. After all, Occurrence stands for prevention and Detection stands for the retrospective discovery of an already made mistake.