SMMT QMD

AIAG / VDA FMEA

Join the conversation: #AQMS2019

Introduction

1 Introduction

This joint publication is the culmination of more than 3 years of collaboration between OEM and Tier 1 supplier members of the AIAG and VDA. The text has been completely rewritten, and the FMEA method has been revised in a few key areas.

The intent is to provide a common foundation for FMEA across the sectors of the automotive industry. While every effort has been made to reach a consensus **it may be necessary to refer to the individual publications or Customer Specific Requirements.**

FMEA-MSR

A new method, Supplemental FMEA for Monitoring and System Response (FMEA-MSR), has been added. This provides a means for the analysis of diagnostic detection and fault mitigation during the customer operation for the purpose of maintaining a safe state or state or regulation compliance.

This handbook supersedes AIAG 4th edition FMEA and VDA Product and Process FMEA Volume 4.

Purpose

1.1. Purpose and Description

FMEA method is used to address the Technical aspect of risk reduction.
FMEA is a team-orientated, systematic, qualitative method intended to:

Evaluate the potential Technical risk of failure of the product or process

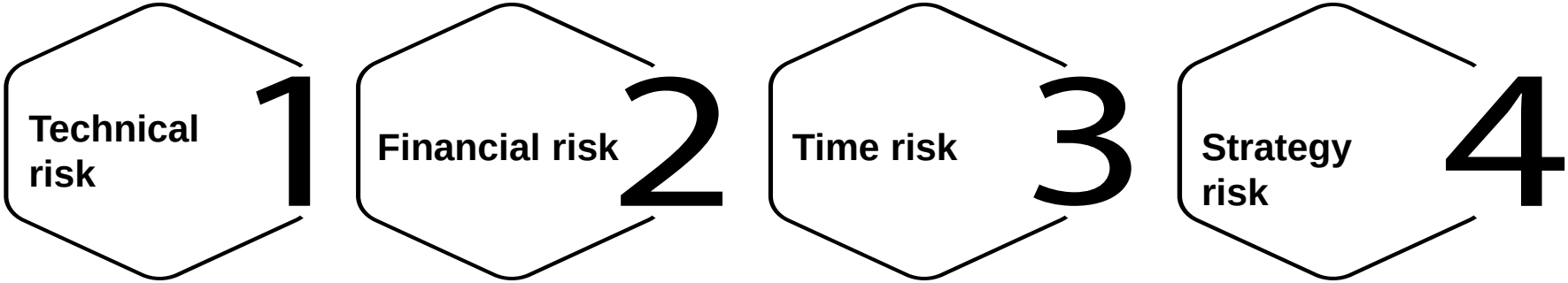
Analyse the causes and effect of those failures

Document preventive and detection actions

Recommend actions to reduce the risk

1.1. Purpose and Description

Manufacturers consider different types of risk including:



The FMEA is used for analysing the technical risk to reduce failures and improve safety in the product and the process.

Scope

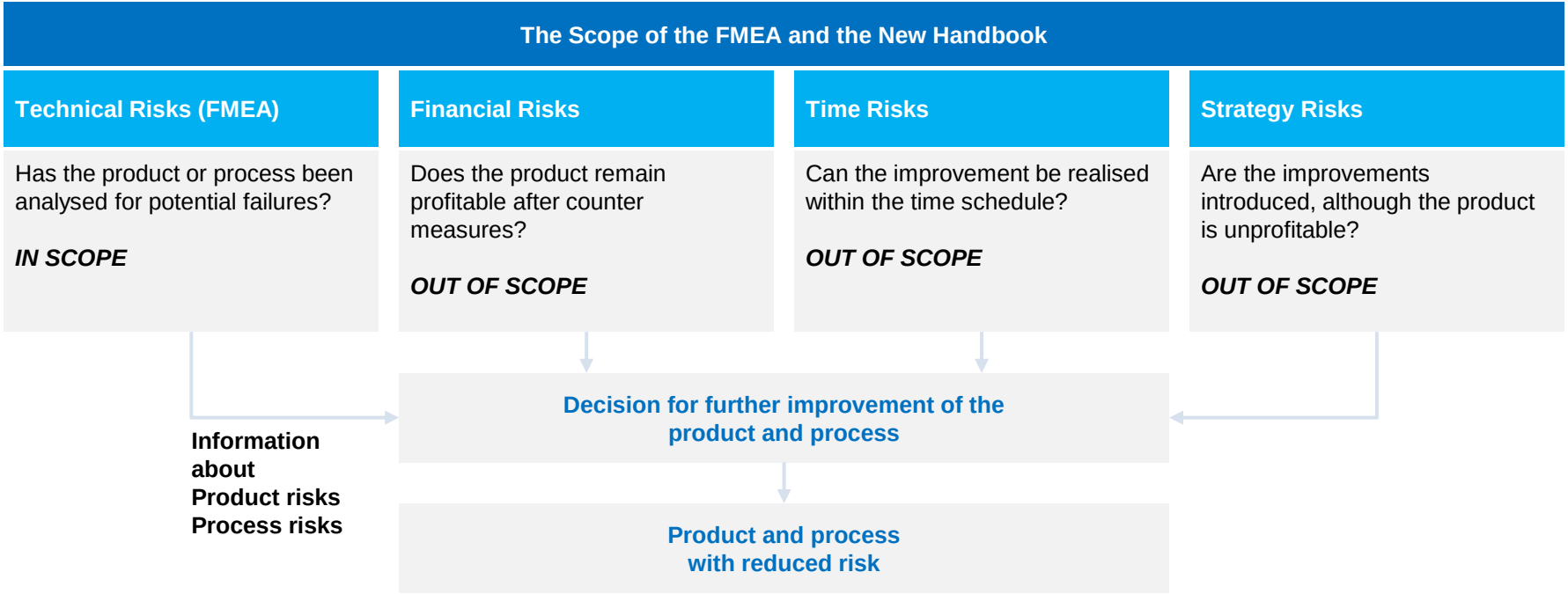


Figure 1.1-1 Aspects of Risks

Objectives and Limits of FMEA

1.2. Objectives of FMEA

To identify the functions of the product or steps of a process and the associated potential failure modes, effects and causes. Furthermore, it is used to evaluate whether the prevention and detection controls already planned are enough and to recommend additional actions. The FMEA documents and tracks actions that are taken to reduce the risk.

Limitations of FMEA

- It is qualitative (subjective), not quantitative (measurable).
- It is a single-point failure analysis, not a multi-point failure analysis.
- It relies on the team's level of knowledge, which may or may not predict future performance.
- It is a summary of the team's decisions, therefore, the quality of the FMEA report is subject to the recording skills of the team.

Purpose

When the FMEA is performed, the following norms are observed:

01

Clear

Potential failure modes are described in technically precise terms, enabling the specialist to assess failure, causes and possible effects.

02

True

The consequences of the potential failures are described accurately (e.g. potential for odour, smoke, fire etc.)

03

Realistic

Failure causes are reasonable. Extreme events are not considered (e.g. falling rocks on road). Failures resulting from intentional misuse are not considered (e.g. deliberate manipulation or sabotage).

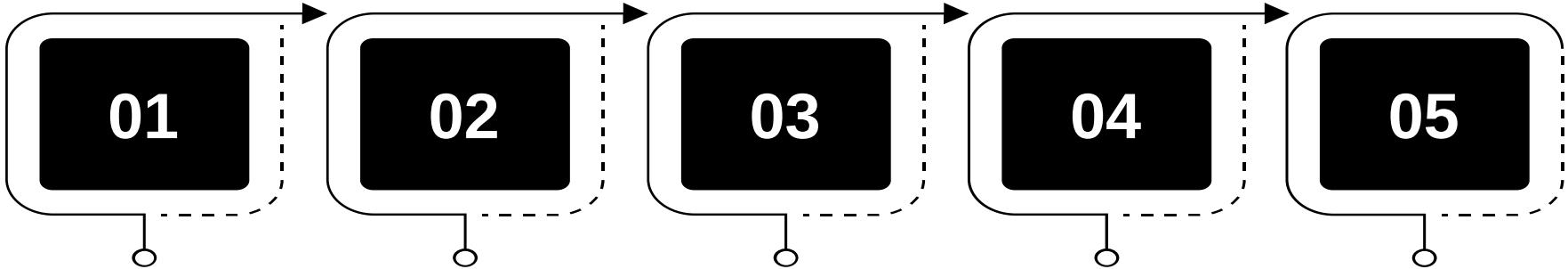
04

Complete

Foreseeable potential failures are not concealed. Completeness refers to the entirety of the product/process under analysis. However, the depth of detail depends on the risk involved.

Transition

1.3.5. Transition Strategy



Existing FMEAs developed using previous AIAG or VDA approach may remain in their original forms for subsequent revisions.

When practical existing FMEA used as a starting point for new programs, it should be converted to reflect the new rating scale, analytical method and format. However, if the team consider the change to be minor to existing product, they may decide to leave the FMEA in existing format.

The organisation should plan the transition from their current FMEA process.

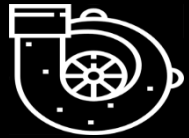
New projects should follow the FMEA method presented in the handbook, unless the company leadership and Customer Specific Requirements (CSRs) mandate a different approach.

The transition date and project milestones should be defined by the company taking into consideration CSRs.

Special Characteristics

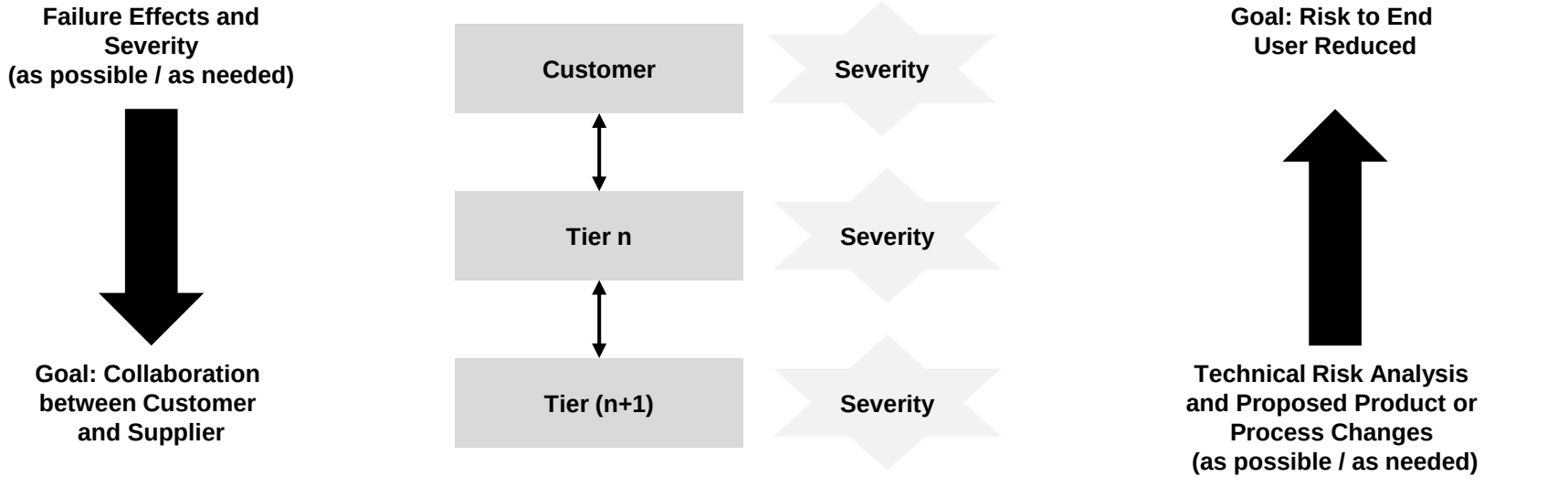
Special Characteristics are intended to provide information regarding which design characteristics require particular attention to process control, which lead directly to a failure of a product function in regards to safety, fit, form, performance, further processing of the product or compliance with government regulations and industry standards.

In the Design FMEA, the filter code column replaces the classification column because Special Characteristics are not required to be shown in the DFMEA.



The Process FMEA contains the column titled “classification”. This column may be used to specify Special Characteristics (e.g. critical, key, major significant) that require additional process controls.

FMEA Collaboration



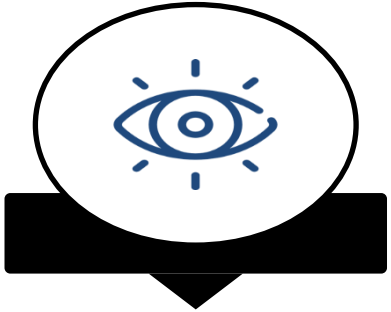
Collaboration between FMEAs

There are opportunities for collaboration between Design and Process FMEAs in the same company, and outside. To help communicate effects and severities, a joined and agreed to severity evaluation can be reviewed between organisations (Tier 1, 2, 3 etc.).

FMEA Layout

There are numerous FMEA tools i.e. software packages that can be used to develop DFMEA and PFMEA, as well as follow up actions.

Companies may develop their own in house database solutions or purchase commercial software.



There are two views of FMEA shown in the handbook.

The software view depicting what the user sees when developing an FMEA using specialist software.

The form view depicts what the user sees when developing an FMEA in a spreadsheet.

Figures in the handbook include examples of how to develop an FMEA using either a structure tree or form sheet.
In either case, the 7-step approach is the same.

7 Step Approach

Systems Analysis			Failure Analysis and Risk Mitigation			Risk Communication
1st Step **Planning and Preparation**	**2nd Step** **Structure Analysis**	**3rd Step** **Function Analysis**	**4th Step** **Failure Analysis**	**5th Step** **Risk Analysis**	**6th Step** **Optimization**	**7th Step** **Results Documentation**
Project Identification	Visualization of the analysis scope	Visualization of functions	Establishment of the Failure chain	Assignment of existing and/or planned controls and rating of failure	Identification of the actions necessary to reduce risks	Communication of results and conclusions of the analysis
Project plan: InTent, Timing, Team, Task, Tools (5T)	**DFMEA &FMEA-MSR:** Structure tree or equivalent block diagram, boundary diagram, digital model, physical parts. **PFMEA:** Structure tree or equivalent process flow diagram.	**DFMEA & FMEA-MSR:** Function tree/net or function analysis form sheet and parameter diagram **PFMEA:** Function tree/net or equivalent process flow diagram	**DFMEA:** Potential Failure Effect, Failure Modes, Failure Causes for each product function. **PFMEA:** Potential Failure Effects, Failure Modes, Failure Causes for each process function **FMEA-MSR:** Potential Failure Causes, Monitoring, System Response, reduced Failure Effect.	**DFMEA & PFMEA:** Assignment of Prevention Controls to the Failure Causes Assignment of Detection Controls to the Failure Causes and/or Failure Modes **FMEA-MSR:** Assignment of a Rationale for Frequency Rating, Assignment of Monitoring Controls Analysis of Provision for functional safety and regulatory compliance	Assignment of responsibilities and deadlines for action implementation	Establishment of content of the documentation
Analysis boundaries: What is included and excluded from the analysis	**DFMEA:** Identification of design interfaces. Interactions, close clearances. **PFMEA:** Identification of process steps and sub-steps	Association of requirements or characteristics to functions Cascade of customer (external and internal) functions with associated requirements	**DFMEA &FMEA-MSR** Identification of product failure causes using a parameter diagram or failure network **PFMEA:** Identification or process failure causes using a fishbone diagram (4M) or failure network	**DFMEA & PFMEA:** Rating of severity, Occurrences and Detection for each failure chain. Evaluation of Action Priority **FMEA-MSR:** Rating of Severity, Frequency and Monitoring for each failure chain. Evaluation of Action Priority	Implementation of actions taken including confirmation of the effectiveness of the actions implemented actions and assessment of risk after actions taken	Documentation of actions taken including confirmation of the effectiveness of the implemented actions and assessment of risk after actions taken
Identification of baseline FMEA with lessons learned	Collaboration between customer and supplier engineering teams (interface responsibility)	Collaboration between engineering teams (systems safety and components)	Collaboration between customer and supplier (Failure Effects)	Collaboration between customer and supplier (Severity)	Collaboration between the FMEA team, management, customer, and suppliers regarding potential failures	Communication of actions to reduce risks, including within the organization, and with customers and/or suppliers as appropriate
Basis of the Structure Analysis step	Basis of the Functional Analysis step	Basis of the Failure Analysis step	Basis of the documentation of failure in the FMEA form and the Risk Analysis step	Basis of the product or process Optimization step	Basis of the refinement of the product requirements and prevention and detection controls	Record of risk analysis and reduction to acceptable levels.

Step 5 Severity Table

Product General Evaluation Criteria Severity (S)			
Potential Failure Effects rated according to the criteria below			Blank until filled in by user
S	**Effect**	**Severity Criteria**	**Corporate or Product Line Examples**
10	**Very High**	Affects safe operation of the vehicle and / or other vehicles, the health of driver or passenger(s) or road users or pedestrians	
9		Noncompliance with regulations	
8	**High**	**Loss** of primary vehicle function necessary for normal driving during expected service life	
7		**Degradation** of primary vehicle function necessary for normal driving during expected service life	
6	**Moderate**	**Loss** of secondary vehicle function	
5		**Degradation** of secondary vehicle function	
4		Very objectionable appearance, sound, vibration, harshness or haptics	
3	**Low**	Moderately objectionable appearance, sound, vibration, harshness, or haptics	
2		Slightly objectionable appearance, sound, vibration, harshness, or haptics	
1	**Very Low**	No discernible effect	

Step 5 Occurrence Table (1/2)

Occurrence Potential (O) for the Product			
Potential Failure Causes rated according to the criteria below. Consider Product Experience and Prevention Controls when determining the best Occurrence estimate (Qualitative rating)			Blank until filled in by user
O	**Prediction of Failure Cause Occurring**	**Occurrence Criteria – DFMEA**	**Corporate or Product Line Examples**
10	**Extremely High**	• First application of new technology anywhere without operating experience and / or under uncontrolled operating conditions. No product verification and / or validation experience • Standards do not exist and best practices have not yet been determined. Prevention controls not able to predict field performance or do not exist	
9	**Very High**	• First use of design with technical innovations or materials within the company. New application or change in duty cycle / operating conditions. No product verification and / or validation experience • Prevention controls not targeted to identify performance to specific requirements	
8		• First use of design with technical innovations or materials on a new application. New application or change in duty cycle / operating conditions. No product verification and / or validation experience • Few existing standards and best practices, not directly applicable for this design. Prevention controls not a reliable indicator of field performance	
7	**High**	• New design based on similar technology and materials. New application or change in duty cycle / operating conditions. No product verification and / or validation experience • Standards, best practices, and design rules apply to the baseline design, but not the innovations. Prevention controls provide limited indication of performance	
6		• Similar to previous designs, using existing technology and materials. Similar application, with changes in duty cycle or operating conditions. Previous testing or field experience. • Standards and design rules exist but are insufficient to ensure that the failure cause will not occur. Prevention controls provide some ability to prevent a failure cause	
5	**Moderate**	• Detail changes to previous design, using proven technology and materials. Similar application, duty cycle or operating conditions. Previous testing or field experience, or new design with some test experience related to the failure • Design addressees lessons learned from previous designs. Best Practices re-evaluated for this design but have not yet been proven. Prevention controls capable of finding deficiencies in the product related to the failure cause and provide some indication of performance	

Step 5 Occurrence Table (2/2)

Occurrence Potential (O) for the Product			
Potential Failure Causes rated according to the criteria below. Consider Product Experience and Prevention Controls when determining the best Occurrence estimate (Qualitative rating)			Blank until filled in by user
O	**Prediction of Failure Cause Occurring**	**Occurrence Criteria – DFMEA**	**Corporate or Product Line Examples**
4	**Moderate**	• Almost identical design with short-term field exposure. Similar application, with minor change in duty cycle or operating conditions. Previous testing or field experience • Predecessor design and changes for new design conform to best practices, standards, and specifications. Prevention controls capable of finding deficiencies in the product related to the failure cause and indicate likely design conformance	
3	**Low**	• Detail changes to known design (same application, with minor change in duty cycle or operating conditions) and testing or field experience under comparable operating conditions, or new design with successfully completed test procedure • Design expected to conform to Standards and Best Practices, considering Lessons Learned from previous designs. Prevention controls capable of finding deficiencies in the product related to the failure cause and predict conformance of production design	
2	**Very Low**	• Almost identical mature design with long term field exposure. Same application, with comparable duty cycle and Operating conditions. Testing or field experience under comparable operating conditions • Design expected to conform to standards and best practices, considering Lessons Learned from previous designs, with significant margin of confidence. Prevention controls capable of finding deficiencies in the product related to the failure cause and indicate confidence in design conformance	
1	**Extremely Low**	• Failure eliminated through prevention control and failure cause is not possible by design	
Product Experience: History of product usage within the company (Novelty of design, application or use case). Results of already completed detection controls provide experience with the design			
Prevention Controls: Use of Best Practices for product design, Design Rules, Company Standards, Lessons Learned, Industry Standards, Material Specifications. Government Regulations and effectiveness of prevention oriented analytical tools including Computer Aided Engineering, Math Modelling, Simulation Studies, Tolerance Stacks and Design Safety Margins			

Action Priority (AP)

- The action Priority (AP) method is introduced in the handbook. It accounts for the thousands of possible combinations of S, O and D. It was created to give more emphasis on **S**everity first, then **O**ccurrence, then **D**etection.
- This logic follows the failure-prevention intent of FMEA. The AP table offers a suggested high-medium-low priority for actions.
- Companies can use a single system to evaluate actions priorities instead of multiple systems required for multiple customers.

Risk Priority Numbers are the product or S x O x D and range from 1 to 1,000. The RPN distribution can provide some information about the range of ratings, but alone is not an adequate method to determine the need for more action, since the RPN gives equal weighting to S, O and D. For this reason, RPN could result in similar risk numbers with very different combinations of S,O and D.

The RPN and S x O x D methods are not included in the handbook.

Action Priority (AP)

Priority High Risk (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 or detection controls.

Action Priority (AP)

It is recommended that potential severity 9-10 Failure Effects with Action Priority High and Medium, at a minimum, be reviewed by management, including the recommended actions that were taken.

This is not the prioritisation of High, Medium or Low risk - it is the prioritisation of the action to reduce risk.

Note:

- It may be helpful to include a statement such as “No further action is needed” in the remarks field as appropriate.

Action Priority (AP) (1/2)

Action Priority (AP) for DFMEA and PFMEA

Action Priority is based on combinations of Severity, Occurrence, and Detection ratings in order to prioritize actions for risk reduction

Effect	S	Prediction of Failure Cause Occurring	O	Ability to Detect	D	Action Priority (AP)	Comments
Product or Plant Effect Very High	9-10	Very High	8-10	Low - Very Low	7-10	H	
				Moderate	5-6	H	
				High	2-4	H	
				Very High	1	H	
		High	6-7	Low - Very Low	7-10	H	
				Moderate	5-6	H	
				High	2-4	H	
				Very High	1	H	
		Moderate	4-5	Low - Very Low	7-10	H	
				Moderate	5-6	H	
				High	2-4	H	
				Very High	1	M	
		Low	2-3	Low - Very Low	7-10	H	
				Moderate	5-6	M	
				High	2-4	L	
				Very High	1	L	
		Very Low	1	Very High - Very Low	1-10	L	

Action Priority (AP) for DFMEA and PFMEA

Action Priority is based on combinations of Severity, Occurrence, and Detection ratings in order to prioritize actions for risk reduction

Effect	S	Prediction of Failure Cause Occurring	O	Ability to Detect	D	Action Priority (AP)	Comments
Product or Plant Effect High	7-8	Very High	8-10	Low - Very Low	7-10	H	
				Moderate	5-6	H	
				High	2-4	H	
				Very High	1	H	
		High	6-7	Low - Very Low	7-10	H	
				Moderate	5-6	H	
				High	2-4	H	
				Very High	1	M	
		Moderate	4-5	Low - Very Low	7-10	H	
				Moderate	5-6	M	
				High	2-4	M	
				Very High	1	M	
		Low	2-3	Low - Very Low	7-10	M	
				Moderate	5-6	M	
				High	2-4	L	
				Very High	1	L	
		Very Low	1	Very High - Very Low	1-10	L	

Action Priority (AP) (2/2)

Action Priority (AP) for DFMEA and PFMEA

Action Priority is based on combinations of Severity, Occurrence, and Detection ratings in order to prioritize actions for risk reduction

Effect	S	Prediction of Failure Cause Occurring	O	Ability to Detect	D	Action Priority (AP)	Comments
Product or Plant Effect Moderate	4-6	Very High	8-10	Low - Very Low	7-10	H	
				Moderate	5-6	H	
				High	2-4	M	
				Very High	1	M	
		High	6-7	Low - Very Low	7-10	M	
				Moderate	5-6	M	
				High	2-4	M	
				Very High	1	L	
		Moderate	4-5	Low - Very Low	7-10	M	
				Moderate	5-6	L	
				High	2-4	L	
				Very High	1	L	
		Low	2-3	Low - Very Low	7-10	L	
				Moderate	5-6	L	
				High	2-4	L	
				Very High	1	L	
		Very Low	1	Very High - Very Low	1-10	L	

Action Priority (AP) for DFMEA and PFMEA

Action Priority is based on combinations of Severity, Occurrence, and Detection ratings in order to prioritize actions for risk reduction

Effect	S	Prediction of Failure Cause Occurring	O	Ability to Detect	D	Action Priority (AP)	Comments
Product or Plant Effect Low	2-3	Very High	8-10	Low - Very Low	7-10	M	
				Moderate	5-6	M	
				High	2-4	L	
				Very High	1	L	
		High	6-7	Low - Very Low	7-10	L	
				Moderate	5-6	L	
				High	2-4	L	
				Very High	1	L	
		Moderate	4-5	Low - Very Low	7-10	L	
				Moderate	5-6	L	
				High	2-4	L	
				Very High	1	L	
		Low	2-3	Low - Very Low	7-10	L	
				Moderate	5-6	L	
				High	2-4	L	
				Very High	1	L	
		Very Low	1	Very High - Very Low	1-10	L	

Severity Table

Product General Evaluation Criteria Severity (S)					
Potential Failure Effects rated according to the criteria below					Blank until filled in by user
S	**Effect**	**Impact to Your Plant**	**Impact to Ship-to Plant (When Known)**	**Impact to End User (When Known)**	**Corporate or Product Line Examples**
10	**High**	Failure may result in acute health and/or safety risk for the manufacturing or assembly worker	Failure may result in an acute health and/or safety risk for the manufacturing or assembly worker	Affects safe operation of the vehicle and/or other vehicles, the health of driver or passenger(s) or roads users or pedestrians	
9		Failure may result in in-plant regulatory non compliance	Failure may result in in-plant regulatory non compliance	Noncompliance with regulations	
8	**Moderately High**	100% of production run affected may have to be scrapped Failure may result in in-plant regulatory non compliance or may have a chronic health and/or safety risk for the manufacturing or assembly worker	Line shutdown greater than full production shift; stop shipment possible; field repair or replacement required (Assembly to end user) other than for regulatory non compliance. Failure may result in in-plant regulatory non compliance or may have a chronic health and/or safety risk for the manufacturing or assembly worker	**Loss** of primary vehicle function necessary for normal driving during expected service life	
7		Product may have to be sorted and a portion (less than 100%) scrap; deviation from primary process; decreased line speed or added man power	Line shutdown from 1 hour up to full production shift; stop shipment possible; field repair or replacement required (assembly to end user) other than for regulatory non compliance	**Degradation** of primary vehicle function necessary for normal driving during expected service life	

Severity Table (cont.)

Product General Evaluation Criteria Severity (S)					
Potential Failure Effects rated according to the criteria below					Blank until filled in by user
S	**Effect**	**Impact to Your Plant**	**Impact to Ship-to Plant (When Known)**	**Impact to End User (When Known)**	**Corporate or Product Line Examples**
6	**Moderately Low**	100% of production run may have to be reworked off line and accepted	Line shutdown up to one hour	**Loss** of secondary vehicle function	
5		A portion of the production run may have to be reworked off line and accepted	Less than 100% of product affected; strong possibility for additional defective product; sort required; no line shutdown	**Degradation** of secondary vehicle function	
4		100% of production run may have to be reworked in station before it is processed	Defective product triggers significant reaction plan; additional defective products not likely; sort not required	Very objectionable appearance, sound, vibration, harshness, or haptics	
3	**Low**	A portion of the production run may have to be reworked in station before it is processed	Defective product triggers minor reaction plan; additional defective products not likely; sort not required	Moderately objectionable appearance, sound, vibration, harshness, or haptics	
2		Slight inconvenience to process, operation, or operator	Defective product triggers no reaction plan; additional defective products not likely; sort not requires feedback to supplier	Slightly objectionable appearance, sound, vibration, harshness, or haptics	
1	**Very Low**	No discernible effect	No discernible effect or no effect	No discernible effect	

Occurrence Table

Occurrence Potential (O) for the Process				
Potential Failure Causes rated according to the criteria below. Consider Product Prevention Controls when determining the best Occurrence estimate. Occurrence is a predictive qualitative rating made at the time of evaluation and may not reflect the actual occurrence. The occurrence rating number is a relative rating within the scope of the FMEA (process been evaluated). For prevention controls with multiple occurrence ratings, use the rating that best reflects the robustness of the control				Blank until filled in by user
O	**Prediction of Failure Cause Occurring**	**Type of Control**	**Prevention Controls**	**Corporate or Product Line Examples**
10	**Extremely High**	None	No prevention controls	
9	**Very High**	Behavioural	Prevention controls will have little effect in preventing failure cause	
8				
7	**High**	Behavioural or technical	Prevention controls somewhat effective in preventing failure cause	
6				
5	**Moderate**		Prevention controls are effective in preventing failure cause	
4				
3	**Low**	Best practices: Behavioural or technical	Prevention controls are highly effective in preventing failure cause	
2	**Very Low**			
1	**Extremely Low**	Technical	Prevention controls are extremely effective in preventing failure cause from occurring due to design (e.g. part geometry) or process (e.g. fixture or tooling design). Intent of prevention control – Failure mode cannot be physically produced due to the failure cause	
Prevention control effectiveness: consider if prevention controls are technical (rely on machines, tool life, tool material, etc.), or use best practices (fixtures, tool design, calibration procedures, error-proofing verification, preventive maintenance, work instructions, statistical process control charting, process monitoring, product design, etc.) or behavioural (rely on certified or non-certified operators, skilled trades, team leaders, etc.) when determining how effective the prevention control will be				

Detection Table

Detection Potential (D) for the Validation of the Process Design				
Detection Controls rated according to the Detection Method Maturity and Opportunity for Detection				Blank until filled in by user
D	**Ability to Detect**	**Detection Method Maturity**	**Opportunity for Detection**	**Corporate or Product Line Examples**
10	**Very Low**	No testing of inspection method has been established or is known	The failure mode will not or cannot be detected	
9		It is unlikely that the testing or inspection method will detect the failure mode	The failure mode is not easily detected through random or sporadic audits.	
8	**Low**	Test or inspection method **has not been** proven to be effective and reliable (e.g. plant has little or no experience with method, gauge R&R results marginal on comparable process or this application., etc.)	Human inspection (visual, tactile, audible), or use of manual gauging (attribute or variable) that should detect the failure mode or failure cause	
7			Machine-based detection (automated or semi-automated with notification by light, buzzer, etc.), or use of inspection equipment such as a coordinate measuring machine that should detect failure mode or failure cause	
6	**Moderate**	Test or inspection method **has been** proven to be effective and reliable (e.g. plant has experience with method, gauge R&R results are acceptable on comparable process or this application., etc.)	Human inspection (visual, tactile, audible), or use of manual gauging (attribute or variable) that will detect the failure mode or failure cause (including product sample checks)	
5			Machine-based detection (semi-automated with notification by light, buzzer, etc.), or use of inspection equipment such as a coordinate measuring machine that will detect failure mode or failure cause (including product sample checks)	

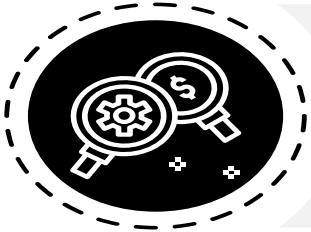
Detection Table

Detection Potential (D) for the Validation of the Process Design				
Detection Controls rated according to the Detection Method Maturity and Opportunity for Detection				Blank until filled in by user
D	**Ability to Detect**	**Detection Method Maturity**	**Opportunity for Detection**	**Corporate or Product Line Examples**
4	**High**	System **has been** proven to be effective and reliable (e.g. plant has experience with method, on identical process or this application), gauge R&R results are acceptable, etc.	Machine-based automated detection method that will detect the failure mode **downstream**, prevent further processing or system will identify the product as discrepant and allow it to automatically move forward in the process until the designated reject unload area. Discrepant product will be controlled by a robust system that will prevent outflow of the product from the facility.	
3			Machine-based automated detection method that will detect the failure mode **in-station**, prevent further processing or system will identify the product as discrepant and allow it to automatically move forward in the process until the designated reject unload area. Discrepant product will be controlled by a robust system that will prevent outflow of the product from the facility.	
2		Detection method **has been** proven to be effective and reliable (e.g. plant has experience with method, error-proofing verifications, etc.)	Machine-based detection method that will detect the cause and prevent failure mode (discrepant part) from being produced.	
1	**Very High**	Failure mode cannot be physically produced as-designed or processed, or detection method proven to **always** detect the failure mode or failure cause		

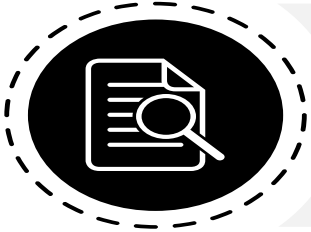
Step 5 Detection Table

Detection Potential (D) for the Validation of the Product Design				
Detection Controls rated according to Detection Method Maturity and Opportunity for Detection				Blank until filled in by user
D	**Ability to Detect**	**Detection Method Maturity**	**Opportunity for Detection**	**Corporate or Product Line Examples**
10	**Very Low**	Test procedure yet to be developed	Test method not defined	
9		Test method not designed specifically to detect failure mode or cause	Pass-Fail, Test-to-Fail, Degradation Testing	
8	**Low**	New test method; not proven	Pass-Fail, Test-to-Fail, Degradation Testing	
7		Proven test method for verification of functionality or validation of performance, quality, reliability and durability; planned timing is later in the product development cycle such that test failures may result in production delays for re-design and/or re-tooling	Pass-Fail Testing	
6	**Moderate**		Test-to-Failure	
5			Degradation Testing	
4	**High**	Proven test method for verification of functionality or validation of performance, quality, reliability and durability; planned timing is sufficient to modify production tools before release for production	Pass-Fail Testing	
3			Test-to-Failure	
2			Degradation Testing	
1	**Very High**	Prior testing confirmed that failure mode or cause cannot occur, or detection methods proven to always detect the failure mode or failure cause		

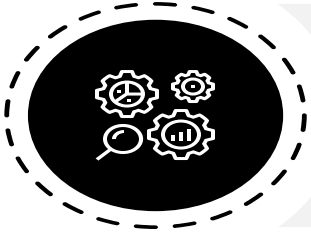
FMEA MSR



A supplemental FMEA for Monitoring and System Response potential failure causes which might occur under customer operating conditions are analysed with respect to their technical effects on the system, vehicle, people and regulatory compliance.



The method considers whether or not Failure Causes or Failure Modes are detected by the systems, or Failure Effects are detected by the driver, customer operations or in-service operation and maintenance operation.



FMEA-MSR adds value by assessing risk reduction as a result of monitoring and response. FMEA-MSR evaluates the current state of risk or failure and derives the necessity for additional monitoring by comparison to the conditions for acceptable residual risk.

FMEA MSR

FMEA-MSR includes the following elements of risk:

A

Severity of harm, regulatory noncompliance, loss or degraded functionality, and unacceptable quality represent by (S).

B

Estimated frequency of a Failure causes in context of an operational situation; represented by (F).

C

Technical possibilities to avoid or limit the Failure Effect via diagnostic detection and automated response, combined with human possibilities to avoid or limit the failure Effect via sensory perception and physical reactions; represented by (M).

The Combination of F and M is an estimate of the probability of occurrence of the Failure Effect, due to the Fault (Failure Causes) and resulting malfunctioning behaviour (Failure Mode).

FMEA MSR

Evaluations

Each failure Mode, Cause and Effect relationship (failure chain or hybrid network) is assessed by the following three criteria:

01

Severity (S)

Represents the Severity of the Failure Effect.

02

Frequency (F)

Represents the Frequency of Occurrence of the cause in a given operational situation, during the intended service life of the vehicle.

03

Monitoring (M)

Represents the Detection potential of the Diagnostic Monitoring functions (detection of the Failure Causes, Failure Mode and/or Failure Effect).

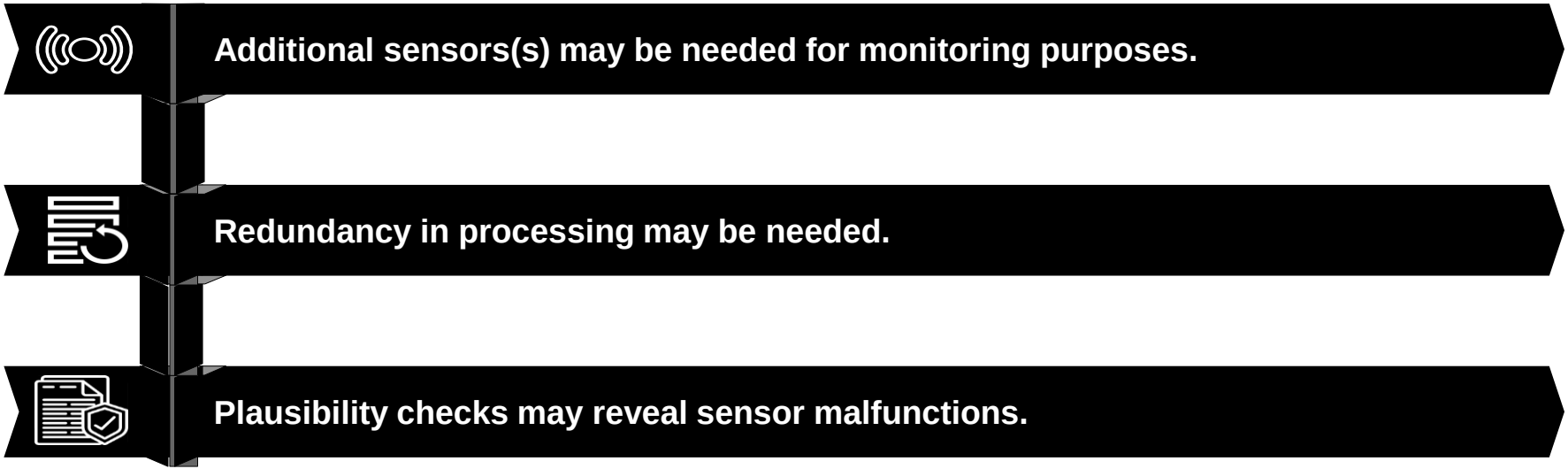
Evaluation numbers from 1 to 10 are used for the S, F, M, where 10 stands for the highest risk. By examining these ratings individually and in combination, the need for risk reduction may be prioritised.

FMEA MSR

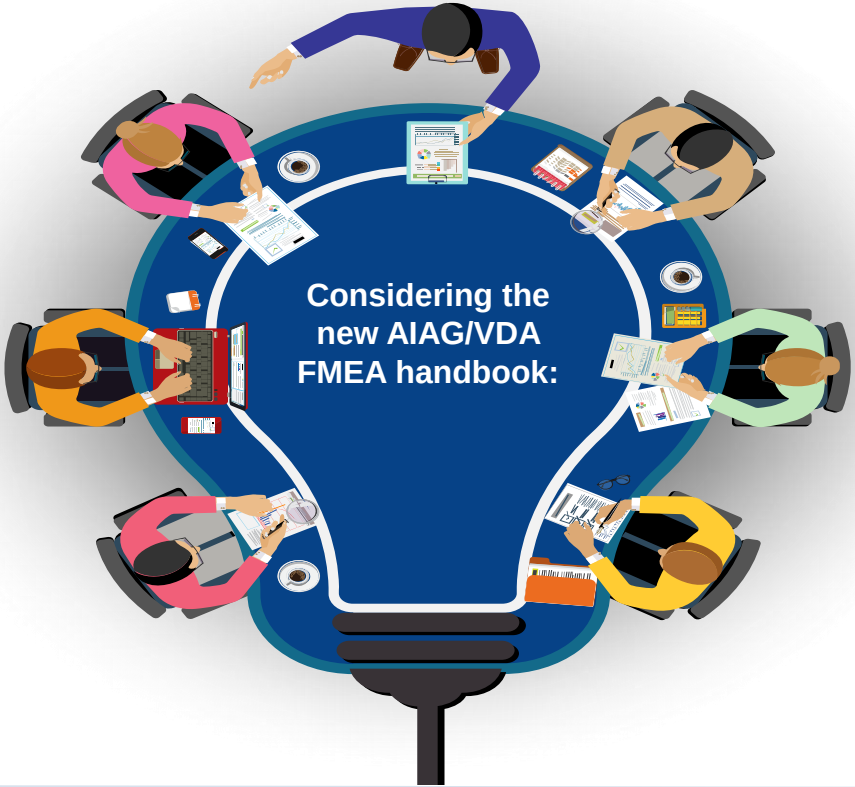
FMEA-MSR Follows the same 7-step Approach

Evaluates the current state of risk of failure under operating conditions (not just risk of harm to persons).

Useful in deciding whether the system design fulfils the performance requirements, with respect to safety and compliance. The results may include items such as:



Exercise



01

Summarise what you consider are the key differences between the new handbook and your current approach to FMEA.

Prepare feedback in your groups.

QUESTIONS?