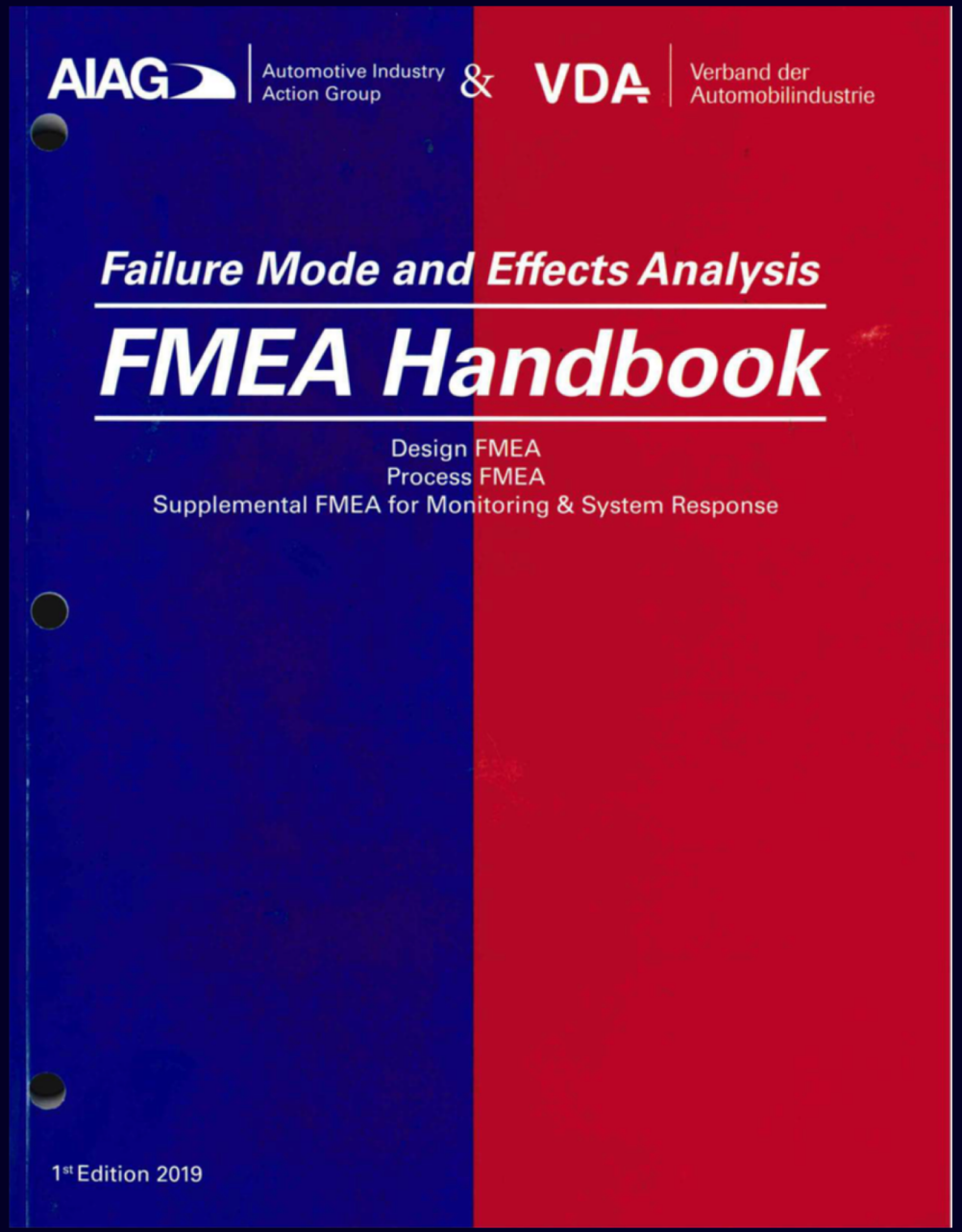
FMEA II


AIAG
Automotive Industry Action Group
&
VDA
Verband der Automobilindustrie
Failure Mode and Effects Analysis
FMEA Handbook
Design FMEA
Process FMEA
Supplemental FMEA for Monitoring & System Response
1st Edition 2019

CONTENIDO (SCOPE)

IN SCOPE	OUT OF SCOPE
PFMEA (PROCESS FMEA)	DFMEA (Design FMEA)
STEP 1: PROJECT IDENTIFICATION	FMEA-MSR (MONITORING SYSTEM RESPONSE)
STEP 2: SCOPE	SPECIAL CHARACTERISTICS
STEP 3: FUNCTIONS	
STEP 4: FAILURE CHAIN	
STEP 5: CONTROLS / RATING	
STEP 6: ACTIONS	
STEP 7: RESULTS	

SEVEN STEPS

SYSTEM ANALYSIS			FAILURE ANALYSIS AND RISK MITIGATION			RISK MITIGATION
1st Step	2nd Step	3rd Step	4th Step	5th Step	6th Step	7th Step
Project Identification	Visualization of the analysis scope	Visualization of functions	Establishment of the Failure Chain	Assignments of existing controls and rating of failures	Identification of the actions necessary to reduce risks	Communication of results and conclusions of the analysis

SEVEN STEPS

SYSTEM ANALYSIS		
1st Step	2nd Step	3rd Step
Project Identification	Visualization of the analysis scope	Visualization of functions
Project Plan	Structure tree or equivalent process flow diagram	Fuction tree/net of equivalent process flow diagram
Analysis Boundaries: What is included and excluded from the analysis	Identification of process steps and sub-steps	Cascade of customer (external and internal) functions with associated requirements
Identification of Base Line FMEA with lessons learned	Collaboration between customer and supplier engineering teams	Collaboration between engineering teams (systems, safety, and components)
Basis for the Structure Analysis Step	Basic for the Function Analysis Step	Basis for the Failure Analysis Step

PROYECTO FMEA

PROYECTO	DESCRIPCIÓN
¿QUÉ QUEREMOS LOGRAR?	
¿CUÁL CLIENTE?	
¿CUÁL PRODUCTO?	
¿CUÁL OPERACIÓN?	
¿CUÁL FALLA?	

PROYECTO FMEA

PROYECTO	DESCRIPCIÓN
¿QUÉ QUEREMOS LOGRAR?	REDUCIR QUEJAS DE CALIDAD EN EL ÁREA DE SOLDADURA
¿CUÁL CLIENTE?	VW
¿CUÁL PRODUCTO?	GOLF
¿CUÁL OPERACIÓN?	SOLDADURA
¿CUÁL FALLA?	SOLDADURA LATERAL DE BAJA PENETRACIÓN

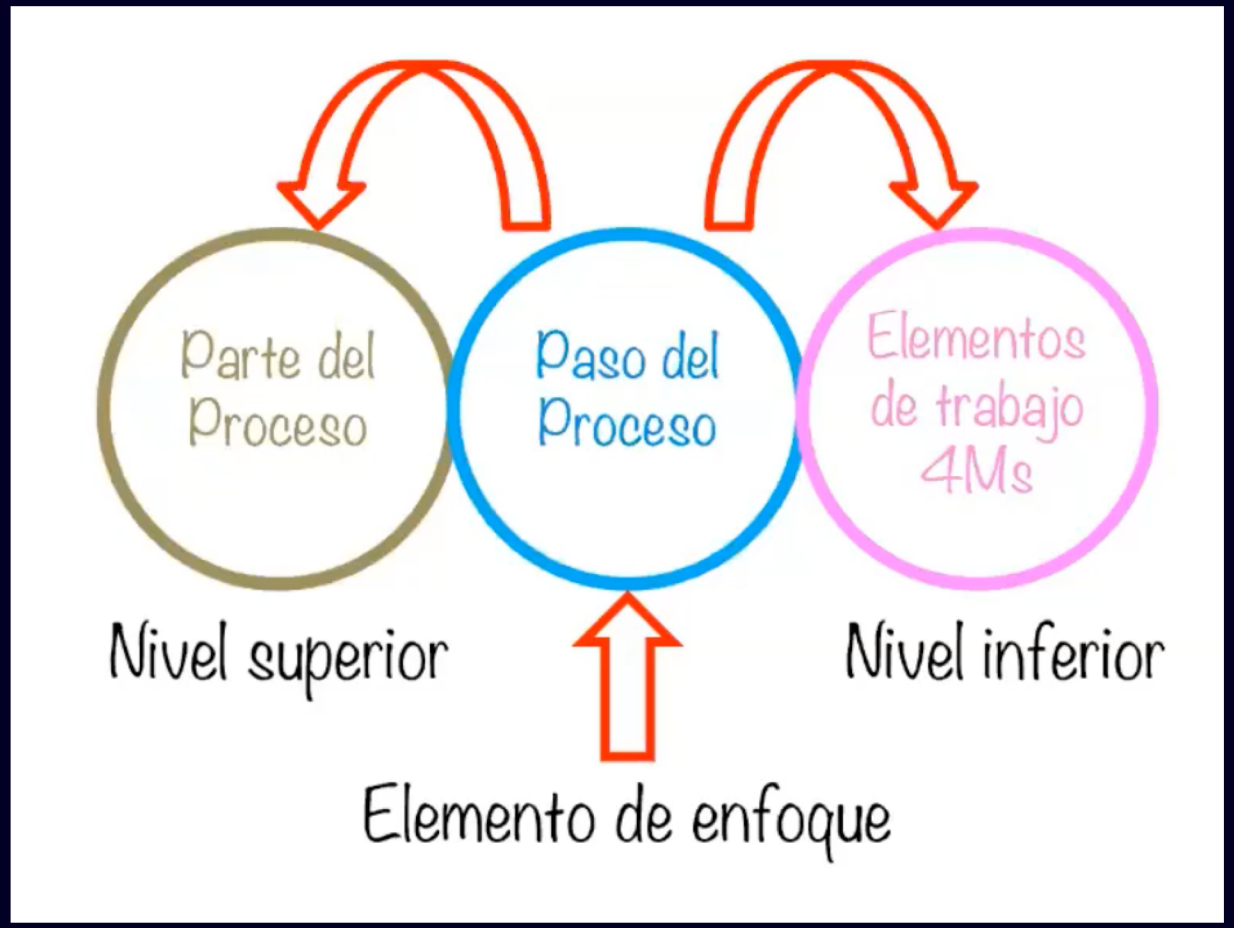
ENCABEZADO (PASO 1)

PLANNING AND PREPARATION (STEP 1)	
Company Name	METANOIA CONSULTING
Manufacturing Location	PLANTA JUAREZ, CHIH
Customer Name	ARMADORA AUTOMOTRIZ
Model Year(s)/Program(s)	2022

Subject	PROCESO SOLDADURA
PFMEA Start Date	17-MAYO-2021
PFMEA Revision Date	
Cross Functional Team	VER EQUIPO TRABAJO

PFMEA ID Number	VWG-SLP300
Process Responsibly	A. MENA
Confidentlally Level	Confidential

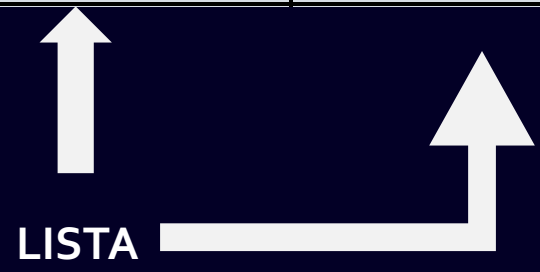
STRUCTURE ANALYSIS (STEP 2)



MATERIAL DIRECTO
MATERIAL INDIRECTO
ENFOCARSE EN LOS MATERIALES QUE SE CONTROLAN EN LA OPERACIÓN

ANÁLISIS DE ESTRUCTURA (PASO 2)

ANÁLISIS DE ESTRUCTURA (PASO 2)				
NIVEL SUPERIOR 1. PARTE DEL PROCESO	2. No. PROCESO	ELEMENTO DE ENFOQUE 2. PASO DEL PROCESO	NIVEL INFERIOR 3. ELEMENTO DE TRABAJO DEL PROCESO	DESCRIPCIÓN*
PARTE AUTOMOTRIZ VWG-SLP300	50	SOLDADURA	Man	OPERADOR
			Machine	ANTORCHA
			Material	MICROALAMBRE
			Environment	GAS AR+CO2



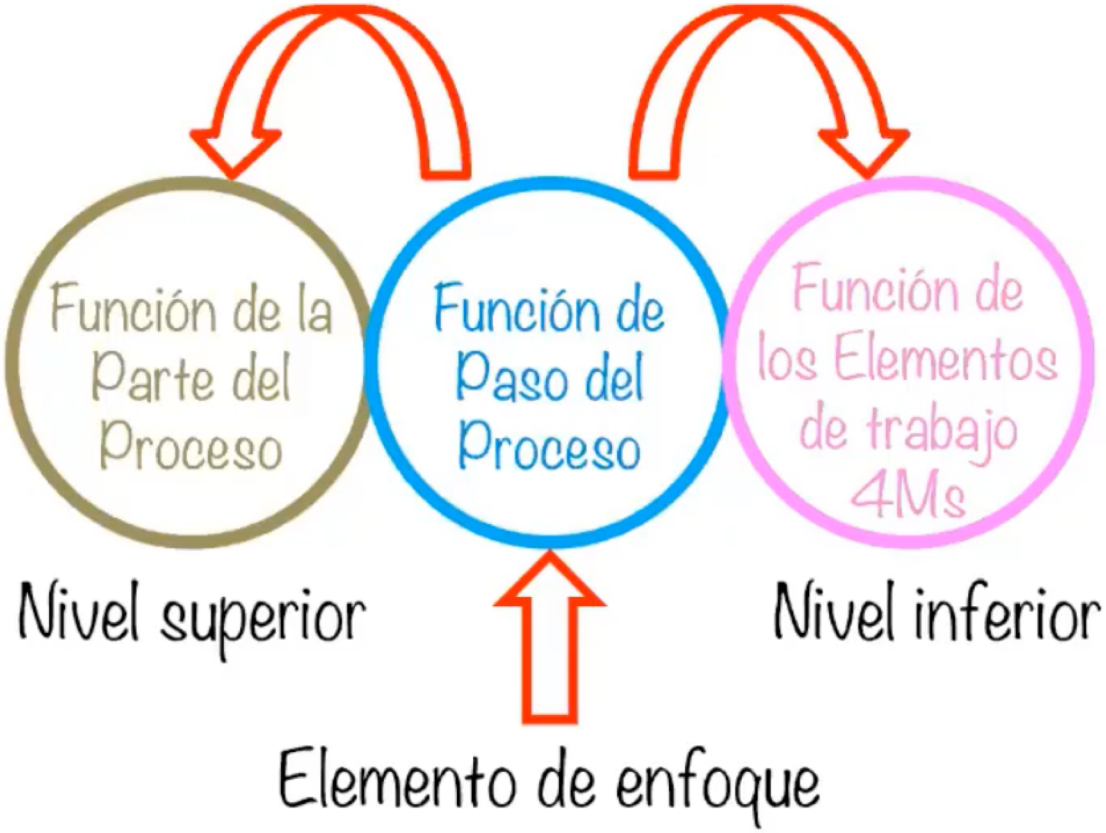
ANÁLISIS FUNCIONAL

- **Función**

- **2.** f. *Tarea* que corresponde realizar a una institución o entidad.

- **10.** *Finalidad* de los mensajes verbale s

- **11.** Relación entre dos conjuntos que asigna a cada elemento del primero un elemento del segundo.
-



ANÁLISIS DE FUNCIÓN (PASO 3)

FUNCTION ANALYSIS (STEP 3)			
NIVEL SUPERIOR 1. FUNCION DE LA PARTE DEL PROCESO		ELEMENTO DE ENFOQUE 2. FUNCIÓN DEL PASO DEL PROCESO	NIVEL INFERIOR 3. FUNCIÓN DEL ELEMENTO DE TRABAJO DEL PROCESO
Supplier Plant	EMBARQUE	PROFUNDIDAD	VELOCIDAD DE AVANCE
Ship-to Plant	ENSAMBLE	LONGITUD DE CORDÓN	ÁNGULO DE SOLDADURA
End User	RIGIDEZ ESTRUCTURAL	POSICIÓN DE CORDÓN	AVANCE MICROALAMBRE
		FORMA DE CORDÓN	CANTIDAD DE GAS
		SIN POROS	MATERIAL DE APORTE
			DIMENSIONES
			MEZCLA DE GASES

CARACTERÍSTICAS DEL PRODUCTO

PASO 2 & 3

ANÁLISIS DE ESTRUCTURA (PASO 2)					ANÁLISIS DE FUNCIÓN (PASO 3)			
NIVEL SUPERIOR 1. PARTE DEL PROCESO	2. No. PROCESO	ELEMENTO DE ENFOQUE 2. PASO DEL PROCESO	NIVEL INFERIOR 3. ELEMENTO DE TRABAJO DEL PROCESO	DESCRIPCIÓN*	NIVEL SUPERIOR 1. FUNCION DE LA PARTE DEL PROCESO		ELEMENTO DE ENFOQUE 2. FUNCIÓN DEL PASO DEL PROCESO	NIVEL INFERIOR 3. FUNCIÓN DEL ELEMENTO DE TRABAJO DEL PROCESO
PARTE AUTOMOTRIZ VWG-SLP300	50	SOLDADURA	Man	OPERADOR	Supplier Plant	EMBARQUE	PROFUNDIDAD	VELOCIDAD DE AVANCE
					Ship-to Plant	ENSAMBLE	LONGITUD DE CORDÓN	ÁNGULO DE SOLDADURA
			Machine	ANTORCHA	End User	RIGIDEZ ESTRUCTURAL	POSICIÓN DE CORDÓN	AVANCE MICROALAMBRE
							FORMA DE CORDÓN	CANTIDAD DE GAS
			Material	MICROALAMBRE			SIN POROS	MATERIAL DE APORTE
								DIMENSIONES
			Environment	GAS AR+CO2				MEZCLA DE GASES

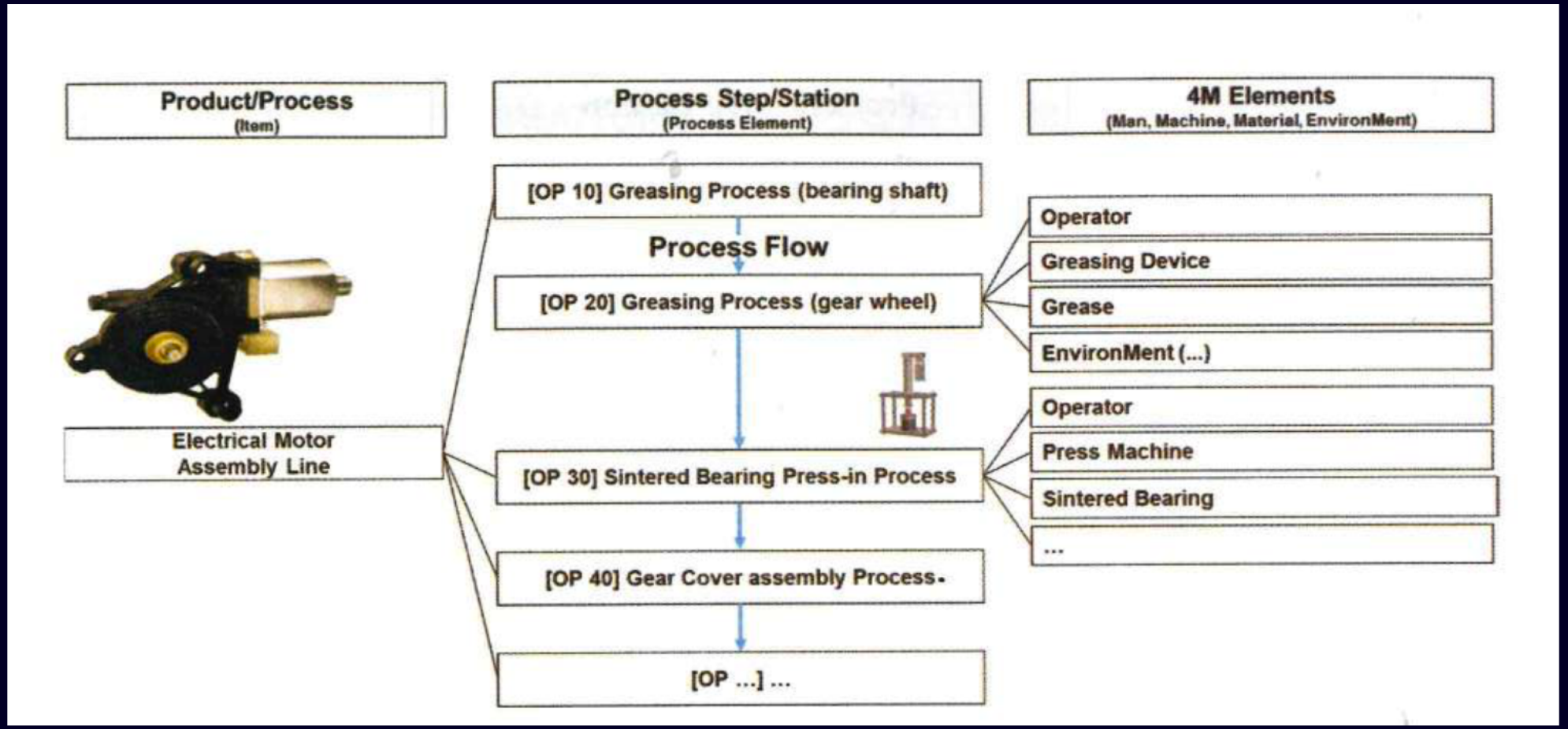
PLANNING AND PREPARATION (STEP 1)

Company Name	Acme Automotive
Manufacturing Location	Plant 6 , Saginaw, Michigan
Customer Name	Jackson Industry
Model Year(s)/Program(s)	2020PX123

Subject	PX123 Manual Column Assembly
PFMEA Start Date	19-Mar-2018
PFMEA Revision Date	25-Sep-2018
Cross Functional Team	See Team List

PFMEA ID Number	654321
Process Responsibly	B Black
Confidentlally Level	Confidential

STRUCTURE TREE (2nd Step)



STRUCTURE ANALYSIS (STEP 2)

STRUCTURE ANALYSIS (STEP 2)			
1. Process Item System, Subsytem, Part Element or Name of Process	2. Process Step Station No.	2. Process Step Name of Focus Element	3. Process Work Element 4M Type
Electric Motor Assy Line	30	Sintered Bearing Press-in Process	Man
Electric Motor Assy Line	30	Sintered Bearing Press-in Process	Machine
Electric Motor Assy Line			

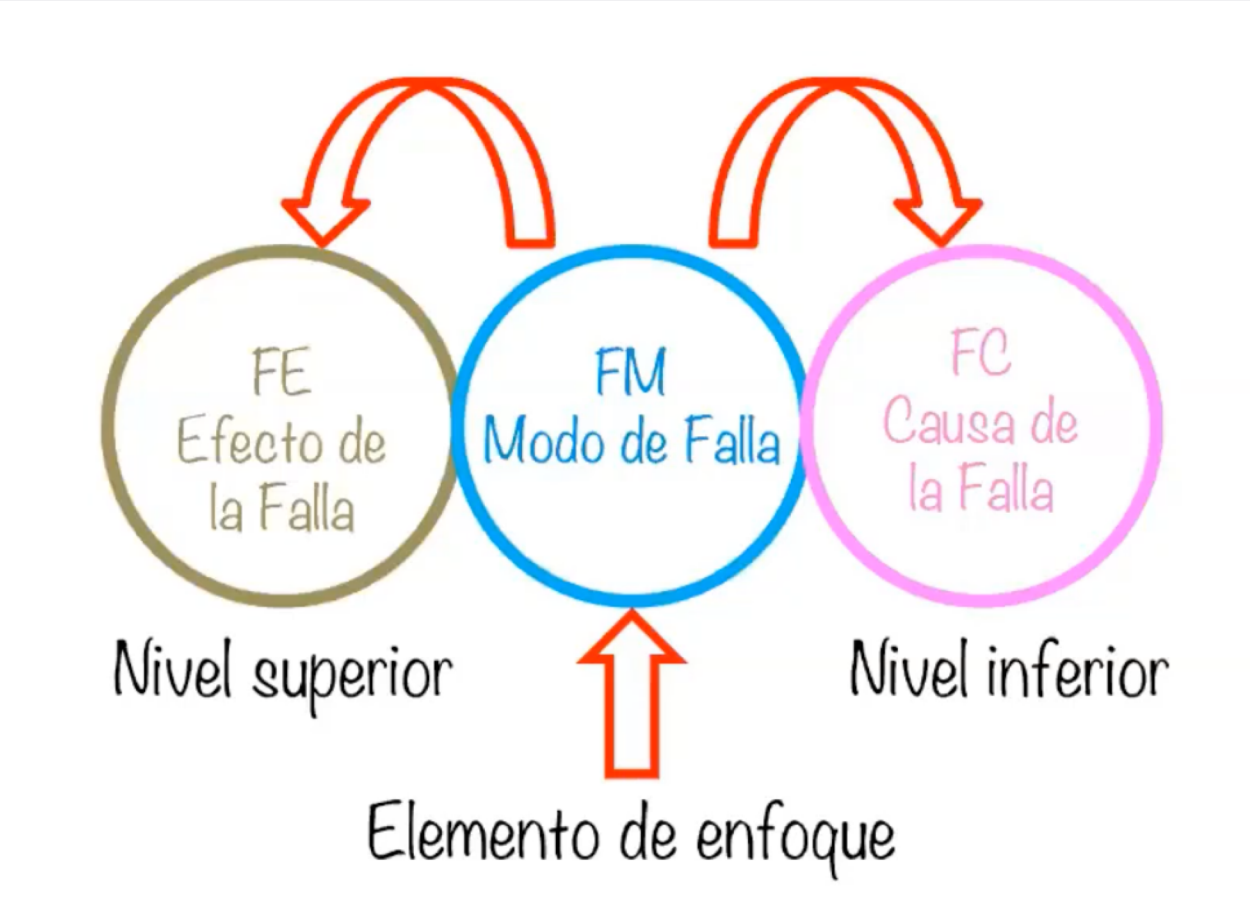
FUNCTION ANALYSIS (STEP 3)

FUNCTION ANALYSIS (STEP 3)			
1. Function of the Process Item Function of System, Subsystem, Part Element or Process		2. Function of the Process Step and Product Characteristic (Quantitative value is option)	3. Function of the Process Work Element and Process Characteristic
Supplier Plant	Assembly of shaft into pole housing assembly	Press in sintered bearing to acieve axial position in pole housing to max gap per print	Machine presses sintered bearing into the pole houising seat until the defined axial position
Ship-to Plant	Assemby of motor to vehicle door		
End User	Window raises and lowers		

SEVEN STEPS (4th, 5th, 6th)

FAILURE ANALYSIS AND RISK MITIGATION		
4th Step	**5th Step**	**6th Step**
Establishment of the Failure Chain	Assignments of existing controls and rating of failures	Identification of the actions necessary to reduce risks
Potential Failure Effects, Failure Modes, Failure Causes for each process function	Assigment of Prevention Controls to the Failure Causes Assigment of Detection Controls to the Failure Causes and/or Failure Mode	Assigment of responsabilities and deadlines for action implementation
Identification of process failure causes using fishbone diagram (4M) or failure network	Rating of Severity, Ocurrence, and Detection for each failure chain Evaluation of Action Priority	Implementation of actions taken including confirmation of the effectiveness of the implemented actions and assessment of risk after actions taken
Collaboration between customer and supplier (Failure Effects)	Collaboration between customer and supplier (Severity)	Collaboration between the FMEA team, management, customers, and suppliers regarding potential failures
Basis for the documentation of failures in the FMEA form and the Risk Analysis Step	Basis for the product or process Optimization Step	Basis for refinement of the product requerimients and prevention and detection controls

ANÁLISIS DE FALLAS (PASO 4)



EFECTO ➔ CONSECUENCIA

MODO ➔ A QUÉ SE DEBE LA CONSECUENCIA

CAUSA ➔ EL PROBLEMA QUE ORIGINA EL MODO DE FALLA

FAILURE ANALYSIS (STEP 4)

1. Failure Effects (FE) to the Next Higher Element and/or End User		Severity (S) of FE	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Work Element
Supplier Plant	Clearnace too small to assemble shaft without potential damage	8	Axial position of sintered bearing is not reached	machine stops before reaching final position
Ship-to Plant	Assembly of motor to door requires additional insertion force with potential damage			
End User	comfort closing time too long			

PASOS 2,3&4

STRUCTURE ANALYSIS (STEP 2)				FUNCTION ANALYSIS (STEP 3)			
1. Process Item System, Subsytem, Part Element or Name of Process	2. Process Step Station No.	2. Process Step Name of Focus Element	3. Process Work Element 4M Type	1. Function of the Process Item Function of System, Subsystem, Part Element or Process		2. Function of the Process Step and Product Characteristic (Quantitative value is option)	3. Function of the Process Work Element and Process Characteristic
Electric Motor Assy Line	30	Sintered Bearing Press-in Process	Man	Supplier Plant	Assembly of shaft into pole housing assembly	Press in sintered bearing to acieve axial position in pole housing to max gap per print	Machine presses sintered bearing into the pole houising seat until the defined axial position
Electric Motor Assy Line	30	Sintered Bearing Press-in Process	Machine	Ship-to Plant	Assemby of motor to vehicle door		
Electric Motor Assy Line				End User	Window raises and lowers		

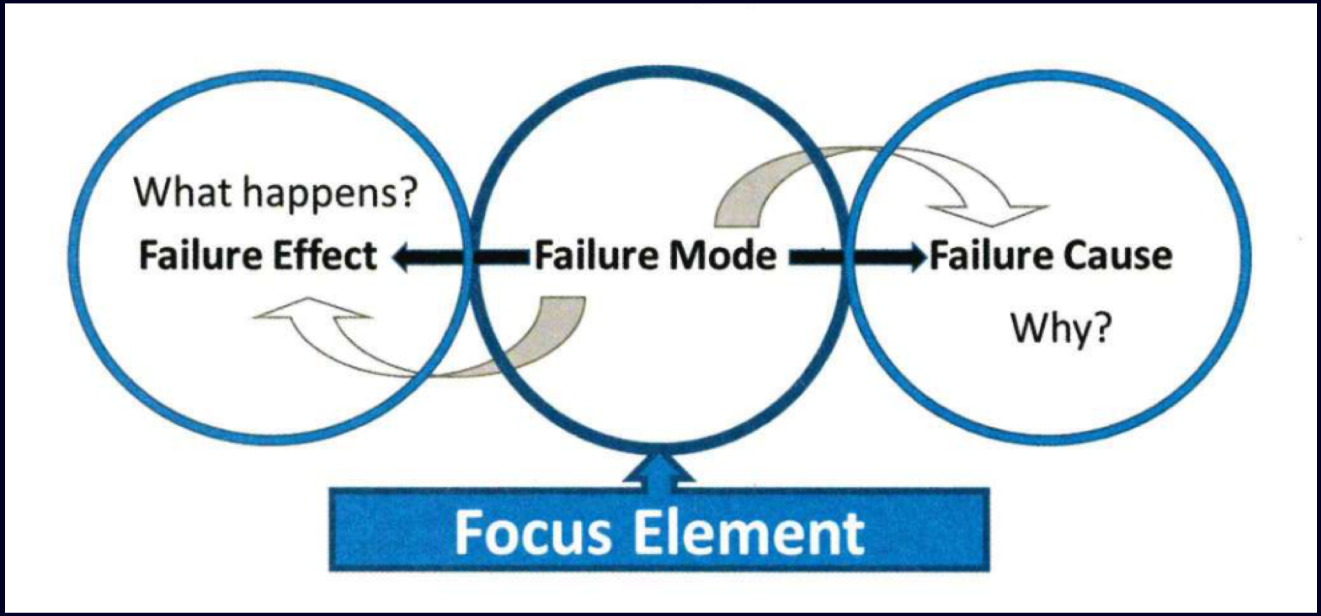
1. Failure Effects (FE) to the Next Higher Element and/or End User		Severity (S) of FE	2. Failure Mode (FM) of the Focus Element	3. Failure Cause (FC) of the Work Element
Supplier Plant	Clearnace too small to assemble shaft without potential damage	8	Axial position of sintered bearing is not reached	machine stops before reaching final position
Ship-to Plant	Assembly of motor to door requires additional insertion force with potential damage			
End User	comfort closing time too long			

STEP 2	STEP 3		STEP 4	
1. Process Item System, Subsytem, Part Element or Name of	1. Function of the Process Item Function of System, Subsystem, Part Element or Process		1. Failure Effects (FE) to the Next Higher Element and/or End User	
Electric Motor Assy Line	Supplier Plant	Assembly of shaft into pole housing assembly	Supplier Plant	Clearnace too small to assemble shaft without potential damage
Electric Motor Assy Line	Ship-to Plant	Assemby of motor to vehicle door	Ship-to Plant	Assembly of motor to door requires additional insertion force with
Electric Motor Assy Line	End User	Window raises and lowers	End User	comfort closing time too long

STEP 2		STEP 3	STEP 4
2. Process Step Station No.	2. Process Step Name of Focus Element	2. Function of the Process Step and Product Characteristic (Quantitative value is option)	2. Failure Mode (FM) of the Focus Element
30	Sintered Bearing Press-in Process	Press in sintered bearing to acieve axial position in pole housing to max gap per print	Axial position of sintered bearing is not reached
30	Sintered Bearing Press-in Process		

STEP 2	STEP 3	STEP 4
3. Process Work Element 4M Type	3. Function of the Process Work Element and Process Characteristic	3. Failure Cause (FC) of the Work Element
Man		
Machine	Machine presses sintered bearing into the pole housing seat until the defined axial position	machine stops before reaching final position

FAILURE CHAIN



EFECTOS DE FALLA

- EFECTOS DE FALLA están relacionados a la función del proceso.
- EFECTOS DE FALLA son descritos en términos de lo que el cliente puede notar o experimentar.
- FALLAS que pueden impactar la seguridad o causar una no-conformidad a alguna regulación deben ser claramente identificadas en el FMEA.
- Clientes pueden ser:
  - Internos (próxima/subsecuente operación)
  - Externos (Próximo nivel TIER)
  - Agencia regulatoria
  - Usuario final del producto o servicio

SEVERIDAD

EFECTOS DE FALLA tienen un nivel de SEVERIDAD acorde a:

- El efecto del modo de falla asumiendo que el defecto es detectado en la planta.
- El efecto del modo de falla asumiendo que el defecto no es detectado antes del embarque a la siguiente planta
- El efecto del modo de falla será detectado por el usuario final

- Severidad (S) implica la Severidad del Efecto de Falla.

SEVERITY

Process General Evaluation Criteria Severity (S)

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 an acute health and/or safety risk for the manufacturing or assembly work.	Failure may result in an acute health and/or safety risk for the manufacturing or assembly work.	Affects safe operation of the vehicle and/or other vehicles, the health of driver or passenger(s) or road users or pedestrians.	
9		Failure may result in in-plant regualatory noncompliance.	Failure may result in in-plant regualatory noncompliance.	Noncompliance with regulations.	
8	Moderately High	100% of production run affected may to be scrapped. Failure may result in in-plant regulatory noncompliance or may have a chronic health and/or safety risk for the manufacturer or assembly worker.	Line shutdown greater than normal production shift; Stop shippment possible; field repair or replacement required (Assembly to End User) other than for regulatory noncompliance) Failure may result in in-plant regulatory noncompliance or may have a chronic health and/or safety risk for the manufacturer or assembly worker.	Loss of primary vehicle function necessary for normal driving during expected service life.	
7		Production may have to be sorted and a portion (less than 100% scapped) Deviation from primary process. Decreased from line speed or added manpower	Line shutdown from one hour up to full production shift; Stop shippment possible; field repair or replacement required (Assembly to End User) other than for regulatory noncompliance	Degradation of primary vehicle function necessary for normal driving during expected service life.	
6	Moderately Low	100% of production 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 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	Deffective 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	Deffective product triggers minor reactios plan; additional defective products not likely; sort not required.	Moderately objectionable appearance, sound, vibration, harshness, or haptics	
2		Slight inonvenience	Deffective product triggers no reactios plan; dditional defective products not likely; sorts not required; requires feedback to supplier	Slightily objectionable appearance, sound, vibration, harshness, or haptics	
1	Very Low	No discernable effect	No discernable effect or no effect	No discernable effect	

MODO DE FALLA: manera en la cuál el proceso puede causar que el producto no provea la función requerida.

CATEGORÍAS	EJEMPLOS
Operación no ejecutada	Maquinado incorrecto de agujeros
Operación incompleta	Superficies sucias
Degradación de la función del proceso	Acabado de superficies incorrecto
Sobreprocesamiento	Conectores mal alineados
Operación no consistente	Pasar partes malas, rechazar partes buenas
Operación inestable	Etiquetas extraviadas
Operación incorrecta	Códigos de barras no detectados
Instalación de partes incorrectas	Software equivocado
Retraso en operaciones	

CAUSA DE LA FALLA

- **CAUSA DE LA FALLA** es una indicación de por qué un modo de falla puede ocurrir.
- Las causas se pueden buscar en la clasificación de Ishikawa (6M):
  - **Mano de Obra: operador, técnico…**
  - **Máquinas / Equipo: robot, moldeadora, sujetadores…**
  - **Medio ambiente: calor, ruido, contaminación…**
  - **Material (indirecto): aceite, grasa…**
  - Medición
  - Método

ANÁLISIS DE RIESGO

PC: Prevention Control
FC: Failure Cause
FM: Failure Mode
DC: Detection Control

RISK ANALYSIS (STEP 5)							
Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Controls (DC) of FC or FM	Detection (D) of FC/FM		PFMEA AP	Special Characteristics	Filter Code
Force adjusted aacording to data sheet	5	100% Check of moor performance curve acc. Acc. Spec. MRKJ5039	4	854	M		

ANÁLISIS DE RIESGO

- **CONTROL DE PREVENCIÓN ACTUALES:**
- Prevenir la causa de falla o reducir su nivel de ocurrencia (frecuencia):
- Tipos de controles de prevención:
  - Operación de máquinas a dos manos
  - Partes de ensamble en una sola posición (Poka Yoke)
  - Mantenimiento equipo
  - Apoyos visuales
  - Instrucciones de trabajo
  - Procedimientos de set-up

ANÁLISIS DE RIESGO

CONTROL DE DETECCIÓN ACTUALES:

Detectar la existencia de una causa y/o modo de falla, ya sea manual o automática.

Tipos de controles de detección:

- Inspección visual
- Inspección visual con una lista de verificación (checklist)
- Inspección óptica con un sistema de cámara
- Prueba de dimensiones con medidor (gage)
- Inspección aleatoria
- Monitoreo de torque
- Funciones de verificación al final de la línea (interruptores de presencia)

OCURRENCIA (FRECUENCIA)

Describe la frecuencia de las causas de falla en el proceso, tomando en cuenta los controles actuales de prevención.

La ocurrencia se analiza de acuerdo a una tabla sin tomar en cuenta los controles de detección.

OCURRENCE

Occurence Potential (O) for the Process

Back to step 5

O	Prediction of failure cause occuring	Type of Control	Prevention Controls	Corporate or Product Line Examples
10	Extremly High	None	No prevention controls.	
9	Very High	Behavioral	Prevention Controls will have little effect in preventing failure cause.	
8				
7	High	Behavioral or Technical	Prevention controls somewhat effective in preventing the failure cause.	
6				
5	Moderate		Prevention controls are effective in preventing the failure cause.	
4				
3	Low	Best Practices: Behavioral or Technical	Prevention controls are highly effective in preventing the failure cause.	
2	Very Low			
1	Extremly Low	Technical	Prevention controls are **extremely** effective in preventing the failure cause due to design (e.g. Part geometry) or process (e.g. Fixture or Tool design). Intent of prevention controls - Failure Mode cannot be physically produced due to the Failure Cause.	

DETECCIÓN (D)

DETECCIÓN es el nivel asociado a la predicción de la mayoría de los procesos de control de una lista de procesos tipo detección.
La DETECCIÓN se evalúa en función de los criterios establecidos en la tabla indicada.
La evaluación de DETECCIÓN no está asociada a los valores de SEVERIDAD y OCURRENCIA.
Algunas preguntas para controles de DETECCIÓN son:

- ¿Cuál prueba es la más efectiva en detectar Causas de Falla o Modos de Falla?
- ¿Qué tamaño de muestra es requerido para detectar la falla?
- ¿Es el procedimiento de la prueba adecuado para detectar esta Modo de Causa/Falla?

DETECTION

Detection Potential (D) for the Validation of the Process Design

Back to step 5

D	Ability to Detect	Detection Method maturity	Opportunity for Detection	Corporate or Product Line Examples
10	Very Low	No testing or 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..)	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 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 on identicial process or this application, gauge R&R results **are acceptable** ..)	Human inspection (visual, tactile, audible), or use of manual gauging (attribute or variable) that **will** detect the failure mode or failure cause.	
5			Machine-based detection (automated or semi-automated with notification by light, buzzer, etc.) or use of inspection equipment such as coordinate measuring machine that **will** detect failure mode or failure cause.	
4	High	System 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..)	Machine based method that will detect the failure mode downstream, prevent further processing or system will identify the product as discrepant and allow it automatically move forward in the process until the designated reject unload area. Discrepant products will be controlled by a robust system that will prevent the outflow of the product from the facility.	
3			Machine based detection that will detect the failure mode in-station, prevent further processing, or system will identify the product as discrepant and allow it automatically move forward in the process until the designated reject unload area. Discrepant products will be controlled by a robust system that will prevent the outflow of the product from the facility.	
2		Detection has been proven to be effective and reliable (e.g. plant has experience with method, error-proofing verifications, etc.).	Machine detection that will detect the cause and prevent the failure mode (discrepant part) from being produced.	
1	Very High	Failure mode cannot be physically produced as-designed or processed, or detection methods proven to **always** detect the failure mode or failure cause.		

SEVERIDAD, OCURRENCIA, DETECCIÓN

EVALUACIÓN	SEVERIDAD	OCURRENCIA	DETECCIÓN
10	ALTA	EXTREMADAMENTE ALTA	MUY BAJA
9		MUY ALTA	
8	MODERADAMENTE ALTA		BAJA
7		ALTA	
6	MODERADAMENTE BAJA		MODERADA
5		MODERADA	
4			ALTA
3	BAJA	BAJA	
2		MUY BAJA	
1	MUY BAJA	EXTREMADAMENTE BAJA	MUY ALTA

AP – PRIORIDAD DE ACCIÓN

El método AP (Action Priority) considera las 1000 combinaciones de S,O, D.

Se creó para dar más énfasis en la severidad (primero), luego la ocurrencia, y después la detección.

La tabla AP sugiere una prioridad ALTA-MEDIA-BAJA para cada acción prioritaria.

RPN (versión anterior) es el producto de SxOxD y va de 1 a 1000. El método RPN le da el mismo valor a S, O , D, creando ambigüedades para la prioridad de acciones. Cuando se utiliza RPN, se sugiere utilizar también el indicador SxO.

ACTION PRIORITY

Action Priority (AP) for DFMEA & PFMEA

Action Priority is based on combination of severity, Occurrence and Detection rating in order to prioritize action for risk reduction.

Effect	S	Prediction of failure cause Occurring	O	Ability to Detect	D	Action Priority (AP)
Product or Plan 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	5-4	Low-Very Low	7-10	H
				Moderate	5-6	H
				High	2-4	H
				Very High	1	M
		Low	3-2	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
Product or Plan 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
Product or Plan 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

AP (P4)

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	
No discernible Effect	1	Very low - Very high	1-10	Very high - Very low	1-10	L	

PFMEA AP LOGIC

Priority	Description
HIGH	**Action** to improve prevention and/or detection controls (or justification on why current controls are adequate) **MUST be taken.**
MEDIUM	**Action** to improve prevention and/or detection controls (or justification on why current controls are adequate) **SHOULD be taken.**
LOW	**Action** to improve prevention and/or detection controls **COULD be taken.**

S	O	D	AP	PFMEA Action Priority Logic
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
9-10	4-5	7-10	H	High priority due to safety and/or regulatory effects that have a **moderate** occurrence rating and **high** detection rating
9-10	4-5	5-6	H	High priority due to safety and/or regulatory effects that have a **moderate** occurrence rating and **moderate** detection rating
9-10	4-5	2-4	M	Medium priority due to safety and/or regulatory effects that have a **moderate** occurrence rating and **low** detection rating
9-10	2-3	7-10	H	High priority due to safety and/or regulatory effects that have a **low** occurrence rating and **high** detection rating
9-10	2-3	5-6	M	Medium priority due to safety and/or regulatory effects that have a **low** occurrence rating and **moderate** detection rating
9-10	2-3	2-4	L	Low priority due to safety and/or regulatory effects that have a **low** occurrence and **low** detection rating
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
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
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** detection rating
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
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 **high** detection rating
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** detection rating
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** detection rating
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** detection rating
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 **moderate** detection rating
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
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
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
2-4	6-7	5-6	H	High priority due to perceived quality (appearance, sound, haptics) or a manufacturing disruptionwith a **high** occurrence and **moderate** detection rating
2-4	6-7	2-4	M	Medium priority due to perceived quality (appearance, sound, haptics) or a manufacturing disruption with a **high** occurrence rating and **low** detection rating
2-4	4-5	7-10	H	High priority due to perceived quality (appearance, sound, haptics) or a manufacturing disruption with a **moderate** occurrence and **high** detection rating
2-4	4-5	5-6	M	Medium priority due to perceived quality (appearance, sound, haptics) or a manufacturing disruption with a **moderate** occurrence and **moderate** detection rating
2-4	4-5	2-4	L	Low priority due to perceived quality (appearance, sound, haptics) or a manufacturing disruption with a **moderate** occurrence and **low** detection rating
2-4	2-3	7-10	M	Medium priority due to perceived quality (appearance, sound, haptics) or a manufacturing disruption with a **low** occurrence and **high** detection rating
2-4	2-3	5-6	L	Low priority due to perceived quality (appearance, sound, haptics) or a manufacturing disruption with a **low** occurrence and **moderate** detection rating
2-4	2-3	2-4	L	Low priority due to perceived quality (appearance, sound, haptics) or a manufacturing disruption with a **low** occurrence and **low** detection rating
2-10	1	1	L	Low priority due to the failure being virtually eliminated through prevention controls
1	1-10	1-10	L	Low priority due to no discernible effect
2-10	1	2-10	Error	O=1 implausible without D=1
2-10	2-10	1	Error	D=1 implausible without O=1

RISK MANAGEMENT (STEP 5)

RISK ANALYSIS (STEP 5)							
Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Controls (DC) of FC or FM	Detection (D) of FC/FM		PFMEA AP	Special Characteristics	Filter Code
Force adjusted aacording to data sheet	5	100% Check of moor performance curve acc. Acc. Spec. MRKJ5039	4	854	M		

SPECIAL CARACTERISTHICS

Categorization of Characteristics		
Standard (Non-key) characteristics	**Special characteristics (or Key characteristics / Significant Characteristics)**	
	Function relevant characteristics (or Significant Characteristics)	**Safety relevant / Governmental regulated characteristics (or Critical characteristics)**
A product or process characteristic, that does not affect a product's function, safety or compliance with governmental regulations. No, or very minor impact on customer satisfaction. Low risk	The variation of this characteristic significantly affect fit, form, function, performance or subsequent processing. High impact on customer satisfaction! Moderate / High risk	The variation of this characteristic significantly affects safety, or compliance with governmental regulations. High impact on safety, environment, function or various governmental regulations! Non-conformance of characteristic may cause serious failure! Very high risk
Example: Length of a USB stick. Even though the stick is longer, than specified in the drawing, it still works, and causes no functional failure.	Example: Width of the USB stick's port (terminal). In case the width of the terminal is not in specification range, the user cannot plug it into the slot. This causes functional failure (non-conformance of fit, form, function)	Example: Pressure in the hydraulic break system. If the pressure is low, it causes the malfunction (functional issue) of the whole breaking system, and on top of that, it may risk injury (safety issue).
Remark: many companies simply do not designate this category.	Remark: some companies use the phrase significant product characteristic, or key characteristics.	Remark: some companies call these critical characteristics.
FMEA severity: 1 – 4	FMEA severity: 5 – 8	FMEA severity: 9 - 10

OPTIMIZATION (STEP 6)

- Determinar acciones para mitigar el riesgo y evaluar la efectividad de esas acciones.
- Los principales objetivos son:
- Identificación de las acciones necesarias para reducir riesgo.
- Asignar responsables y tiempos para implementación de acciones.
- Implementación y documentación de acciones emprendidas incluyendo confirmación de la efectividad de la implementación de las acciones y evaluación del riesgo después de dicha implementación
- Colaboración entre el equipo FMEA, administración, clientes, y proveedores con respecto a fallas potenciales
- Base para el refinamiento de los requerimientos del producto y controles de prevención y detección

OPTIMIZATION (STEP 6)

- La optimización es más efectiva en el siguiente orden:
  - Modificaciones de diseño para mitigar o eliminar el efecto de falla (FE)
  - Modificaciones de diseño para reducir la ocurrencia (O) o la causa de falla (FC)
  - Incrementar la habilidad de detección (D) para la causa o modo de falla (FC/FM)

- Responsabilidades: Cada acción debe indicar un responsable y fecha para completarla.

OPTIMIZATION (STEP 6)

- Estatus de las acciones:
  - Abierto/Open: No se ha definido ninguna acción.
  - Decisión pendiente: La acción se ha definido pero no se ha autorizado.
  - Implementación pendiente: La acción se ha definido/autorizado pero no se ha implementado.
  - Completo: La acción se ha implementado y se ha demostrado su efectividad.
  - No implementado: Se decide no implementar la acción (puede ser que la organización no cuente con los recursos necesarios)

OPTIMIZATION (STEP 6)

Evaluación:

- Una vez implementada la acción se deben evaluar la OCURRENCIA y DETECCIÓN y generar un nuevo código de AP.

OPTIMIZATION (STEP 6)												
PFMEA Preventive Action	PFMEA Detection Action	Responsible Peson's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Severity (S) of FE	Occurrence (O) of FC	Detection (D) of FC/FM	Special Characteristics		PFMEA AP	Remarks
				Open			8	3	2		832	L	

SEVEN STEPS

RISK MITIGATION
7th Step
Communication of results and conclusions of the analysis
Establishment of content of the documentation
Documentation of actions taken including confirmation of the effectiveness of the implemented actions and assesment of risk after actions taken
Communication of actions to reduce risks, including within the organization, and with customers and/or supplier as appropriate
Record of risk analysis and reduction to aceptable levels

DOCUMENTACIÓN DE RESULTADOS

- El objetivo de la documentación de resultados es resumir y comunicar los resultados del análisis de los Modos de Falla y Efectos.
- Los principales objetivos de la documentación son:
- Comunicar los resultados y conclusiones del análisis
- Documentar las acciones tomadas incluyendo confirmación y efectividad de las acciones implementadas y la evaluación del riesgo después de la implementación de las acciones
- Comunicación de las acciones tomadas para reducir riesgo, incluyendo dentro de la organización, con clientes y proveedores según sea apropiado
- Obtener una evaluación de riesgo a niveles aceptables

REPORTE

- El contenido puede incluir lo siguiente:
- A. Declaración del estatus final comparado con las metas establecidas en un inicio
  - Plan Proyecto
    a. FMEA Intent – Propósito de este FMEA
    b. FMEA Timing – Fecha límite para el FMEA
    c. FMEA Team – Lista de participantes
    d. FMEA Task – Alcance del FEMA
    e. FMEA Tool – Cómo se llevó a cabo el método de análisis utilizado
- B. Resumen del alcance del análisis e identificar las cosas nuevas.

REPORTE

- C. Resumen de cómo se desarrollaron las funciones .
- D. Resumen de –al menos- las fallas de alto riesgo según las determinó el equipo y proveer una copia de las tablas de evaluación para S/O/D y el método de AP (tabla AP)
- E. Resumen de las acciones llevadas a cabo y/o planeadas para contrarrestar las fallas de alto riesgo incluyendo el estatus de esas acciones
- F. Plan de compromiso y tiempos para mejorar acciones FMEA
- Compromiso y tiempos para cerrar acciones abiertas
- Compromiso para revisar el PFMEA durante la producción para asegurar la exactitud del análisis comparado con el diseño del producto
- Compromiso para documentar “cosas que fueron mal” durante el PFMEA para el beneficio de futuros análisis.