

# PROCESS IMPROVEMENT QUALITY MANAGEMENT\_4

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# Risk

- ISO 9001:2015 risk-based thinking
- ISO 31000:2018 (2015) Risk management — Guidelines
- ISO 31010:2010 Risk management — Risk assessment techniques

# Risk

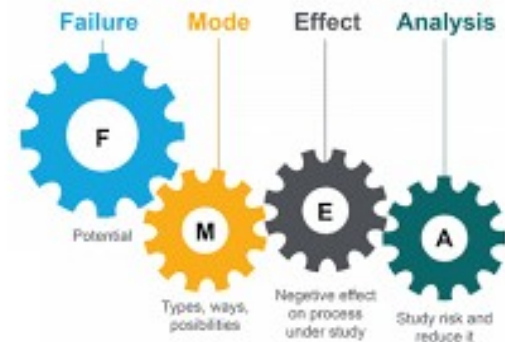
- Risk is the effect of uncertainty, and any uncertainty can have positive or negative effects. A positive deviation from a risk can lead to opportunity, but not all positive effects of risk lead to opportunities.
- Negative - risk
- Positive - opportunity

# Risk analysis methods

## FAULT TREE ANALYSIS



## FMEA



## Kockázati mátrix

**Kármérték**

Katastrofális	Előrejelzés, káros	Előrejelzés, káros	Előrejelzés, káros	Előrejelzés, káros	Előrejelzés, káros
Nagy	Előrejelzés, káros	Előrejelzés, káros	Előrejelzés, káros	Előrejelzés, káros	Előrejelzés, káros
Közepes	Előrejelzés, káros	Előrejelzés, káros	Előrejelzés, káros	Előrejelzés, káros	Előrejelzés, káros
Alacsony	Előrejelzés, káros	Előrejelzés, káros	Előrejelzés, káros	Előrejelzés, káros	Előrejelzés, káros
Nem számottevő	Előrejelzés, káros	Előrejelzés, káros	Előrejelzés, káros	Előrejelzés, káros	Előrejelzés, káros

**Bekövetkező valószínűsége**

Nagyon valószínű	Valószínű	Feltételezhető	Valószínű	Nagyon valószínű
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**Kockázati szintek:**

- Nagyon magas
- Magas
- Közepes
- Alacsony



# FMEA aims & usage

## Target

- Error analysis, mapping, elimination of the most significant errors
- Risk analysis
- Increase reliability
- Review of control processes



## When

- New product, process
- Risk analysis
- Safety

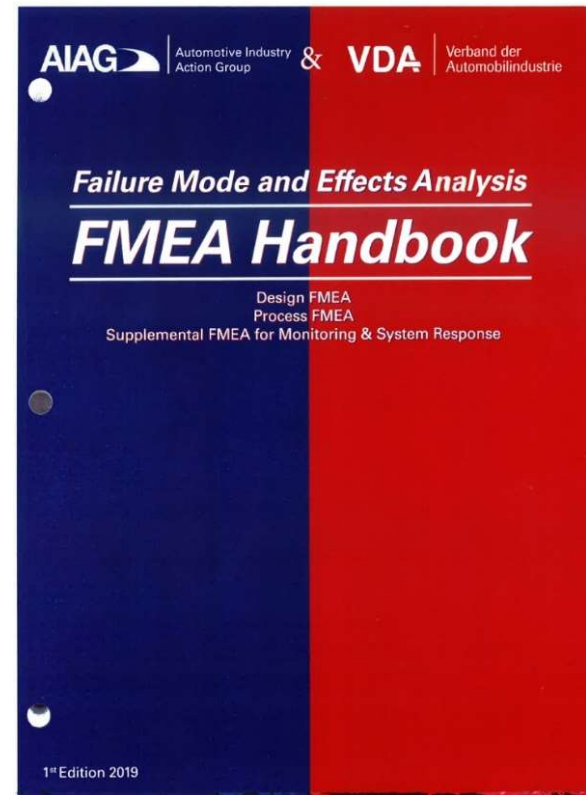
# Types of FMEA

- Design FMEA
- Process FMEA



# FMEA new approach - steps

1. Planning
2. System analysis
3. Function analysis
4. Failure analysis
5. Risk analysis
6. Optimalization
7. Documentation





# Old example

Folyamat Művelet Prozess Function  Követelmények Requirements	Hibalehetőség Potential Failure Mode	A hiba lehetséges következ- ménye(i) Potential Effect(s) of Failure	Jelentőség Sev	BESOROLÁS CLASS	Lehetséges hiba(ok) Potential Cause(s) / Mechanism(s) of Failure	Előfordulás Occur	Jelenlegi intézkedések a folyamatok felügyeletére a - megelőzés ill. a Current Design Controls - Prevention	Jelenlegi intézkedések a folyamatok felügyeletére a - feltárás területén Current Design Controls - Detection	Feltárás Detec	R. P. N.
60 Production release	Production without release	Functional / visual failures	6	SC custo- mer marking or ▽	Production start not according to the process	2	Production release process: H- 04-00785  Process steps: - Material preparation - Tool preparation with first part production - first part release after the measurement of the first shoot  Production release has to be documented on workplan	SPC-check, visual check	6	72
70 Production Injection moulding	Pollutation on the part	Visual problems on the parts	5	-	Tool pollutation,oil flowing, not proper washer	2	Washer change,regulary maintanance on the tool, see tool file and maintenance plan at the tool order	Visual check according to QDB and failure catalog	7	70



# 1. Planning

- a. Legal requirements
- b. Customer requirements
- c. BOM (Bill of Material)
- d. Drawings, models
- e. Previous FMEA
- f. Coversheet
- g. Baseline

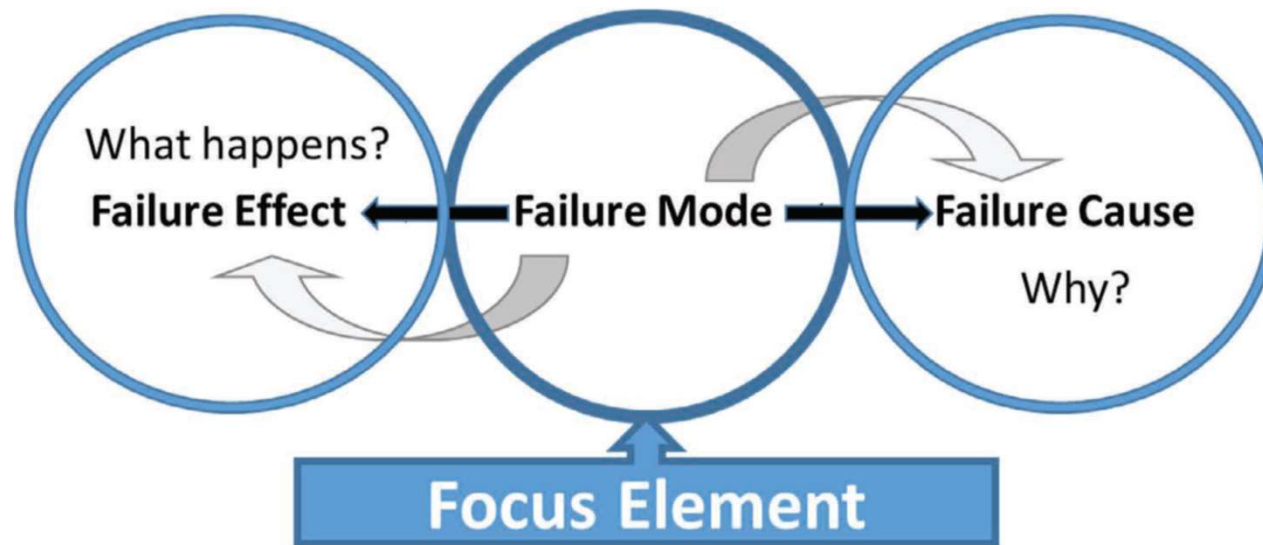
Example: Process Failure Mode and Effects Analysis (Process FMEA)					
Planning and Preparation (Step 1)					
Company Name:	Acme Automotive	Subject:	PX123 Manual Column Assembly		
Manufacturing Location:	Plant 6, Saginaw, Michigan	PFMEA Start Date:	19-Mar-2018	PFMEA ID Number:	654321
Customer Name:	Jackson Industry	PFMEA Revision Date:	25-Sep-2018	Process Responsibility:	B. Black
Model Year(s) / Program(s):	2020 PX123	Cross Functional Team:	See Team List	Confidentiality Level:	Confidential

## 2. System analysis/3. Function analysis

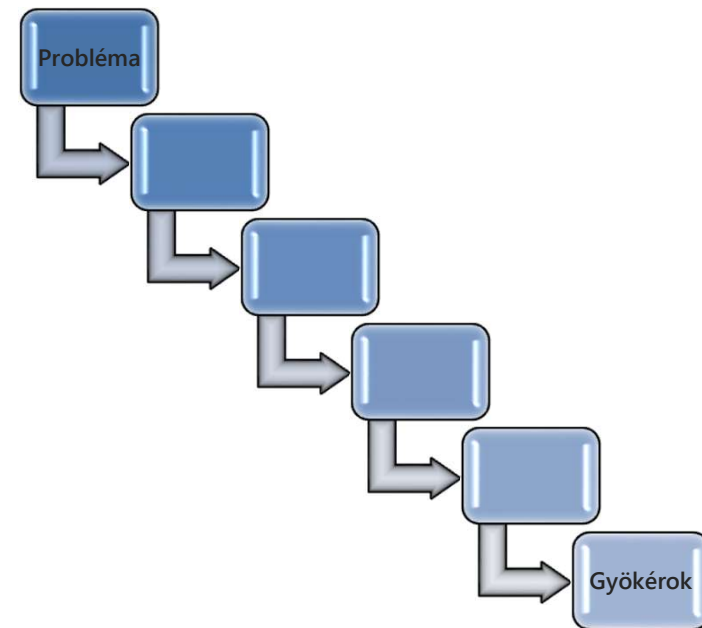
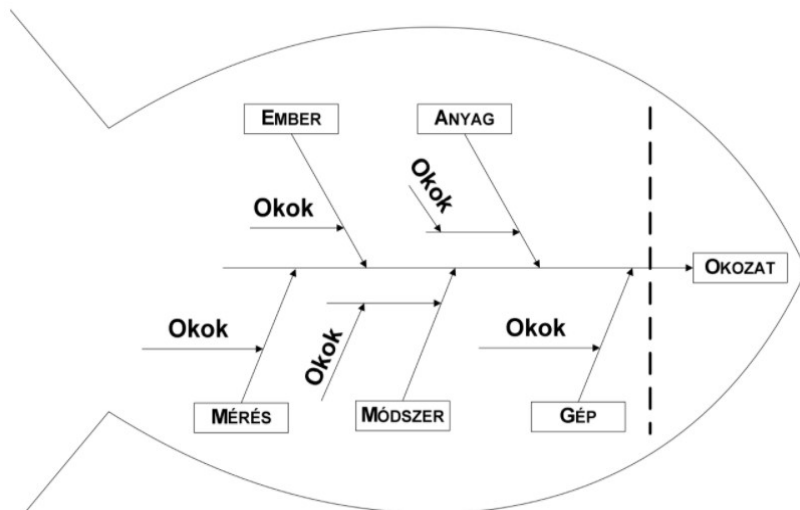
- a. Customer identification
- b. System structure
- c. Components vs processes
- d. What is the function?
- e. Customer requirements
- f. Parameters
- g. Special characteristics(PFMEA)

# 4. Failure analysis

## a. Possible effect, mode, cause definition



# Rootcause analysis



# 5. Risk analysis

## Severity

- Effect of the failure

Process 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 an 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 road users or pedestrians.	
9		Failure may result in in-plant regulatory noncompliance	Failure may result in in-plant regulatory noncompliance	Noncompliance with regulations.	
8	Moderately high	100% of production run affected may have to be scrapped. Failure may result in in-plant regulatory noncompliance 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 noncompliance. Failure may result in in-plant regulatory noncompliance 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%) scrapped; deviation from primary process; decreased line speed or added manpower	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 noncompliance	Degradation of primary vehicle function necessary for normal driving during expected service life.	

# Occurrence

- Efficiency of preventive actions

Occurrence Potential (O) for the Process				
<p>Potential Failure Causes rated according to the criteria below. Consider 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 being evaluated). For Prevention Controls with multiple Occurrence Ratings, use the rating that best reflects the robustness of the control.</p>				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	Behavioral	Prevention controls will have little effect in preventing failure cause.	
8				
7	High	Behavioral 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: Behavioral 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 controls - Failure Mode cannot be physically produced due to the Failure Cause.	



# Detection

- Efficiency of the checking method

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 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, 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.	



# Measurement

- RPN (Risk Priority Number)
  - $S \cdot O \cdot D$  (1-1000)
  - Limit
- AP (Action Priority)

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.						Blank until filled in by user	
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	

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# New example

PFMEA RISK ANALYSIS (STEP 5)							PFMEA OPTIMIZATION (STEP 6)												
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 (Optional)	Prevention Action	Detection Action	Responsible Person's Name	Target Completion Date	Status	Action Taken with Pointer to Evidence	Completion Date	Severity (S)	Occurrence (O)	Detection (D)	Special Characteristics	PFMEA AP	Remarks
Force adjusted acc. data sheet	5	100% check of motor performance curve acc. spec. MRKJ5038..	2	M			Selected press with position control sensor	Selected press with force monitoring	Process Engineer Mr. Paul Duncan	dd. mm. yyyy	open			8	3	2		L	

## 6. Optimization/7. Documentation

- Introduction of promotions based on limit values to reduce risk
- Determination of deadline and responsible for measures reduction
- Reassessment
- Documentation