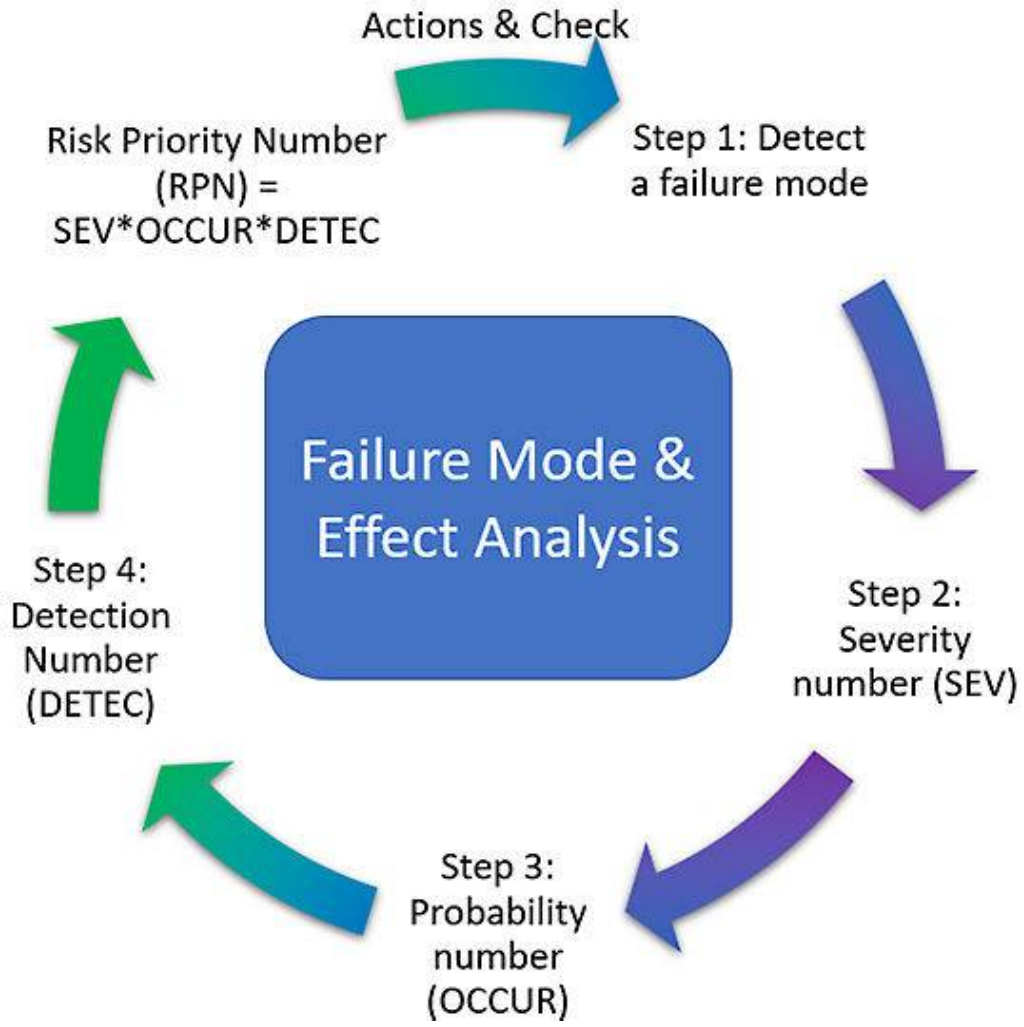
DFMEA- DESIGN FAILURE MODE EFFECTIVE ANALYSIS



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FMEA - FAILURE MODE AND EFFECTS ANALYSIS (FMEA)

What is FMEA?

- FMEAs is a risk identification and risk reduction tool.

Why FMEA?

- Today, quality is one of the most critical factors of a product (or service) for the customer.
- Applying FMEA at the right phases of the product development process can help a company not only prevent the costly quality problem but also help them build high-quality product/service.

When FMEA?

At initial stage of prototype.

Example: Repairing a molding die while production running is hard and costly

than doing it from the prototype phase.

PURPOSE OF FMEA

- to recognize and evaluate the potential failure of a product/ process and the effects of the failure
- to identify action that could eliminate or reduce the chance of such potential failure occurring
- to document the entire process

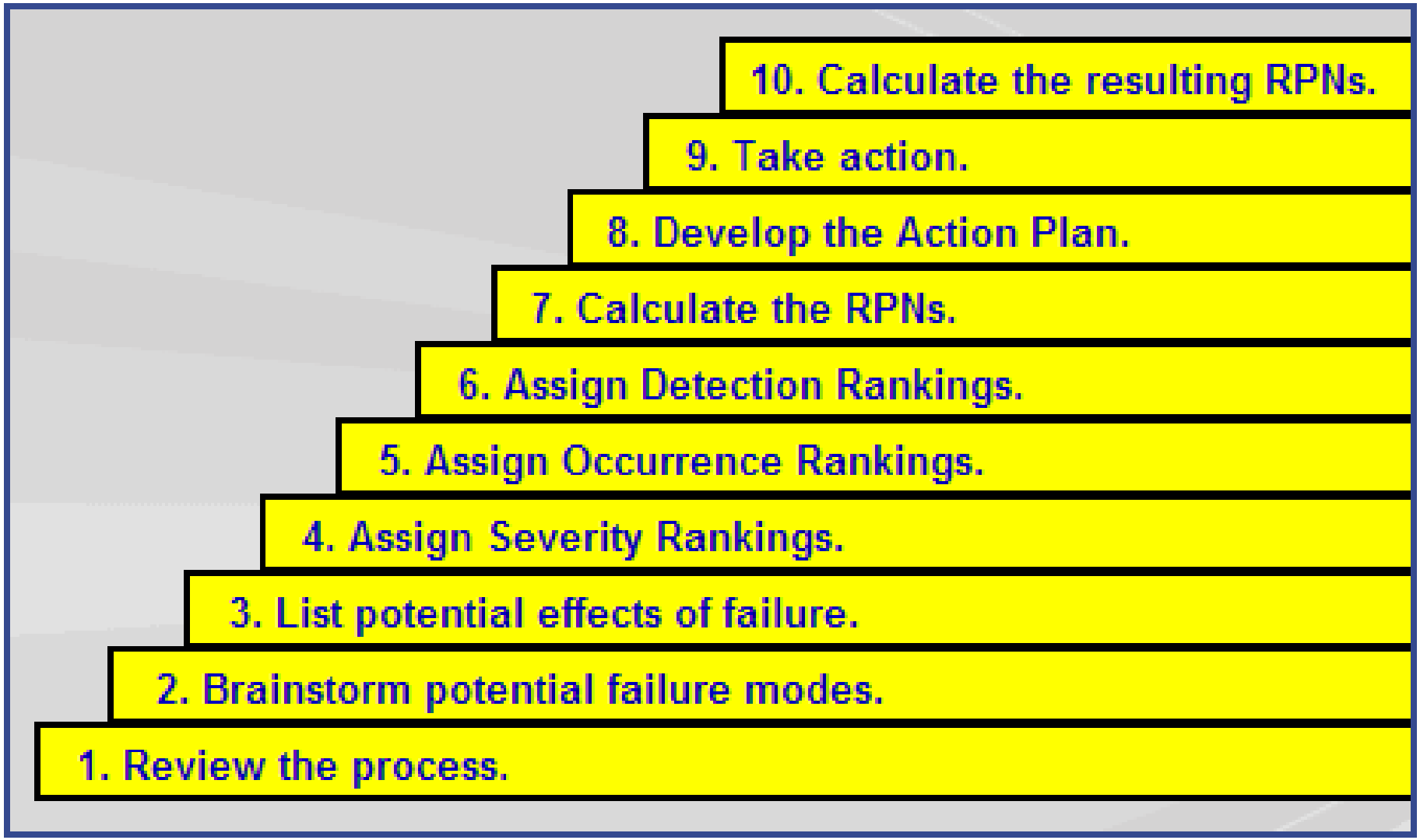
DFMEA

- Design failure mode and effect analysis (**DFMEA**)
- It is a part of design review.
- DFMEA reduces the risk through Risk Priority Number (RPN) By comparing the before and after RPN.
- **RPN** = Severity x Occurrence x Detection (S x O x D)

DFMEA Team

- One person doesn't know everything, especially with a complicated area as failures analysis. It require knowledge and experience of many departments in a company.
- Typically, a cross-functional team should handle Failure Mode and Effect Analysis in an organization

10 STEPS OF FMEA PROCESS



DFMEA TEMPLATE WITH EXAMPLE

t Number: PT34325-4053	Market: Japan	Team: Alex Drinal, Peter Loombard, Katie Samdras, Lin Woodlord			
t Name/Description: Ball Point Pen		Design Engineer Leader: Lin Woodlord	Document Number: DF325-12	Orginal Date: Feb 10, 2019	
HandFree-P6	Year: 2019	Approved by: Mike Handson	Revision No.: 002	Revision Date: May 14, 2019	

Function	Requirements	Potential Failure Mode	Potential Effect(s) of Failure	Severity	Classification	Potential Causes(s) of Failure	Current Design Controls Prevention	Occurrence	Current Design Controls Detection	Detection	RPN	Recommended Action(s)	Responsibility & Target Completion Date	Action Results				
														Actions Taken & Effective Date	Severity	Occurrence	Detection	RPN
/ ses ink aper ply	Delivery proper ink amount onto paper	Not enough ink	Pen skip or Required heavy pressure while writing	7	A	Ball diameter is too big	Study tolerance of ball diameter and line weight and color	6	Writing test to detect if problem occurs	3	126							
						Narrow pen angle when writing	Study common range of writing angle	4		10	280	Writing Test with varying pen angles of the pen	Katie Nov, 24		7	3	2	42
						Not enough presure on the pen	Study the minimum presure of users and make sure ink can be dispnersed with minium presure	4	Writing test with minum presure on the paper	2	56							
		Too much ink	Globs or drip left behind the letters	7	A	Ball diameter is too small	Study tolerance of ball diameter and its effects to line weith and color	3	Writing test to detect if problem occurs	3	63							
						Pressure of user on the pen too much	Study user's pressure range	3	Writing test with high presure	3	63							
	The ball runs smoothly	Smoothly	Inconsistent line Skip or Glob left behind	8		Inproper selection of dimenson of the ball and ball socket	Study the tolerance of ball and ball socket and select the correct range	4	Writing test with miniumum presure on the paper	2	64							
						Improper selection of the ball roughness tolerance	Select surface roughness base on the standard	2	Check the prototype capability of ball surface	3	48							

Severity Rankings

Ranking	Effect	Design FMEA Severity	Process FMEA Severity
10	Hazardous-no warning	affects safe operation without warning	may endanger machine or operator without warning
9	Hazardous- w/ warning	affects safe operation with warning	may endanger machine or operator with warning
8	Very High	makes product inoperable	major disruption in operations (100% scrap)
7	High	makes product operable at reduced performance (customer dissatisfaction)	minor disruption in operations (may require sorting and some scrap)
6	Moderate	results in customer discomfort	minor disruption in operations (no sorting but some scrap)
5	Low	results in comfort and convenience at a reduced level	minor disruption in operations (portion may require rework)
4	Very Low	results in dissatisfication by most customers.	minor disruption in operations (some sorting and portion may require rework)
3	Minor	results in dissatisfication by average customer.	minor disruption (some rework but little affect on production rate)
2	Very Minor	results in dissatisfication by few customers.	minor disruption (minimal affect on production rate)
1	None	No effect	No effect

Detection Rankings

Ranking	Effect	Design FMEA Detection	Process FMEA Detection
10	Absolute uncertainty	No chance that design control will detect cause mechanism and subsequent failure.	No known process control to detect cause mechanism and subsequent failure.
9	Very remote	Very remote chance that design control will detect cause mechanism and subsequent failure.	
8	Remote	Remote chance that design control will detect cause mechanism and subsequent failure.	Remote chance that process control to detect cause mechanism and subsequent failure.
7	Very Low	Very low chance that design control will detect cause mechanism and subsequent failure.	
6	Low	Low chance that design control will detect cause mechanism and subsequent failure.	Low chance that process control to detect cause mechanism and subsequent failure.
5	Moderate	Moderate chance that design control will detect cause mechanism and subsequent failure.	
4	Moderately High	Moderately high chance that design control will detect cause mechanism and subsequent failure.	
3	High	very remote chance that design control will detect cause mechanism and subsequent failure.	High chance that process control to detect cause mechanism and subsequent failure.
2	Very High	Very high chance that design control will detect cause mechanism and subsequent failure.	
1	Almost Certain	Design control will almost certainly detect cause mechanism and subsequent failure.	Current control almost certain to detect cause mechanism and failure mode.

OCCURRENCE RANKING

Likelihood	Criteria : Severity of Effect on Product (Customer Effect)	Rank
Very high	≥ 100 per thousand	10
	≥ 1 in 10	
High	50 per thousand	9
	1 in 20	
	20 per thousand	8
	1 in 50	
	10 per thousand	7
	1 in 100	
Moderate	2 per thousand	6
	1 in 500	
	0.5 per thousand	5
	1 in 2,000	
	0.1 in thousand	4
	1 in 10,000	
Low	0.01 per thousand	3
	1 in 1,00,000	
	≤ 0.001 per thousand	2
	1 in 1,000,000	
Very Low	Failure is eliminated through preventive control.	1

References

- **1**. https://www.iqasystem.com/news/fmea-template-for-excel/
- 2. https://asq.org/quality-resources/lean

Thank You