FMEA in 10 steps

A quick guide including forms

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FMEA - Failure Mode and Effect Analysis	Business:	Page:
Product/Process:	Feature:	Date:

FMEA in 10 steps		
Step 1	Explanation of product or process	The product or process expert provides an explanation of how the product or process works. Use drawings, diagrams or models for this as far as available. If the process already exists, walk through the different processing stations.
Step 2	Brainstorm failure modes	Use Post-It sticky notes to describe several possible failure modes in short sentences. (Don't think about how often or how likely). Stick the notes on a wall or plate. Use a brainstorming technique such as: each in turn, building on the failure mode of the person to your left; or walk (in mind) step by step through the process or product. Finally, group the failure modes according to place or function in the product or process.
Step 3	Inventory consequences	Stick one or more notes with the consequences of the failure method behind each failure method. So always answer the question: "If the failure mode occurs, what is the consequence?" Fill in place, method of failure and consequence on the FMEA form
Step 4	Rate the severity of each consequence	Rate the severity of each impact on a scale from 1 to 10, depending on the severity of the impact. The enclosed classification list can be used for this, but it is also conceivable to draw up a classification list tailored to one's own situation.
Step 5	Determine cause and probability of occurrence	Determine the possible cause of each failure mode and rate the probability of occurrence with a number from 1 to 10, the greater the probability of occurrence. Use available information if possible.
Step 6	Determine detection method and probability of discovery	Determine how it is currently detected whether a failure mode or consequence has occurred and rate this method with a number from 1 to 10, the smaller the chance of detection.
Step 7	Calculate RPN[1]	Calculate the Risk Priority Number (Severity x Frequency x Detection) for each failure mode. Group the failure modes by descending RPN. In other words, put the failure mode with the highest RPN at the top of the list.
Step 8	Determine which failure modes need to be addressed	Determine an RPN above which action will be taken. For each failure state whether action will be taken to prevent it.
Step 9	Determine and implement the actions to reduce the RPN	For each selected failure mode, determine what action to take to reduce the RPN. Try to eliminate the failure mode in the first place. If this does not work, try to reduce the chance of occurrence. The last option remains to increase the chance of detection. Determine who will carry out the action with what budget and when it should be ready.
Step 10	Determine the new RPN[1]	Calculate the new RPN value based on the improvements.

[1]) RPN = Risk Priority Number = Severity x Frequency x Detection

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FMEA Team			
No.	**Name**	**Organizational Function**	**Code***
1.			
2.			
3.			
4.			
5.			
6.			

*) V = Chairman, N = Note-taker, X = Expert, P = Project leader, K = Client

Are all relevant disciplines represented? Yes No
Action:

Is there sufficient variety of knowledge and experience available?
Yes No Action:

Is the customer involved?
Yes No Action:

Comments

Describe the product or process[1]

Describe the limits of the FMEA[2]

	Desired results[3]	**Budget**	**Ready**
☐	FMEA Analysis		
☐	Recommendations for improvement		
☐	Implement improvements		
☐	Reporting and/or presentation improvements		

1) Briefly describe the function and/or operation of the product
2) Describe specifically where the FMEA begins and ends. What still belongs to the product or process under consideration and what does not.
3) Tick what belongs to the assignment of this team?

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seriousness (product)		
Score	**Description**	**Definition**
10	Dangerously high	Failure can seriously injure customer or staff member
9	Very high	Failure leads to failure to comply with legal standards and regulations.
8	Very high	Failure to do so will render the product defective and unusable.
7	High	Failure leads to customer dissatisfaction
6	Average	Failure will render the product partially unusable or defective
5	Low	Failure leads to customer complaints
4	Very low	Failure can be corrected, but leads to poorer performance of the product
3	Minimal	Failure leads to annoyance for the customer but he can fix it himself without compromising the performance of the product
2	low	The failure is not noticed by the customer and has only a minor effect on the operation of the product
1	No	Failure is not noticed by the customer and has no effect on the operation of the product.

Severity (trial)		
Score	**Description**	**Definition**
10	Dangerously high	Failure can seriously injure staff member
9	Very high	Failure leads to failure to comply with legal standards and regulations.
8	Very high	Failure leads to the possibility that unsatisfactory products end up with the customer.
7	High	Failure leads to having to reject products already made.
6	Average	Failure cannot be corrected in the short term and leads to a long-term standstill of the process.
5	Low	Failure leads to having to repair products already made.
4	Very low	Failure can be corrected, but leads to limited downtime of the process.
3	Minimal	Failure leads to annoyance, but can be remedied without significant process downtime.
2	low	The failure is not noticed and has only a minor effect on the operation of the process.
1	No	Failure is not noticed and has no effect on the proper functioning of the process.

Frequency (probability of failure)		
Score	**Description**	**Definition**
10	Extremely often (failure is unavoidable)	More than once a day or a chance of more than 3 in 10 (C_{pk}< 0.33)
9	Very often	Once every three or four days or a chance of 3 in 10 (C_{pk}~0.33)
8	Often	Once a week or a probability of 5 per hundred (C_{pk}~0.67)
7	very regular	Once a month or 1 in 100 (C_{pk}~0.83)
6	Regularly	Once every 3 months or 3 per 1000 (C_{pk} ~1.00)
5	Intermittent	Once every 6 months to a year or 1 in 10,000 (C_{pk}~ 1.17)
4	Occasionally	Once a year or 6 in 100,000 (C_{pk}~1.33)
3	Low	Once every one to three years or 6 per 10,000,000 (C_{pk}~ 1.67)
2	low	Once every three to five years or 2 every 1,000,000,000 (C_{pk}~2.00)
1	Nil (failure is highly unlikely)	Once every five or more years or less than 2 every 1,000,000,000 (C_{pk}> 2.00)

Detection (chance of timely discovery)		
Score	**Description**	**Definition**
10	Virtually excluded	The product is not inspected or the defect is undetectable.
9	Very unlikely	The product is randomly checked and released on the basis of AQL (Acceptable Quality Level).
8	Unlikely	The product is randomly checked and released on the basis of zero defects in the sample.
7	Very low	The product is 100% manually checked.
6	Low	The product is 100% manually checked with go/no-go or some other form of error prevention.
5	Average	Some form of SPC process control is performed and the product undergoes a final check off-line.
4	More than average	SPC process control is used and there is an immediate response to going outside the control limits.
3	Probably	A qualified SPC process control is used with a C_{pk}> 1.33
2	Very probably	All products are 100% automatically checked.
1	Almost sure	The defect is clearly visible or 100% automatic control takes place with regular calibration and preventive maintenance of the control equipment.

C_{pk}= Minimum { (upper tolerance limit – nominal value) / (3 x standard deviation), (nominal value – lower tolerance limit) / (3 x standard deviation)} The extent to which the process is able to produce within tolerance. Aim for C_{pk}>= 1.33.

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Number	Place, part or function	Possible Failure Mode	Possible Consequence	seriousness	Possible cause	Frequency	Current mode of detection	Detection	RPN (ExFxD)	Action (Yes No)

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Recommendations					Realization				
Number	Recommended measure	Budget cost	out to feed by means of	To be carried out before date	Date ready	seriousness	Frequency	Detection	RPN