

The FMEA Tool

Agenda

- Abbreviations
- FMEA
 - What is an FMEA and why to use it
 - Steps involved in an FMEA
 - How to use an FMEA
- Simple Risk Assessment Tool
 - Steps for Simple Risk A
 - Risk Assessment Grid
- FMEA Exercise
- Discussion

Abbreviations

- FMEA – Failure mode and effects analysis
- SEV – Severity
- OCC – Occurrence
- DET – Detection
- RPN – Risk Priority Number ($SEV * OCC * DET$)

Purpose of an FMEA

To evaluate the risks associated with the steps in a process, any process

An FMEA functions by using a structured methodology to;

- Facilitate process improvement
- Identify the ways in which a process can fail and rank the severity of the failure
- Estimating the risk associated with each step
- To evaluate the effectiveness of current controls
- Prioritize all of the above

Steps in the FMEA

1. For each Process Step, list ways that it can vary or go wrong (Failure Modes)
2. Identify Effects associated with each Failure Mode
3. List all Causes for each Failure Mode (These could be outputs from a previous process step or additional inputs to this step).
4. List the Current Controls for each Cause
5. Create Severity, Occurrence, and Detection rating scales
6. Assign Severity, Occurrence and Detection ratings to each Cause
7. Calculate the risk priority number for each potential Failure mode scenario
8. Determine recommended actions, with responsible parties assigned and estimated date of completion, to reduce High RPNs - Estimate effect of Actions on RPN (SEV, OCC, DET).
9. Take appropriate actions and re-calculate all RPNs

FMEA Components

Process Step/Function	Potential Failure Mode	Potential Failure Effects	S E V	Potential Causes	O C C	Current Controls	D E T	R P N
What is the process step/function under investigation?	In what way could the process step/function potentially fail to meet process requirements or intent?	What is the impact on the Key Output Variables (Customer Requirements) or internal requirements?	How Severe is the effect to the customer?	What are the causes of this Failure Mode? Typical failure cause result from process inputs.	How often does cause or FM occur?	What are the existing controls and procedures (inspection and test) that prevent the cause or the Failure Mode? Should include an SOP number.	How well can you detect cause or FM?	

What is the process step being analyzed?

What is the Effect on the Outputs?

What can go wrong with the Input? / Why does this happen?

How can this be found?

In what way could the process step fail to meet requirements?

How Bad?

How Often?

How well can we detect?

Risk Priority Number (RPN)

- The output of an FMEA is the Risk Priority Number
- The RPN is a calculated number based on information you provide regarding
 - the potential failure modes,
 - the effects, and
 - the current ability of the process to detect the failures before reaching the customer
- The severity of the effects * rating on how often it occurs * ability to detect

RPN = Severity X Occurrence X Detection

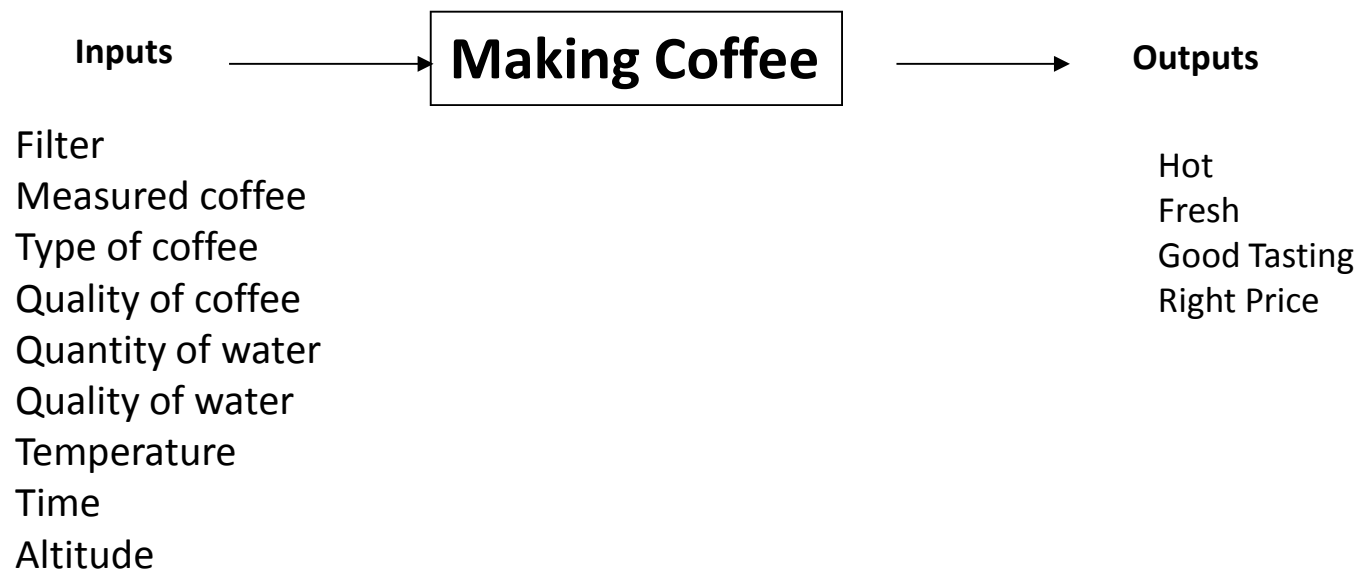
Effects

Causes

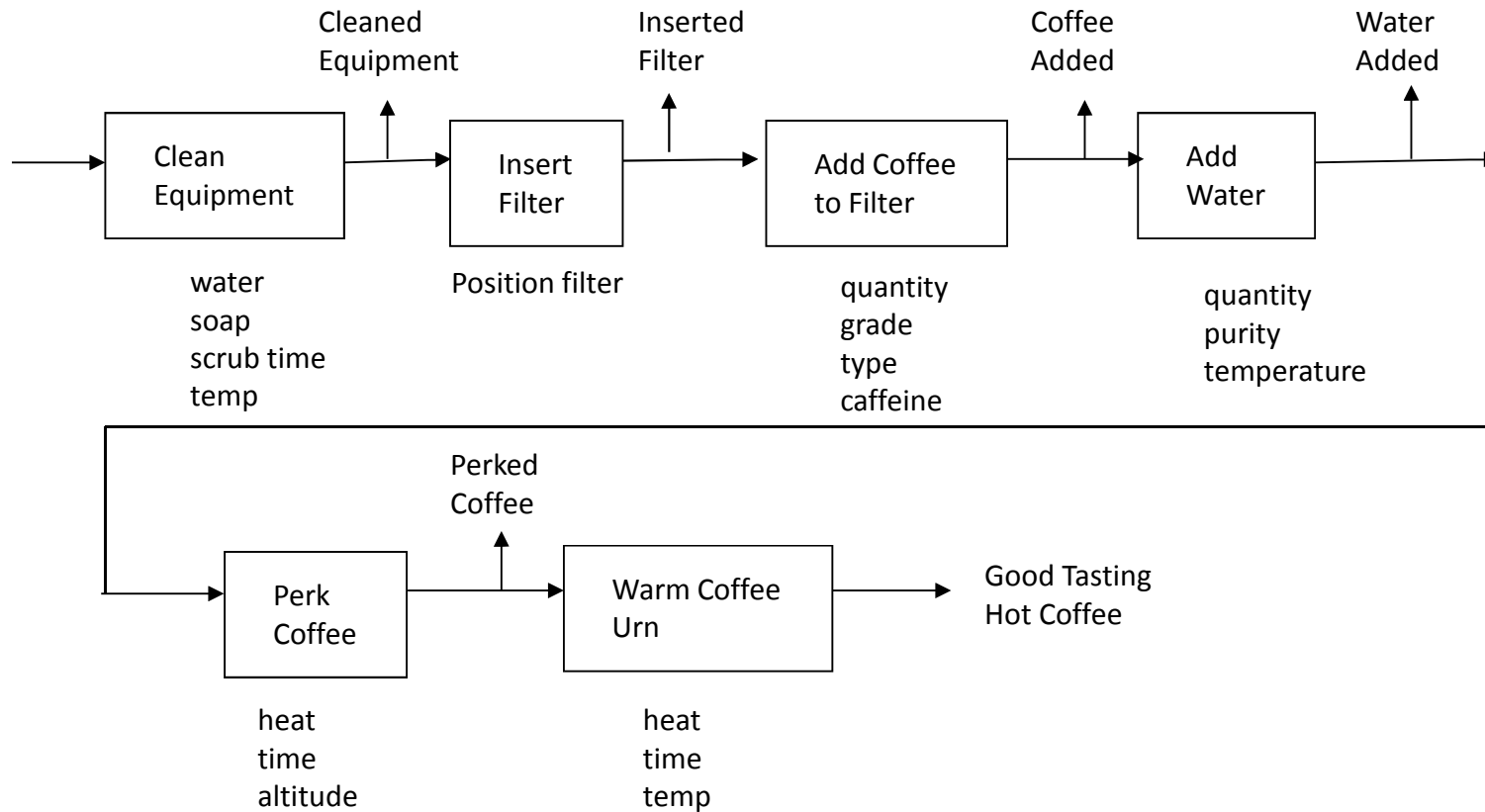
Controls

The Risk Priority Numbers are then sorted and actions are recommended for the top issues

Example: Making Coffee: Inputs and Outputs



Making Coffee – Process Map



Coffee – Starting the FMEA

Process Step/Function	Potential Failure Mode	Potential Failure Effects	S E V	Potential Causes	O C C	Current Controls
What is the process step/function under investigation?	In what way could the process step/function potentially fail to meet process requirements or intent?	What is the impact on the Key Output Variables (Customer Requirements) or internal requirements?	How Severe is the effect to the customer?	What are the causes of this Failure Mode? Typical failure cause result from process inputs.	How often does cause or FM occur?	What are the existing controls and procedures (inspection and test) that prevent the cause or the Failure Mode? Should include an SOP number.
Clean equipment	Equipment not clean	Bad tasting coffee		Not enough water		
				Residual soap		
				Insufficient scrub time		
				Insufficient rinse		
Insert filter	Filter not centered	Grounds in coffee		Filter not installed on center		
				Filter slipped from center		
				Filter wrong size		
Add grounds to coffee	Too much grounds	Too strong coffee		Not measured properly poured in too much		
		Grounds in coffee		Not measured properly poured in too much		
Add grounds to coffee	Too little grounds	Too weak coffee		Not measured properly poured in too little		

Mitigate the Risk

- Determine recommended actions, with responsible parties assigned and estimated date of completion, to reduce High RPNs - Estimate effect of Actions on RPN (SEV, OCC, DET).
- Take appropriate actions and re-calculate all RPNs

R P N	Actions Recommended	Resp.	Actions Taken	S E V	O C C	D E T	R P N
	What are the actions for reducing the occurrence of the cause, or improving detection?	Who is Responsible for the recommended action?	Note the actions taken. Include dates of completion.				

FMEA Summary

- The FMEA is used to record information about failures and their causes
- Input to the FMEA can begin from information gained from the Process Map or SOP
- Take “just do it” actions as they are uncovered
- Including factors which contribute to severe failures in the Data Collection plan may provide information to be used in Improvement and Control Phases.

Simple Risk Assessment Tool

Used to assess a project, event or
simple process

Steps

- 1 Brainstorm any obstacle / challenge (risk) you can envision
- 2 Evaluate probability of this occurring (low, medium, high)
- 3 Evaluate impact on project / process if this were to occur (low, medium, high)
- 4 Use Grid to Assign Risk Category
- 5 For Red and Yellow items - how can you reduce risk?
- 6 Identify mitigators, and revisit periodically

Risk Grid Assessment

Probability of Occurrence	High	Yellow Light: Proceed with Caution	Red Light: Address before Proceeding	Red Light: Do Not Proceed
	Medium	Yellow Light: Proceed with Caution	Yellow Light: Proceed with Caution	Red Light: Reassess Project
	Low	Green Light: Proceed	Yellow Light: Proceed with Caution	Red Light: Address before Proceeding
		Low	Medium	High
		Impact on Project		

Example

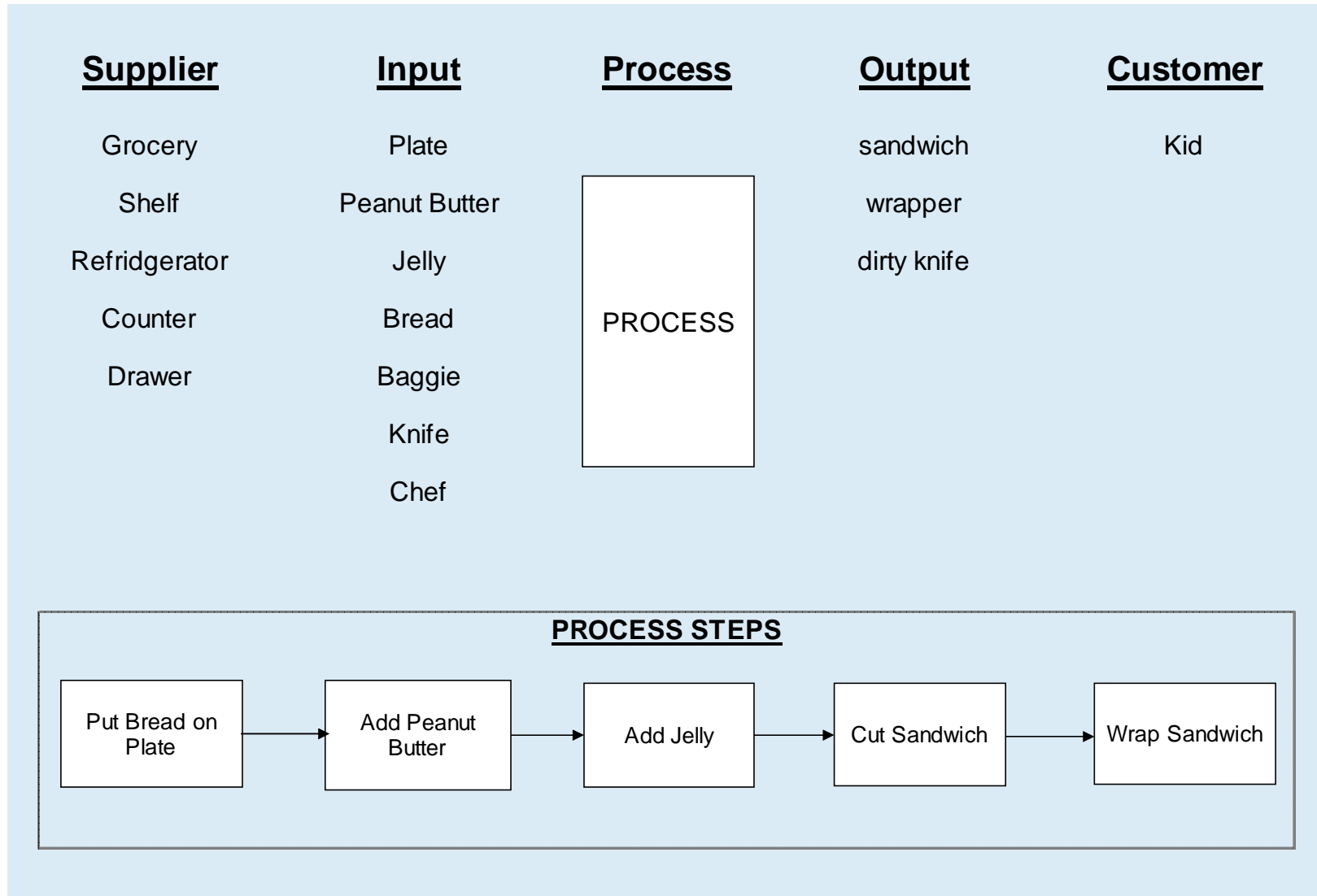


Risk Description	Probability of Occurrence	Impact on Project	Category Rating	Action	New Status
Resource for New Process	High	High	Red Light: Do Not Proceed	Finance to resolve resource issue	Plan for Staffing Established
Documentation offsite	High	High	Red Light: Do Not Proceed	Billing Manager needs to be involved. Need to involve new insurance manager	Adressed in Staffing Plan
Billing done offsite	High	High	Red Light: Do Not Proceed	Billing Manager needs to be involved. Need to involve new insurance manager	New Insurance manager hired and in loop
Resource vs. Payoff	Low	Medium	Yellow Light: Proceed with Caution	Build measure into process	
IT Constraints	High	High	Red Light: Do Not Proceed	Involve programers. Use RFS process	Go to manual process if necessary - 2nd phase automated
CAP Contracts	Low	Low	Green Light: Proceed	Need communication from Managed Care	

Exercise

- Work in teams
- Use the SIPOC provided for the process
- Start to create a FMEA on making a Peanut Butter and Jelly Sandwich

Process



Discussion

- How did it go?
- Where did you have trouble?
- Can you think of other applications?
- Questions?
- ASQ Information - <http://asq.org/learn-about-quality/process-analysis-tools/overview/fmea.html>