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Failure Mode Effects Analysis (FMEA)

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Learning Objectives

Upon successful completion of this module, the student should be able to:

- Understand the definition and purpose of an FMEA
- Understand the different types of FMEAs
- Understand the FMEA process and how it ties to process mapping
- Understand the relationship between Failure Mode, Cause, and Effect
- Understand how to construct an FMEA

FMEA

- FMEA (Failure Mode and Effects Analysis) is a systematic method for identifying, analyzing, prioritizing and documenting potential failure modes, their effects on system, product and process performance, and the possible causes of failure.

Why Use FMEAs

- Identify potential failure modes and analyze risks
- Identify critical process parameters
- Rank order potential process deficiencies
- Help focus on prevention of process problems
- Document and track actions taken to reduce risk associated with failure modes
- Increase client satisfaction
- Improve quality, reliability, and safety of product

When to Start an FMEA

- When new processes are being developed
- When existing processes are being changed
- When processes fail to perform as intended
- When potential problems are envisioned, or there are many unknowns
- When the process requires major improvement

How will your project benefit from an FMEA ?

Common Pitfalls in Preparing FMEAs

- Wrong team make-up
  - Size, expertise, attitude, experience, etc.
- Taking on too much; analyzing every step
  - Focus on big hitter steps
- **Failure modes not linked to Ys on process map**
- **Causes not linked to Xs on process map**
- Inconsistent rankings from start to finish
  - Be sure to review each column of rankings, and adjust for consistency, before calculating final RPNs
- Agonizing over rankings
  - Keep the process and the team flowing; review/adjust later

Keys to Successful Implementation

- Motivated team members
- Cross-functional representation on the team
- Analyze the process as is, not how it could be
- Start small and learn from your successes
- Treat as a living document; reflect latest changes
- Execute recommended actions
- Integrate into your development process
- Follow the spirit, not the form
- Practice, practice, practice!

Three Approaches To The FMEA

- Two major approaches:
  - Starting with the Process Map
  - Starting with the Cause & Effect Matrix

Starting With C&E Matrix

- The C&E Matrix defined the important issues by helping to prioritize:
  - Important customer requirements
  - Process inputs that could potentially impact these requirements
- Prioritize the Key Process Inputs Variables (KPIV) according to their impact on the output variables

Focus on inputs that highly impact

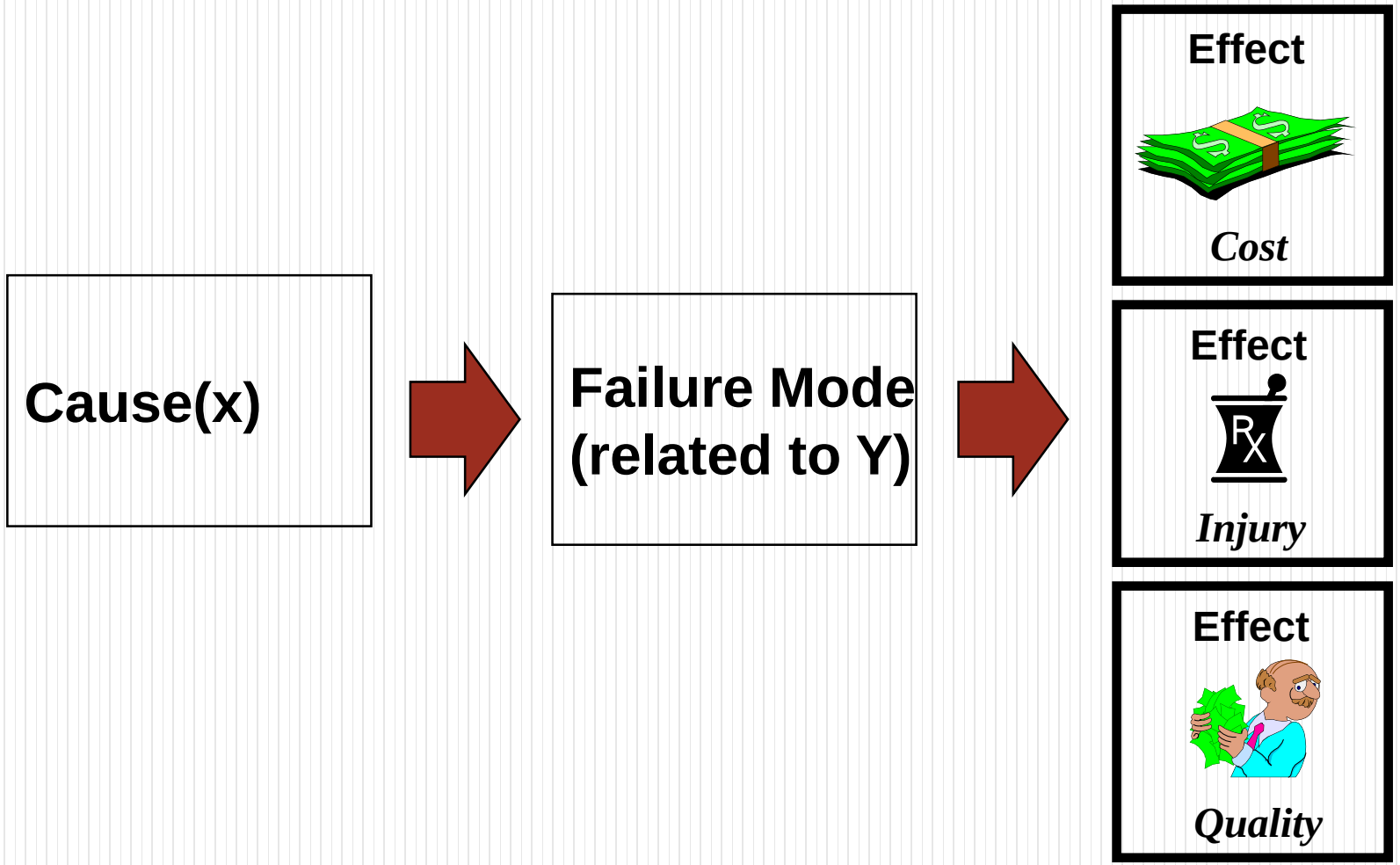
a large number of outputs

Aircraft Landing Process

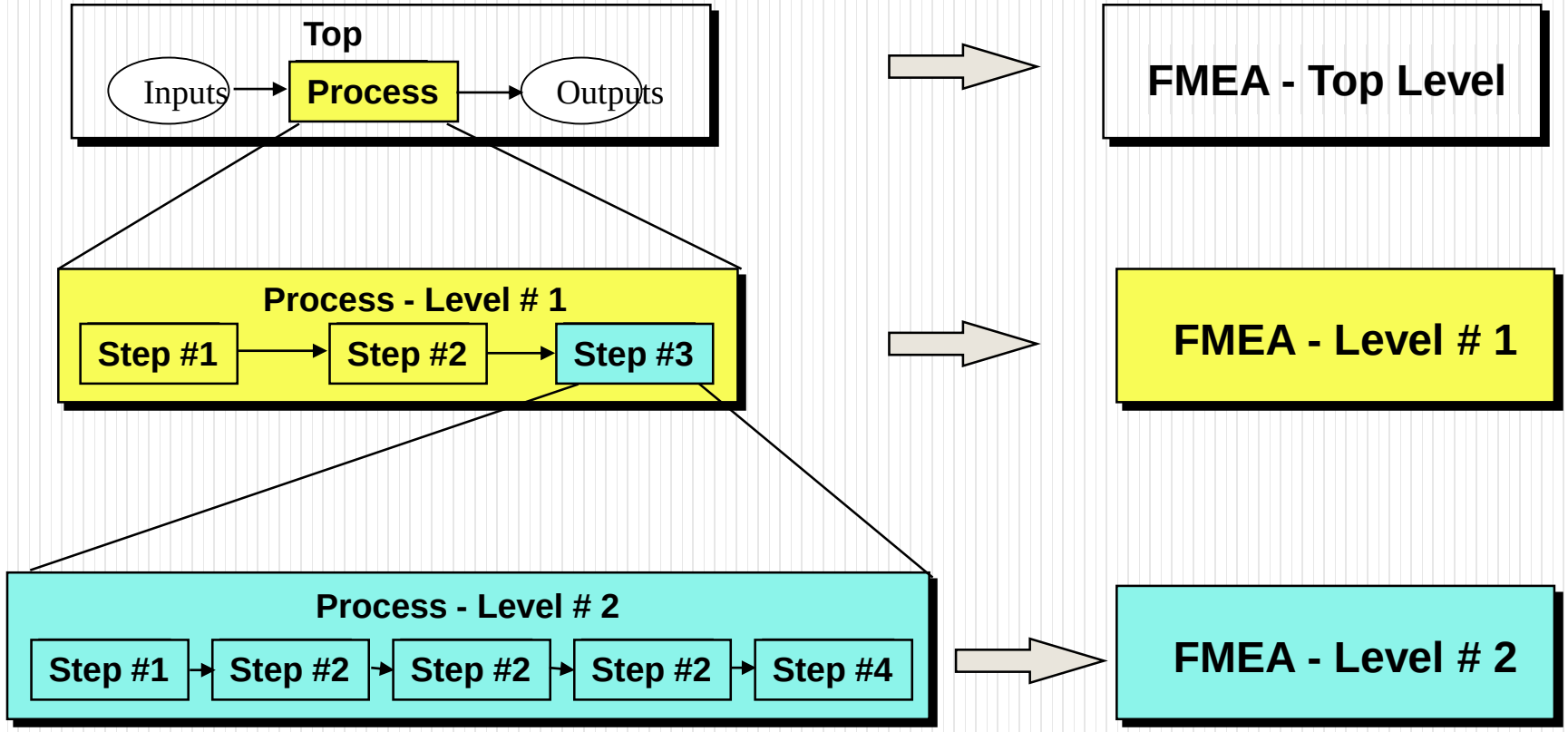
- What can go wrong with the landing? (Failure Mode)
- What is the effect (Failure Effect)
- What causes variation in the landing?
- (Causes)
- How can we detect the variation in the inputs/ outputs before the Customer does?

  (Detection Processes)

Cause - Failure Mode – Effect Continuum



Like Process Maps, FMEAs Come in Hierarchies



FMEA Types

- Process FMEA
  - Used to analyze manufacturing and administration processes and identify potential process failure modes
- Design/Product FMEA
  - Used to analyze product and identify potential product failure modes early in the development cycle
- Defect FMEA
  - Used to analyze and prioritize defects to prevent reoccurrence

Process FMEA

- Helps analyze manufacturing and assembly processes to reduce the occurrence and improve detection of defects.
- Assists in the development of process control plans.
- Establishes a priority for process improvement activities.
- Documents the rationale behind process changes and helps guide future process improvement plans.
- IS PROACTIVE! Should be started when new processes are designed or when old processes are changed.

The FMEA Form

Process/Product
Failure Modes and Effects Analysis Form
(FMEA)

Processor Product Name:		Prepared by:	Page ____ of ____
Responsible:		FMEA Date (Orig) _____ (Rev) _____	

Process Step / Input	Potential Failure Mode	Potential Failure Effects	SEVERITY	Potential Causes	OCCURRENCE	Current Controls	DETECTION	RPN	Actions Recommended	Resp.	Actions Taken	SEVERITY	OCCURRENCE	DETECTION	RPN
What is the process step and Input under investiga-tion?	In what ways does the Key Input go wrong?	What is the impact on the Key Output Variables (Customer Requirements)?		What causes the Key Input to go wrong?		What are the existing controls and procedures (inspection and test) that prevent either the cause or the Failure Mode?			What are the actions for reducing the occurrence of the cause, or improving detection?		What are the completed actions taken with the recalculated RPN?				
								0							0
								0							0
								0							0
								0							0
								0							0

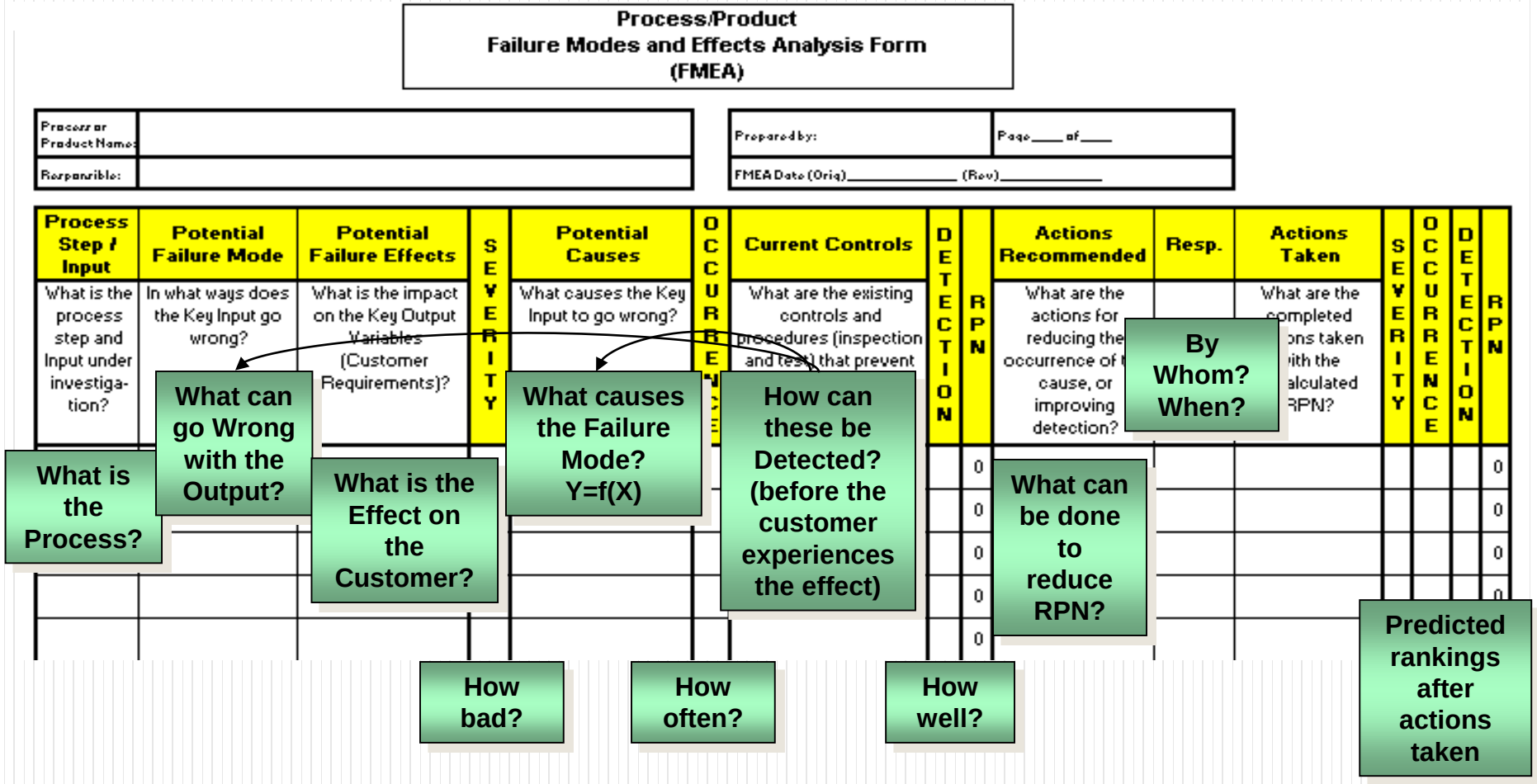
Identify failure modes and their effects

Identify causes of the failure modes and controls

Prioritize

Determine and assess actions

FMEA Thought Map



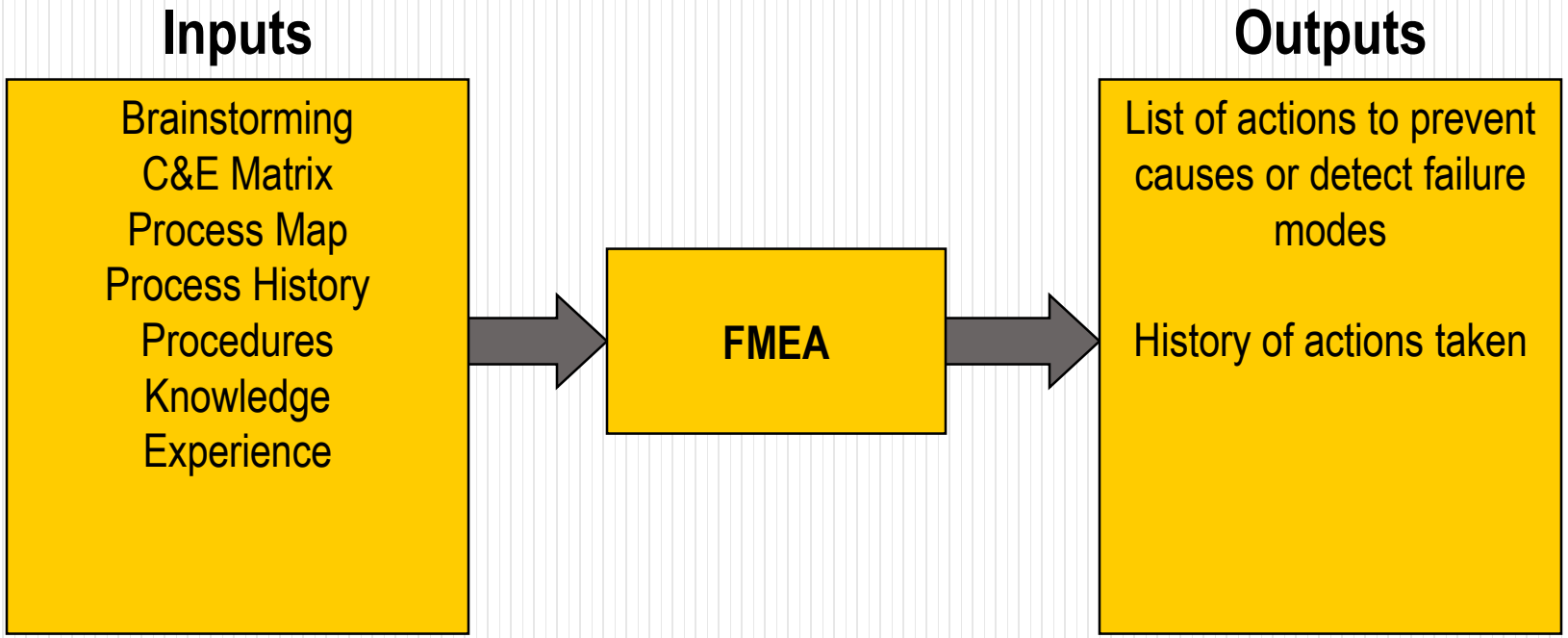
FMEA Procedure

1. For each process input (start with high value inputs), determine the ways in which the input can go wrong (failure mode)
2. For each failure mode, determine effects
   - Select a severity level for each effect
3. Identify potential causes of each failure mode
   - Select an occurrence level for each cause
4. List current controls for each cause
   - Select a detection level for each cause

FMEA Procedure

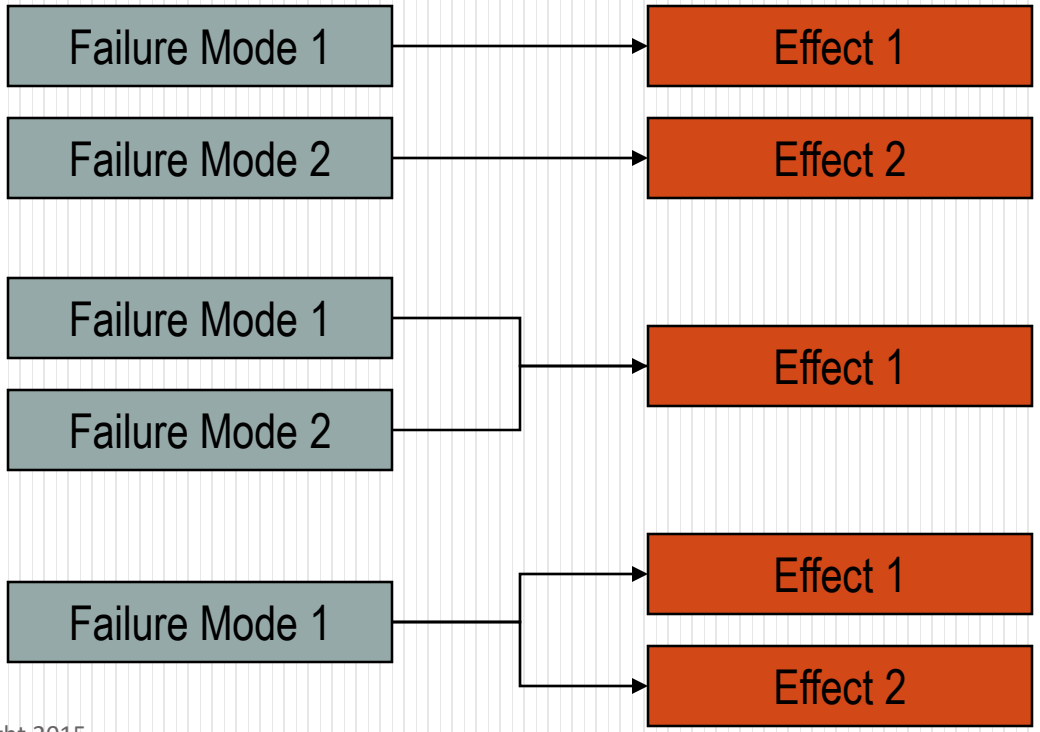
5. Calculate the Risk Priority Number (RPN)
6. Develop recommended actions, assign responsible persons, and take actions
   - Give priority to high RPNs
   - MUST look at severities rated a 10
7. Assign the predicted severity, occurrence, and detection levels and compare RPNs

FMEA Inputs and Outputs



Failure Modes and Effects

- The relationship between failure modes and effects is not always 1 to 1.



Severity, Occurrence, and Detection

- Severity
  - Importance of the effect on customer requirements
    - Often can't do anything about this
- Occurrence
  - Frequency with which a given cause occurs and creates failure modes
- Detection
  - The ability of the current control scheme to detect or prevent a given cause

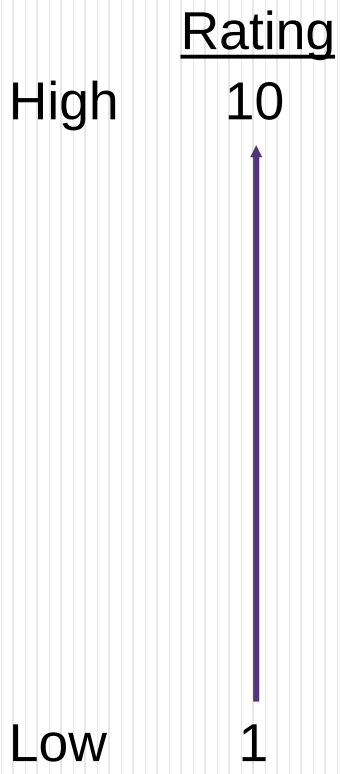
Rating Scales

- There are a wide variety of scoring anchors, both quantitative or qualitative
- Two types of scales are 1-5 or 1-10
- The 1-5 scale makes it easier for the teams to decide on scores
- The 1-10 scale allows for better precision in estimates and a wide variation in scores (most common)

Rating Scales

- Severity
  - 1 = Not Severe, 10 = Very Severe
- Occurrence
  - 1 = Not Likely, 10 = Very Likely
- Detection
  - 1 = Likely to Detect, 10 = Not Likely to Detect

Rating Definitions



Severity	Occurrence	Detection
Hazardous without warning	Very high and almost inevitable	Cannot detect or detection with very low probability
Loss of primary function	High repeated failures	Remote or low chance of detection
Loss of secondary function	Moderate failures	Low detection probability
Minor defect	Occasional failures	Moderate detection probability
No effect	Failure unlikely	Almost certain detection

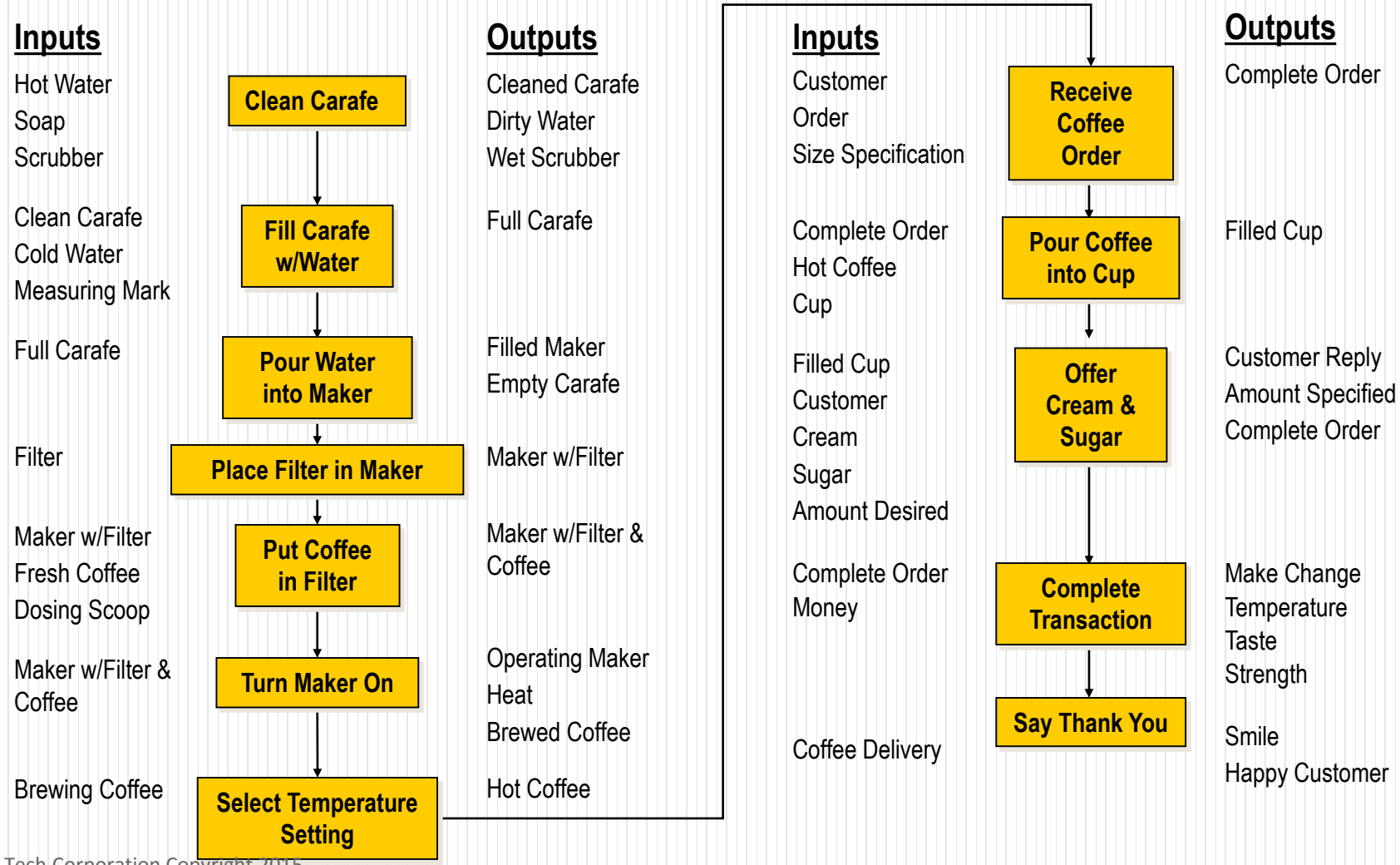
Risk Priority Number (RPN)

- RPN is the product of the severity, occurrence, and detection scores.

FMEA Example

- We will conduct an FMEA on a truck stop example used to create a C&E Matrix.
- A Black Belt wants to improve customer satisfaction with the coffee served at the truck stop.
- The process map and completed C&E matrix follow.

Truck Stop Coffee Process Map



Truck Stop Coffee C&E Matrix

		Temp of Coffee	Taste	Strength		Process Outputs
		8	10	6		Importance
Process Step	----- Process input -----	--------- Correlation of Input to Output ---------				--------- Total ---------
						0
Clean Carafe		0	3	1		36
Fill Carafe with Water		0	9	9		144
Pour Water into Maker		0	1	1		16
Place Filter in Maker		0	3	1		36
Put Coffee in Filter		0	9	9		144
Turn Maker On		3	1	0		34
Select Temperature Setting		9	3	3		120
Receive Coffee Order		0	0	1		6
Pour Coffee into Cup		3	1	3		52
Offer Cream & Sugar		3	9	3		132
Complete Transaction		1	1	1		24
Say Thank You		0	0	0		0
						0
						0
						0
						0
						0
						0
						0
						0
						0
						0
						0
						0

We will focus on one of the two steps with the highest scores

Step 1: Determine Potential Failure Modes

Process/Product
Failure Modes and Effects Analysis Form
(FMEA)

Process or Product Name:		Prepared by:	Page ____ of ____
Responsible:		FMEA Date (Orig) _____ (Rev) _____	

Process Step/Input	Potential Failure Mode	Potential Failure Effects	SEVERITY	Potential Cause	OCCURRENCE	Current Controls	DETECTION	RPN	Actions Recommended	Resp.	Actions Taken	SEVERITY	OCCURRENCE	DETECTION	RPN
What is the process step and Input under investigation?	In what ways does the Key Input go wrong?	What is the impact on the Key Output Variables (Customer Requirements)?		What causes the Key Input to go wrong?		What are the existing controls and procedures (inspection and test) that prevent eith the cause or the Failure Mode?			What are the actions for reducing the occurrance of the Cause, or improving detection?		What are the completed actions taken with the recalculated RPN?				
Fill Carafe with water	Wrong amount of water							0							0
	Water too warm							0							0
	Carafe not clean							0							0
								0							0
								0							0

Step 2: Identify Effects and Assign Severity Score

Process/Product
Failure Modes and Effects Analysis Form
(FMEA)

Process or Product Name:		Prepared by:	Page ____ of ____
Responsible:		FMEA Date (Orig) _____ (Rev) _____	

Process Step/Input	Potential Failure Mode	Potential Failure Effects	SEVERITY	Potential Cause	OCCURRENCE	Current Controls	DETECTION	RPN	Actions Recommended	Resp.	Actions Taken	SEVERITY	OCCURRENCE	DETECTION	RPN
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Fill Carafe with water	Wrong amount of water	Coffee too strong or too weak	8					0							0
	Water too warm	Coffee too strong	8					0							0
	Carafe not clean	Foreign objects in coffee	10					0							0
		Bad taste	10					0							0
								0							0

Step 3: Identify Potential Causes and Assign Occurrence Score

Process/Product
Failure Modes and Effects Analysis Form
(FMEA)

Process or Product Name:		Prepared by:	Page ____ of ____
Responsible:		FMEA Date (Orig) _____ (Rev) _____	

Process Step/Input	Potential Failure Mode	Potential Failure Effects	SEVERITY	Potential Cause	OCCURRENCE	Current Controls	DETECTION	RPN	Actions Recommended	Resp.	Actions Taken	SEVERITY	OCCURRENCE	DETECTION	RPN
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Fill Carafe with water	Wrong amount of water	Coffee too strong or too weak	8	Faded level marks on carafe	3			0							0
		Coffee too strong or too weak	8	Water spilled from carafe	5			0							0
	Water too warm	Coffee too strong	8	Faucet not allowed to run and cool	8			0							0
		Coffee too strong	8	Employee not aware of need for cool water	7			0							0
	Carafe not clean	Foreign objects in coffee	10	Carafe not washed	4			0							0
		Bad taste	10	Carafe stored improperly	7			0							0
								0							0

Step 4: List Current Controls and Assign Detection Score

Process/Product
Failure Modes and Effects Analysis Form
(FMEA)

Process or Product Name:		Prepared by:	Page ____ of ____
Responsible:		FMEA Date (Orig) _____ (Rev) _____	

Process Step/Input	Potential Failure Mode	Potential Failure Effects	SEVERITY	Potential Cause	OCCURRENCE	Current Controls	DETECTION	RPN	Actions Recommended	Resp.	Actions Taken	SEVERITY	OCCURRENCE	DETECTION	RPN
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Fill Carafe with water	Wrong amount of water	Coffee too strong or too weak	8	Faded level marks on carafe	4	Visual Inspection	4	128							0
		Coffee too strong or too weak	8	Water spilled from carafe	5	None	9	360							0
	Water too warm	Coffee too strong	8	Faucet not allowed to run and cool	8	Finger	4	256							0
		Coffee too strong	8	Employee not aware of need for cool water	7	None	10	560							0
	Carafe not clean	Foreign objects in coffee	10	Carafe not washed	4	Visual Inspection	4	160							0
		Bad taste	10	Carafe stored improperly	5	Training	5	350							0
								0							0

Step 5: Calculate RPNs

Process/Product
Failure Modes and Effects Analysis Form
(FMEA)

Process or Product Name:		Prepared by:	Page ____ of ____
Responsible:		FMEA Date (Orig) _____ (Rev) _____	

Process Step/Input	Potential Failure Mode	Potential Failure Effects	SEVERITY	Potential Cause	OCCURRENCE	Current Controls	DETECTION	RPN	Actions Recommended	Resp.	Actions Taken	SEVERITY	OCCURRENCE	DETECTION	RPN
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	Water too warm	Coffee too strong	8	Faucet not allowed to run and cool	8	Finger	4	256							0
		Coffee too strong	8	Employee not aware of need for cool water	7	None	10	560							0
	Carafe not clean	Foreign objects in coffee	10	Carafe not washed	4	Visual Inspection	4	160							0
		Bad taste	10	Carafe stored improperly	7	Training	5	350							0
								0							0

Step 6: Develop Recommended Actions, Assign Responsible Persons & Take Actions

Process/Product
Failure Modes and Effects Analysis Form
(FMEA)

Process or Product Name:		Prepared by:	Page ___ of ___
Responsible:		FMEA Date (Orig) _____ (Rev) _____	

Process Step/Input	Potential Failure Mode	Potential Failure Effects	SEVERITY	Potential Cause	OCCURRENCE	Current Controls	DETECTION	RPN	Actions Recommended	Resp.	Actions Taken	SEVERITY	OCCURRENCE	DETECTION	RPN
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		Coffee too strong or too weak	8	Water spilled from carafe	5	None	9	360	Train employees	Flo	Employees trained				0
	Water too warm	Coffee too strong	8	Faucet not allowed to run and cool	8	Finger	8	512	Train employees	Flo	Employees trained				0
		Coffee too strong	8	Employee not aware of need for cool water	7	None	10	560	Train employees	Flo	Employees trained				0
	Carafe not clean	Foreign objects in coffee	10	Carafe not washed	4	Visual Inspection	4	160	Appoint inspector before storage	Alice	Vera is the new inspector				0
		Bad taste	10	Carafe stored improperly	7	Training	5	350	Create storage bin and train employees	Alice	New storage bin in place and employees trained				0
								0							0

Take Action

- The objective of corrective action is to reduce one or more of the ratings:
  - Severity Rating
    - Generally the only way to reduce the severity rating is through a design change
  - Occurrence Rating
    - The occurrence rating can be reduced by removing or mitigating the causes, through various process improvement methods
  - Detection Rating
    - Improving the detection processes are generally the only way to reduce the detection rating
- Assignment of RESPONSIBILITY and target COMPLETION DATES are required at this point

Step 7: Assign the Predicted Severity, Occurrence, and Detection Levels & Compare RPNs

Process/Product
Failure Modes and Effects Analysis Form
(FMEA)

Processor Product Name:		Prepared by:	Page___ of___
Responsible:		FMEA Date (Orig)_____ (Rev)_____	

Process Step/Input	Potential Failure Mode	Potential Failure Effects	SEVERITY	Potential Cause	OCCURRENCE	Current Controls	DETECTION	RPN	Actions Recommended	Resp.	Actions Taken	SEVERITY	OCCURRENCE	DETECTION	RPN
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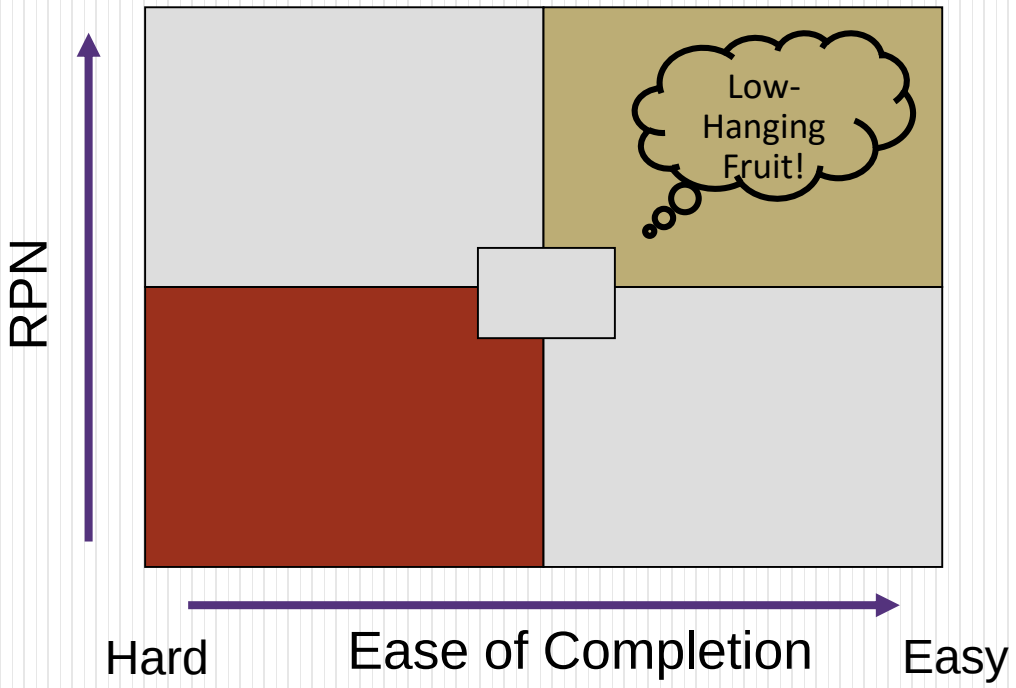
		Coffee too strong or too weak	8	Water spilled from carafe	5	None	9	360	Train employees	Flo	Employees trained	8	2	7	112
	Water too warm	Coffee too strong	8	Faucet not allowed to run and cool	8	Finger	8	512	Train employees	Flo	Employees trained	8	2	6	96
		Coffee too strong	8	Employee not aware of need for cool water	7	None	10	560	Train employees	Flo	Employees trained	8	1	8	64
	Carafe not clean	Foreign objects in coffee	10	Carafe not washed	4	Visual Inspection	4	160	Appoint inspector before storage	Alice	Vera is the new inspecto	10	1	4	40
		Bad taste	10	Carafe stored improperly	7	Training	5	350	Create storage bin and train employees	Alice	New storage bin in place and employees trained	10	2	3	60
								0							0

Graphical Interpretation of Action Priorities

- Rate the actions based on ‘Ease of Completion’ on the X axis
- Plot the RPN’s versus ease in the respective quadrants
- Address low-hanging fruit issues in the top right quadrant first



FMEA Checklist

- Are levels of the failure mode consistent?
- Are the failure modes specific?
- Have all the Ys been considered?
- Are the assigned values for SEV, OCC, and DET consistent?
- Are all failure modes & causes linked to the Process Map?

FMEAs are Living Documents

- FMEAs are updated whenever a change is being considered
  - to a product's design, application, material, etc.
  - to a product's manufacturing or assembly process.
  - to an administrative process.
- When is an FMEA complete?
  - a Design/Product FMEA is considered complete when the original or updated design is released.
  - a Product FMEA is never complete and can always be updated.
  - a Process FMEA is never complete unless the process is removed.

Summary

In this module you have learned about:

- The definition and purpose of an FMEA
- The different types of FMEAs
- The FMEA process and how it ties to process mapping
- The relationship between Failure Mode, Cause, and Effect
- Constructing an FMEA