

Failure Mode and Effects Analysis

Reduce the risk of failure in your processes

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Agenda

- What is FMEA?
- When do you use it?
- How do you use it?
- Affinity Diagrams--input into the FMEA
- How do you interpret a FMEA?
- Pareto Charts--show results

What is FMEA?

- FMEA--a tool to identify risks in your process
- Can be used in multiple places in process improvement
 - Determine where problems are
 - Help identify cause/effect relationships
 - Highlight risks in solutions and actions to take
- Starts with input from processes
- Identifies three risk categories
 - Severity of impact
 - Probability of occurrence
 - Ability to detect the occurrence

When to Use

- Early stages (Define) to understand process and identify problem areas
- Analyze data (Analyze) to help identify root causes
- Determine best solutions (Improve) with lowest risk
- Close out stage (Control) to document improvement and identify actions needed to continue to reduce risk

FMEA Worksheet

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

Process Step	Key Process Input	Potential Failure Mode	Potential Failure Effect	Sev	Potential Causes	Occ	Current Controls	Det	RPN	Actions Recommended	Sev	Occ	Det	RPN

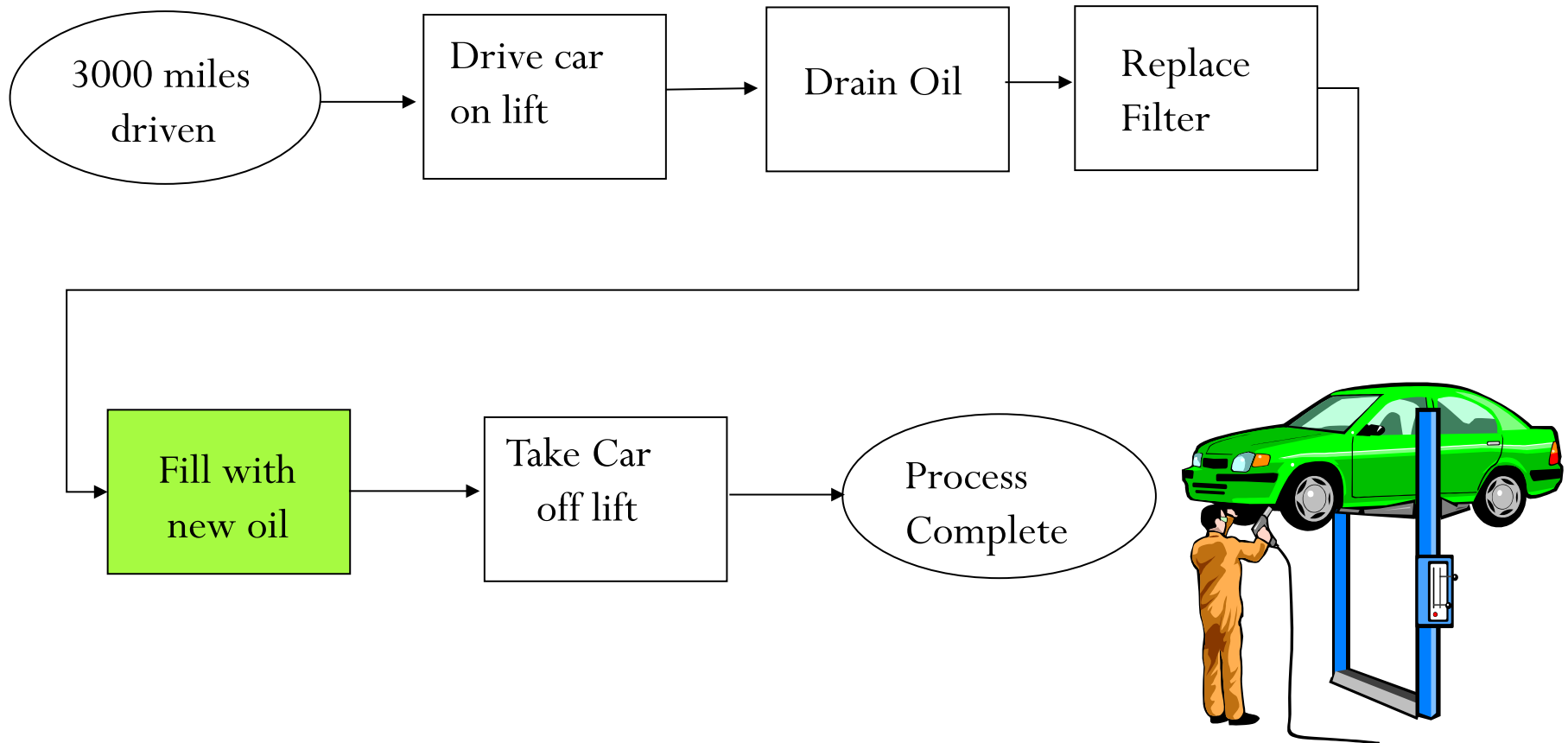
Sev - Severity of the failure (what impact will it have on our process?)
Occ – How likely is the event to occur (probability of occurrence)
Det – How likely can the event be detected in time to do something about it
RPN – Risk Priority Number (multiply Sev, Occ, and Det)

How To Complete the FMEA

General Suggestions

- Use large white board or flip chart with a FMEA form drawn on it during the generation phase
- Focus the team on the specific area of study (product or process).
- Have process map available
- Have all subassemblies and component part of a product.

Process to Change Oil in a Car



How to Complete the FMEA

Step 1. Complete header information

Step 2. Identify steps in the process

Step 3. Brainstorm potential ways the area of study could theoretically fail (failure modes)

Suggestion: Use Affinity Diagram as a brainstorming tool

Affinity Diagram

- Brainstorming method
- Often done without speaking
- Brainstorm ideas (problems, solutions, etc.)
- Record on sticky notes
- Place on board or wall randomly
- Categorize issues—move as often as you wish
- Once categorized, discuss and agree on categories

FMEA Worksheet

Process or Product Name	Change Oil in Car	Prepared by: Leon	Page <u>1</u> of <u>1</u>
Person Responsible	Leon Mechanic	Date (Orig) <u>27 Sep 2007</u> Revised _____	

Process Step	Key Process Input	Potential Failure Mode	Potential Failure Effect	Sev	Potential Causes	Occ	Current Controls	Det	RPN	Actions Recommended	Sev	Occ	Det	RPN
Fill with new oil	New Oil—Mechanic	Wrong type of oil	Engine wear											
		No oil added	Engine Failure											

Sev - Severity of the failure (what impact will it have on our process?)

Occ - How likely is the event to occur (probability of occurrence)

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How to Complete the FMEA

Step 4

- For each failure mode, determine impact or effect on the product or operation using criteria table (next slide)
- Rate this impact in the column labeled SEV (severity)

Severity (SEV) Rating

SEV	Severity	Product/Process Criteria
1	None	No effect
2	Very Minor	Defect would be noticed by most discriminating customers. A portion of the product may have to be reworked on line but out of station
3	Minor	Defect would be noticed by average customers. A portion of the product (<100%) may have to be reworked on line but out of station
4	Very Low	Defect would be noticed by most customers. 100% of the product may have to be sorted and a portion (<100%) reworked
5	Low	Comfort/convenience item(s) would be operable at a reduced level of performance. 100% of the product may have to be reworked
6	Moderate	Comfort/convenience item(s) would be inoperable. A portion (<100%) of the product may have to be scrapped
7	High	Product would be operable with reduced primary function. Product may have to be sorted and a portion (<100%) scrapped.
8	Very High	Product would experience complete loss of primary function. 100% of the product may have to be scrapped
9	Hazardous Warning	Failure would endanger machine or operator with a warning
10	Hazardous w/ out Warning	Failure would endanger machine or operator without a warning

FMEA Worksheet

Process or Product Name	Change Oil in Car	Prepared by: Leon	Page ____ of ____
Person Responsible	Leon Mechanic	Date (Orig) __27 Sep 2007__ Revised _____	

Process Step	Key Process Input	Potential Failure Mode	Potential Failure Effect	Sev	Potential Causes	Occ	Current Controls	Det	RPN	Actions Recommended	Sev	Occ	Det	RPN
Fill with new oil	New Oil—Mechanic	Wrong type of oil	Engine wear	2										
		No oil added	Engine Failure	10										

Sev - Severity of the failure (what impact will it have on our process?)

Occ - How likely is the event to occur (probability of occurrence)

Det - How likely can the event be detected in time to do something about it

RPN - Risk Priority Number (multiply Sev, Occ, and Det)

How to Complete the FMEA

Step 5

- For each potential failure mode identify one or more potential causes (Could use Affinity Diagram again to brainstorm ideas)
- Rate the probability of each potential cause occurring based on criteria table (next slide)
- Place the rating in the column labeled OCC (occurrence).

FMEA Occurrence (OCC Rating)

OCC	Occurrence	Criteria
1	Remote	1 in 1,500,000 Very unlikely to occur
2	Low	1 in 150,000
3	Low	1 in 15,000 Unlikely to occur
4	Moderate	1 in 2,000
5	Moderate	1 in 400 Moderate chance to occur
6	Moderate	1 in 80
7	High	1 in 20 High probability that the event will occur
8	High	1 in 8
9	Very High	1 in 3 Almost certain to occur
10	Very High	> 1 in 2

FMEA Worksheet

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Process Step	Key Process Input	Potential Failure Mode	Potential Failure Effect	Sev	Potential Causes	Occ	Current Controls	Det	RPN	Actions Recommended	Sev	Occ	Det	RPN
Fill with new oil	New Oil—Mechanic	Wrong type of oil	Engine wear	2	Mis-labeled	3								
		No oil added	Engine Failure	10	Hurrying	3								

Sev - Severity of the failure (what impact will it have on our process?)

Occ - How likely is the event to occur (probability of occurrence)

Det - How likely can the event be detected in time to do something about it

RPN - Risk Priority Number (multiply Sev, Occ, and Det)

How to Complete the FMEA

Step 6

- Identify current controls or detection
- Rate ability of each current control to prevent or detect the failure mode once it occurs using criteria table (next slide)
- Place rating in DET column

FMEA Detection (DET) Rating

DET	Detection	Criteria
1	Almost Certain	Current Controls are almost certain to detect/prevent the failure mode
2	Very High	Very high likelihood that current controls will detect/prevent the failure mode
3	High	High Likelihood that current controls will detect/prevent the failure mode
4	Mod. High	Moderately High likelihood that current controls will detect/prevent the failure mode
5	Moderate	High Likelihood that current controls will detect/prevent the failure mode
6	Low	Low likelihood that current controls will detect/prevent failure mode
7	Very Low	Very Low likelihood that current controls will detect /prevent the failure mode
8	Remote	Remote likelihood that current controls will detect/prevent the failure mode
9	Very Remote	Very remote likelihood that current controls will detect/prevent the failure mode

FMEA Worksheet

Process or Product Name	Change Oil in Car	Prepared by: Leon	Page ____ of ____
Person Responsible	Leon Mechanic	Date (Orig) __27 Sep 2007__ Revised _____	

Process Step	Key Process Input	Potential Failure Mode	Potential Failure Effect	Sev	Potential Causes	Occ	Current Controls	Det	RPN	Actions Recommended	Sev	Occ	Det	RPN
Fill with new oil	New Oil from supplier	Wrong type of oil	Engine wear	2	Misread oil chart for vehicle	3	None	9						
		No oil added	Engine Failure	10	Hurrying	3	Engine light	3						

Sev - Severity of the failure (what impact will it have on our process?)

Occ – How likely is the event to occur (probability of occurrence)

Det – How likely can the event be detected in time to do something about it

RPN – Risk Priority Number (multiply Sev, Occ, and Det)

How to Complete the FMEA

Step 7

Multiply SEV, OCC and DET ratings and place the value in the RPN (risk priority number) column. The largest RPN numbers should get the greatest focus. For those RPN numbers which warrant corrective action, recommended actions and the person responsible for implementation should be listed.

$$\text{SEV} * \text{OCC} * \text{DET} = \text{RPN}$$

$$(2 * 3 * 9 = 54)$$

Process Step	Key Process Input	Potential Failure Mode	Potential Failure Effect	Sev	Potential Causes	Occ	Current Controls	Det	RPN	Actions Recommended	Sev	Occ	Det	RPN
Fill with new oil	New Oil from supplier	Wrong type of oil	Engine wear	2	Misread oil chart for vehicle	3	None	9	54					
		No oil added	Engine Failure	10	Hurrying	3	Engine light	3	90					

FMEA Rankings

		Severity	Occurrence	Detection
		<u>Rating</u>	Hazardous without warning	Very high and almost inevitable
High	10	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
Low	1	No effect	Failure Unlikely	Almost certain detection

Source: The Black Belt Memory Jogger, Six Sigma Academy

Action Results

Step 8

- After corrective action has been taken, place summary of the results in the 'Actions Recommended' block
- Assign new value for:
 - Severity
 - Occurrence
 - Detection
- Calculate new RPN number

FMEA Worksheet

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Fill with new oil	New Oil from supplier	Wrong type of oil	Engine wear	2	Misread oil chart for vehicle	3	None	9	54					
		No oil added	Engine Failure	10	Hurrying	3	Engine light	3	90	Oil level checked by partner	10	3	1	30

Sev - Severity of the failure (what impact will it have on our process?)

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FMEA Example

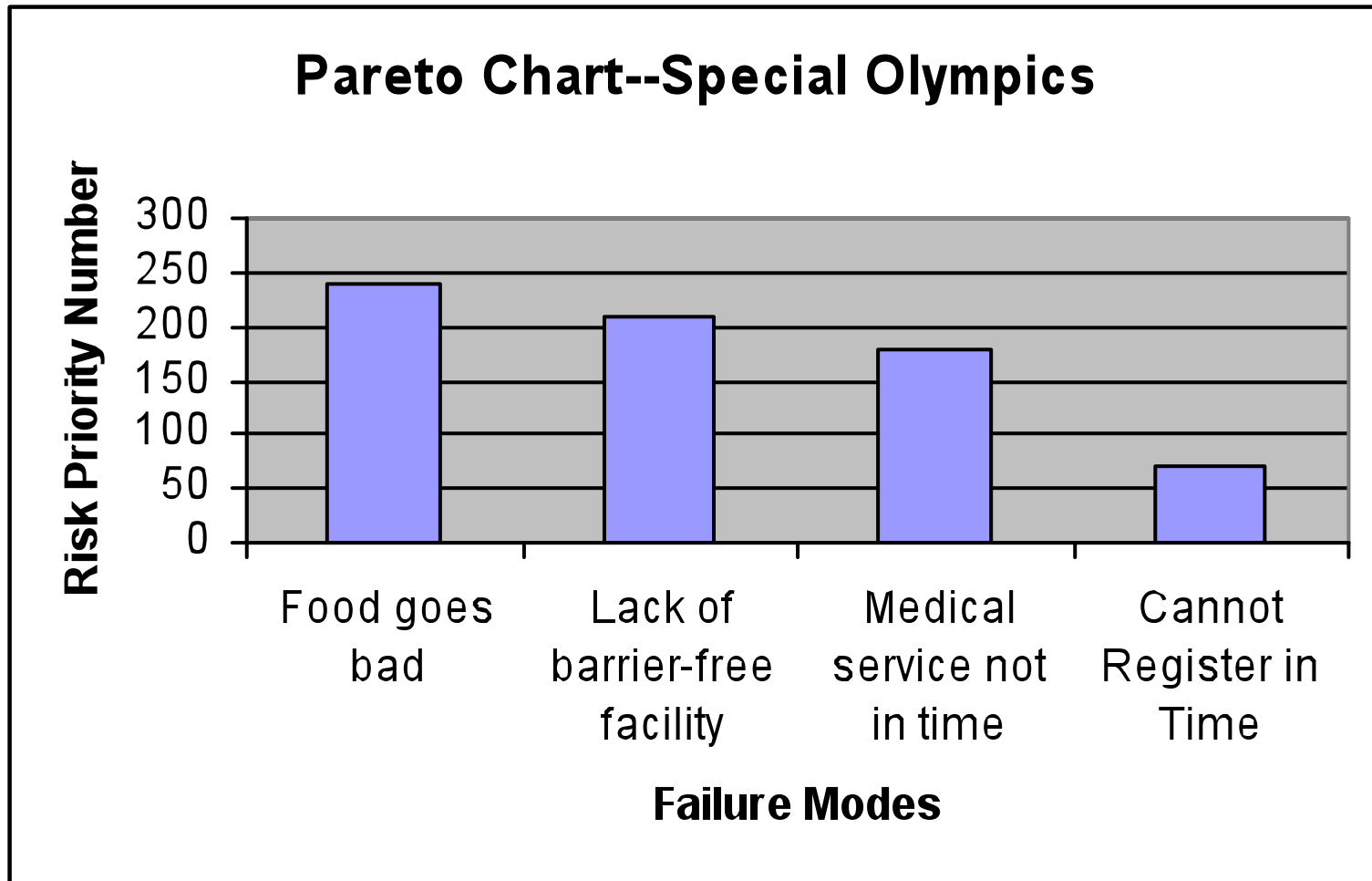
Process or Product Name:		Hotel Service at Special Olympics				Prepared by:				Page ____ of ____				
Person Responsible:		Joe Quality				Date (Orig) _____ Revised _____								
Process Step	Key Process Input	Potential Failure Mode	Potential Failure Effect	S e v	Potential Causes	O c c	Current Controls	D e t	R P N	Actions Recommended	S e v	O c c	D e t	R P N
Register guest	Service Desk	Cannot Register in time	Complaints	5	Lack of language and communication skills, support of volunteers not sufficient	4	No plan on training content; training and volunteer support sufficient	3	72					
Provide Guest Services	Guest Support	Lack of barrier-free facility	Inconvenience and injury	10	Cannot provide barrier-free facility	3	Providing barrier-free facility	7	210					
Provide Meals	Food Service	Food goes bad	Disease or injury	10	Past shelf life	6	No control of raw material	8	240					
Provide Medical Service	Medical Service	Service not in time	Illness changes for worse	10	No 24 Hour service	6	12 hour service	3	180					

Source: Quality Digest/ August 2006 *Quality Service at the Special Olympics World Games*, Tang Xiaofen

Pareto Chart

- Sorted Bar Chart with the bars arranged in descending order from left to right
- Useful in taking a spreadsheet of data and showing which category stands out from the rest.
- Identify where the biggest “pain” occurs in process
- Help determine where to focus our efforts
- Based on 80/20 rule

Pareto Chart—Example



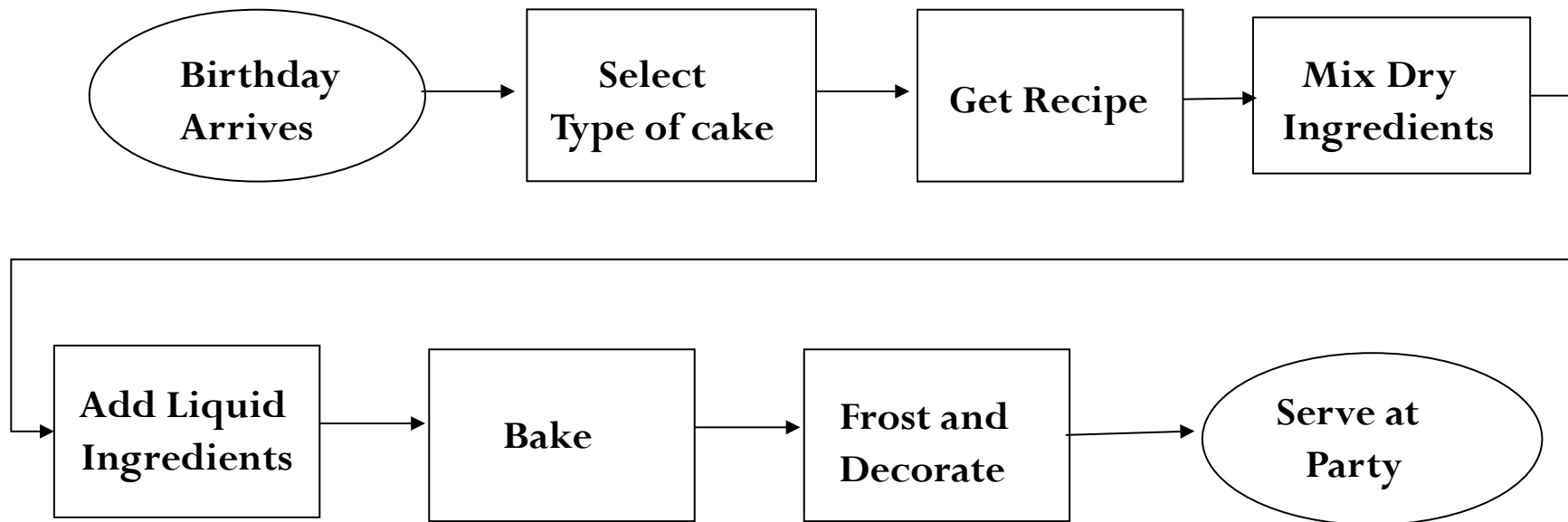
Pareto Chart Hints

- List categories in descending order on horizontal line & frequencies on vertical line
- Look for the 80/20 breakpoint
- Break down tall pole into another Pareto Chart for further analysis
- Involve customer/sponsor in selecting area to focus on

Group Exercise

- Build a FMEA to identify problem areas to be addressed in your process (Cake Baking)
 - Identify process step(s) to analyze
 - Brainstorm (use Affinity Diagram if desired) for possible failure modes, effects, causes and detection controls
 - Rate severity, occurrence, and detection
 - Analyze results with a Pareto Chart
- Report to the group

Baking a Cake

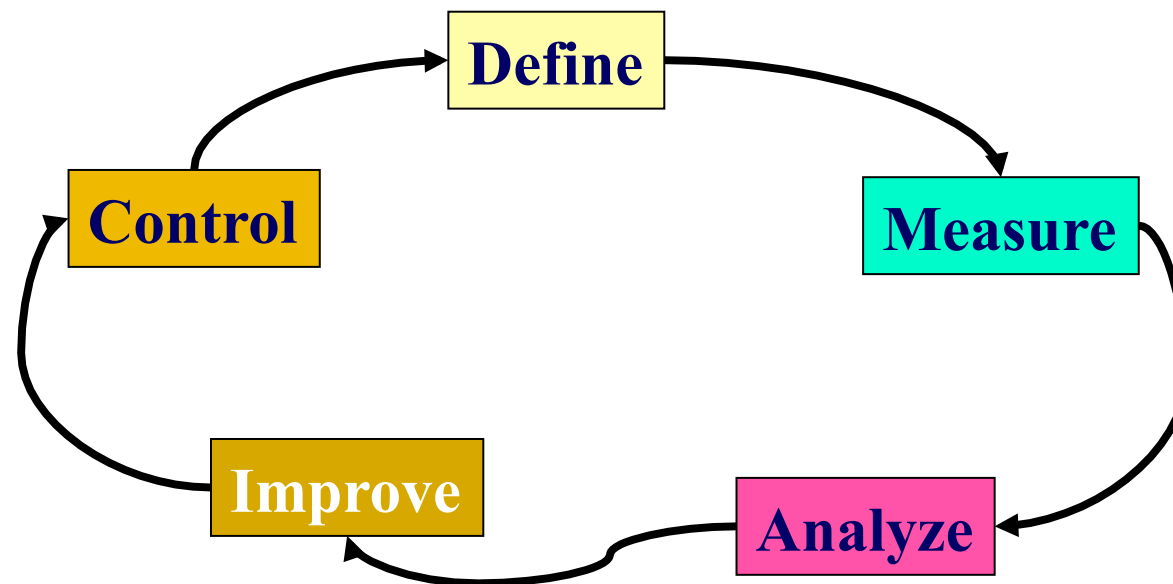


Summary

- FMEA identifies risk in our processes
 - Impact/Severity
 - Probability of Occurrence
 - Detection
- Helps identify what can go wrong and what we should fix
- Can be used in multiple stages of process improvement
- Affinity Diagram—Brainstorming tool
- Pareto Chart—Measures pain

Continuous Improvement

- Process improvement not a linear process
- Never really ends
- Journey not a destination



Challenge

*“We are what we repeatedly do.
Excellence, therefore, is not an act but a
habit.”*

-- Aristotle

Questions / Evaluations

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