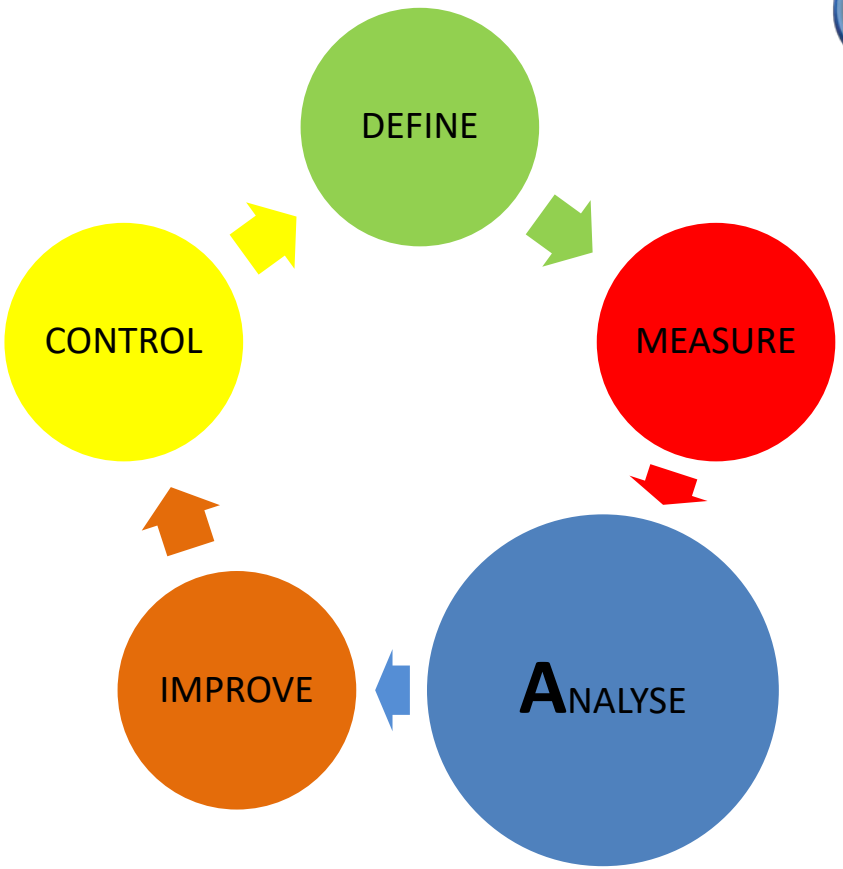
Problem 05
Risk Assessment

E326 – Lean Manufacturing & Six Sigma

SCHOOL OF ENGINEERING

DMAIC



- Evaluate a process to identify **where and how** it might fail
- Assess the relative impact of different failures, in order to identify the parts of the process that are most in need of change/improvement

Objectives of Analyse phase:

- To stratify and analyse the opportunity to identify a specific problem and define an easily understood problem statement
- To identify and validate the root causes that assure the elimination of “real” root causes and thus the problem the team is focused on
- To determine true sources of variation and potential failure modes that lead to customer dissatisfaction

What is FMEA?

- FMEA is an acronym that stands for Failure Modes and Effects Analysis.
- When criticality is considered, FMEA is often referred to as FMECA (Failure Modes, Effects, and Criticality Analysis).
- It is one of the most widely used and effective tools for developing quality designs, processes, and services.
- It is a tool designed to
  - identify potential failure modes for a product or process,
  - assess the risk associated with those failure modes,
  - rank the issues in terms of importance and
  - carry out corrective actions to address the most serious concerns.

FMEA Applications

- FMEA can be applied to any process or product in any industry.
- It is most effective when applied to new products or processes.
- It is also used for existing processes or products that are undergoing a major design change which could affect reliability.
- Some areas of application:
  - Reliability Improvement
  - Product Design
  - Continual Improvement
  - Problem Solving
  - Manufacturing & Assembly processes
  - Advanced product quality planning

Types of FMEA

- FMEA is most commonly applied but not limited to design (Design FMEA) and manufacturing processes (Process FMEA). There are several types of FMEAs, some are used much more often than others.

- The types of FMEA are:

  - System - focuses on global system functions
  - Design/Product - focuses on product, components and subsystems
  - Process - focuses on manufacturing and assembly processes
  - Service - focuses on service functions
  - Software - focuses on software

FMEA Roadmap (Product FMEA)

Step 1: Describe the Product

Step 2: Define the Product Functions

Step 3: Identify Potential Failure Modes

Step 4: Describe Effects of Failure Modes

Step 5: Determine Causes of Failure

Step 6: Detection Methods / Current Controls

Step 7: Calculate and Prioritize Risks

Step 8: Take Action

Step 9: Reassess Risks

http://www.scbuk.com/pfmea.html

FMEA Roadmap (Process FMEA)

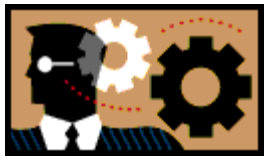
Step 1: Describe the Process

Step 2: Define the Process Functions

Step 3: Identify Potential Failure Modes

Step 4: Describe Effects of Failure Modes

Step 5: Determine Causes of Failure



Step 6: Detection Methods / Current Controls

Step 7: Calculate and Prioritize Risks

Step 8: Take Action

Step 9: Reassess Risks

http://www.scbuk.com/pfmea.html

Basic Steps of FMEA

1. Describe the product or process

- Describe the product or process by developing a detailed drawing of the product or flowchart of the process.
- Ensure that each FMEA team member understands the the workings of the components and basic process flow by physically walking through the process.
- This is especially important if you have team members who do not work on the process on a daily basis.
- For the process flowchart, label each component with a sequential reference number which will be used through the FMEA process.

Basic Steps of FMEA

2. Define the product or process functions

- Review the product or process functions and determine the functions
- For each components, list its intended function or functions: the value-adding role that the component performs or provides.

Basic Steps of FMEA

3. Identify Potential Failure Modes

- A **failure mode** is defined as the manner in which a component, subsystem, system, process, etc. could potentially fail to meet the design intent or a characterization of the way a product or process fails.
- A failure mode in one component can serve as the cause of a failure mode in another component.
- Using the list of components and related functions generated in Step 1 and 2, as a team, brainstorm the potential failure modes for each function.
- Examples of potential failure modes:
  - Deformation
  - Cracking
  - Corrosion
  - Open / Short Electric Circuit

Basic Steps of FMEA

4. Describe Effects of Failure Modes

- A **failure effect** is defined as the result of a failure mode on the function of the product/process as perceived by the customer.
- Keep in mind the internal as well as the external customer
- Determine the effects associated with each failure mode. The effect is related directly to the ability of that specific component to perform its intended function.
- Examples of failure effects:
  - Noise
  - Injury to the user
  - Bad performance
  - Inoperability of the product or process

Basic Steps of FMEA

5. Determine Causes of Failure

- A **failure cause** is defined as a design weakness that may result in a failure.
- It is usually presumed that the *cause chronologically precedes the effect*. Examples describing the relationship:
  - *The presence of heat causes water to boil.*
  - *The ice cubes cause the water to turn cold.*
  - *A heavy blow to the arm causes a bruise.*
  - *The pushing of the accelerator caused the car to go faster.*

- Examples of potential causes:
  - *Improper operating conditions / alignment*
  - *Contamination*
  - *Excessive loading / voltage / current*

Basic Steps of FMEA

6. Detection Methods / Current Controls

- Current Controls (design or process) are the mechanisms that prevent the cause of the failure mode from occurring or which detect the failure before it reaches the Customer.
- Identify testing, analysis, monitoring, and other techniques that can or have been used on the same or similar products/processes to detect failures.

7. Calculate and Prioritize Risks

- After listing the causes and failure effects of each failure, these causes and failure effects are then evaluated by three criteria and the associated risk indices:
  - severity (S),
  - likelihood of occurrence (O) or also often known as probability (P)
  - inability of controls to detect it (D)

Basic Steps of FMEA

- Severity of Effect: The intent of the ranking is to help the analyst determine whether a failure would be a minor nuisance or a catastrophic occurrence to the customer.

- Likelihood of Occurrence: Numerical weight should be assigned to each cause that indicates how likely that cause is or the probability of the cause occurring.

- Current Detectability: Detection is an assessment of the likelihood that the current controls (design and process) will detect the cause of the Failure Mode or the Failure Mode itself, thus preventing it from reaching the customer.

Each index ranges from 1 (lowest risk) to 10 (highest risk).

For example, a **severity index** of 1 shows that the failure is a minor nuisance; while a **severity index** of 5 shows that the failure is of moderate severity to the analyst.

The overall risk of each failure is the product of Severity (S), Occurrence (O), and Detection (D) rankings called **Risk Priority Number (RPN):**

RPN = S x O x D

Severity Evaluation Criteria

Effect	Criteria: Severity of Effect on Product (Customer Effect)	Rank	Effect	Criteria: Severity of Effect on Process (Manufacturing/Assembly Effect)
Failure to Meet Safety and/or Regulatory Requirements	Potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation without warning.	10	Failure to Meet Safety and/or Regulatory Requirements	May endanger operator (machine or assembly) without warning.
	Potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation with warning.	9		May endanger operator (machine or assembly) with warning.
Loss or Degradation of Primary Function	Loss of primary function (vehicle inoperable, does not affect safe vehicle operation).	8	Major Disruption	100% of product may have to be scrapped. Line shutdown or stop ship.
	Degradation of primary function (vehicle operable, but at reduced level of performance).	7	Significant Disruption	A portion of the production run may have to be scrapped. Deviation from primary process including decreased line speed or added manpower.
Loss or Degradation of Secondary Function	Loss of secondary function (vehicle operable, but comfort / convenience functions inoperable).	6	Moderate Disruption	100% of production run may have to be reworked off line and accepted.
	Degradation of secondary function (vehicle operable, but comfort / convenience functions at reduced level of performance).	5		A portion of the production run may have to be reworked off line and accepted.
Annoyance	Appearance or Audible Noise, vehicle operable, item does not conform and noticed by most customers (> 75%).	4	Moderate Disruption	100% of production run may have to be reworked in station before it is processed.
	Appearance or Audible Noise, vehicle operable, item does not conform and noticed by many customers (50%).	3		A portion of the production run may have to be reworked in-station before it is processed.
	Appearance or Audible Noise, vehicle operable, item does not conform and noticed by discriminating customers (< 25%).	2	Minor Disruption	Slight inconvenience to process, operation, or operator.
No effect	No discernible effect.	1	No effect	No discernible effect.

Occurrence Evaluation Criteria

Likelihood of Failure	Criteria: Occurrence of Cause - PFMEA (Incidents per items/vehicles)	Rank
Very High	≥ 100 per thousand ≥ 1 in 10	10
High	50 per thousand 1 in 20	9
	20 per thousand 1 in 50	8
	10 per thousand 1 in 100	7
Moderate	2 per thousand 1 in 500	6
	.5 per thousand 1 in 2,000	5
	.1 per thousand 1 in 10,000	4
Low	.01 per thousand 1 in 100,000	3
	≤.001 per thousand 1 in 1,000,000	2
Very Low	Failure is eliminated through preventive control.	1

Prevention/Detection Evaluation Criteria

Opportunity for Detection	Criteria: Likelihood of Detection by Process Control	Rank	Likelihood of Detection
No detection opportunity	No current process control; Cannot detect or is not analyzed.	10	Almost Impossible
Not likely to detect at any stage	Failure Mode and/or Error (Cause) is not easily detected (e.g., random audits).	9	Very Remote
Problem Detection Post Processing	Failure Mode detection post-processing by operator through visual/tactile/audible means.	8	Remote
Problem Detection at Source	Failure Mode detection in-station by operator through visual/tactile/audible means or post-processing through use of attribute gauging (go/no-go, manual torque check/clicker wrench, etc.).	7	Very Low
Problem Detection Post Processing	Failure Mode detection post-processing by operator through use of variable gauging or in-station by operator through use of attribute gauging (go/no-go, manual torque check/clicker wrench, etc).	6	Low

Prevention/Detection Evaluation Criteria

Opportunity for Detection	Criteria: Likelihood of Detection by Process Control	Rank	Likelihood of Detection
Problem Detection at Source	Failure Mode or Error (Cause) detection in-station by operator through use of variable gauging or by automated controls in-station that will detect discrepant part and notify operator (light, buzzer, etc.). Gauging performed on setup and first-piece check (for set-up causes only).	5	Moderate
Problem Detection Post Processing	Failure Mode detection post-processing by automated controls that will detect discrepant part and lock part to prevent further processing.	4	Moderately High
Problem Detection at Source	Failure Mode detection in-station by automated controls that will detect discrepant part and automatically lock part in station to prevent further processing.	3	High
Error Detection and/or Problem Prevention	Error (Cause) detection in-station by automated controls that will detect error and prevent discrepant part from being made.	2	Very High
Detection not applicable; Error Prevention	Error (Cause) prevention as a result of fixture design, machine design or part design. Discrepant parts cannot be made because item has been error-proofed by process/product design.	1	Almost Certain

Basic Steps of FMEA

8. Take Action

- The RPN (ranging from 1 to 1000) is used to prioritize all potential failures to decide upon actions leading to reduce the risk, usually by reducing likelihood of occurrence or improving controls for detecting the failure.
- Determine recommended action(s) to address potential failures that have high RPN. These actions could include the followings:
  - specific inspection, testing or quality procedures;
  - selection of different components or materials;
  - de-rating of electronic components;
  - limiting environmental stresses or operating range;
  - redesign of the item to avoid the failure mode;
  - monitoring mechanisms; performing preventative maintenance; and inclusion of back-up systems or redundancy.

- Assign Responsibility and a Target Completion Date for these actions. This makes responsibility clear-cut and facilitates tracking.

Basic Steps of FMEA

9. Reassess Risks

- Indicate Actions Taken.
- After these actions have been taken, re-assess the severity, probability and detection and review the revised RPNs.
- Are there any further actions required?
- Update the FMEA as the design or process changes, the assessment changes or new information becomes known.

Risk Ranking (Criticality Analysis)

- How do we determine how serious a risk that the hazard or failure poses?
- Taking Action based on Risk Ranking Matrix / Table
  - As a means of eliminating the subjectivity in prioritizing corrective actions based on RPNs, a method named 'criticality analysis' was developed (as part of Mil-Std 1629A).
  - The organization may choose to develop risk ranking tables to assist in the decision-making process.
  - Quantitative Assessment: RPN Number
  - Qualitative Assessment: Risk Ranking

Ranking Matrix (Sample 1)

Sample 1

Occurrence \ Severity	10	<=8	<=6	<=4	<=2
10	100	80	60	40	20
<=8	80	64	45	32	16
<=6	60	48	36	24	12
<=4	40	32	24	16	8
<=2	20	16	12	8	4

Most dangerous risk

Usually considered acceptable, needing no action

Left for illustration only (based on Minitab Quality Companion rating scale of 1-10):

The make-up of risk-ranking matrix has to be decided upon before starting the assessment.

Example:

If Severity level = Class 8 and Occurrence = Class 6

Thus,

Risk ranking = 8 * 6 = 48

Identify high, medium and low priorities based on the risk ranking.

Risk Ranking (Criticality Analysis)

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  - The organization may choose to develop risk ranking tables to assist in the decision-making process.
  - Quantitative Assessment: RPN Number
  - Qualitative Assessment: Risk Ranking

Sample 2

Ranking Matrix (Sample 2)

Severity / Occurrence	1	2	3	4	5	6	7	8	9	10
1	N	N	N	N	N	N	N	N	A	A
2	N	N	N	N	N	N	10	8	A	A
3	N	N	N	N	N	N	8	7	A	A
4	N	N	N	N	N	10	7	6	A	A
5	N	N	N	N	10	8	6	5	A	A
6	N	N	N	10	8	7	5	4	A	A
7	N	N	10	8	7	6	4	3	A	A
8	N	10	8	7	6	5	3	3	A	A
9	N	8	7	6	5	4	2	2	A	A
10	N	7	6	5	4	3	1	1	A	A

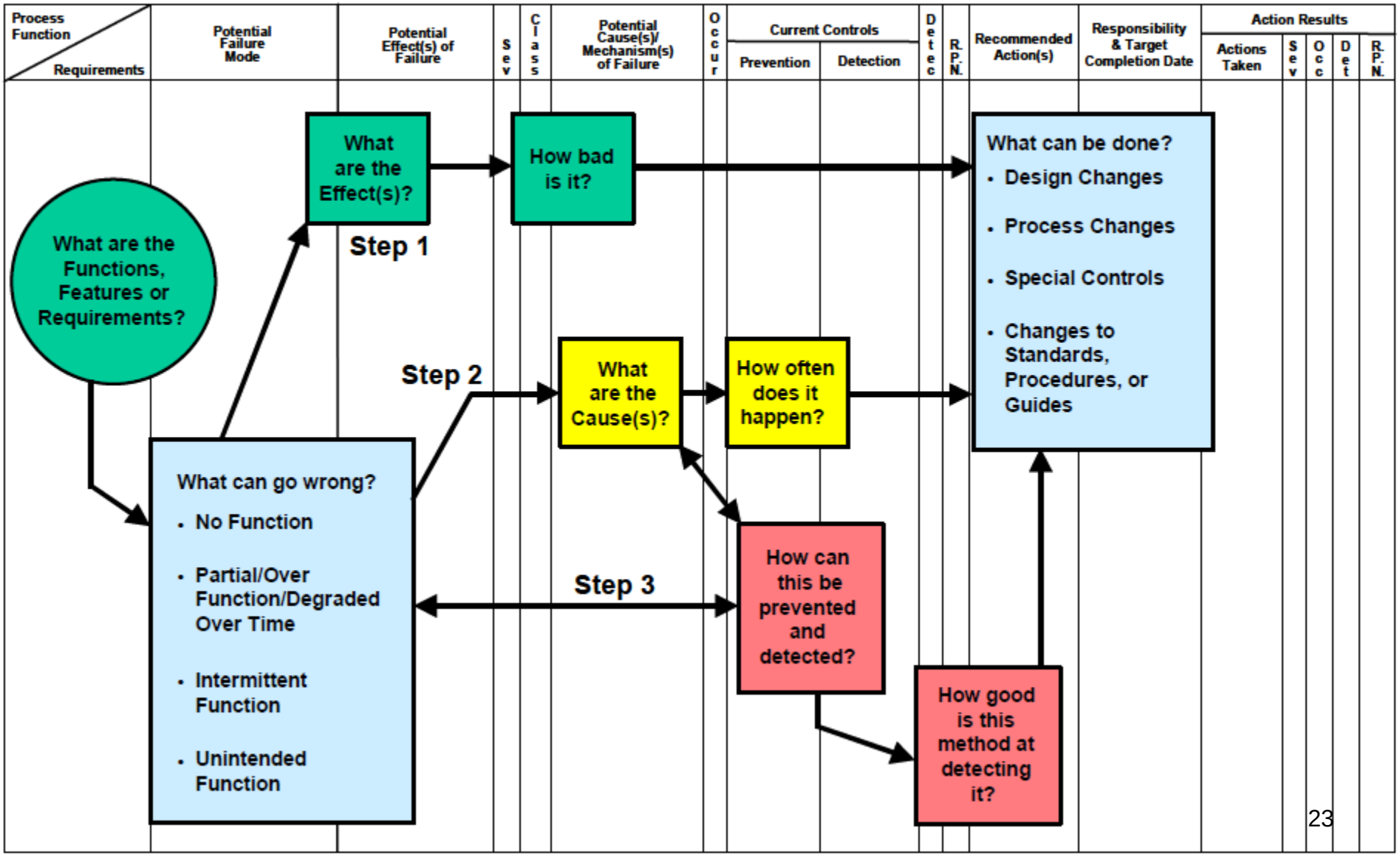
Example:
If Severity level = Class 9 and Occurrence = Class 3
‘A’ means corrective action required

If Severity level = Class 3 and Occurrence = Class 6
‘N’ means no corrective action required

If Severity level = Class 8 and Occurrence = Class 6
Rating of ‘4’ means corrective action required only when ‘Detection Rating’ is equal or greater than 4.

N = No corrective action is required
A = Corrective action is required
# = Corrective action is required if the Detection rating is equal or greater than the given number

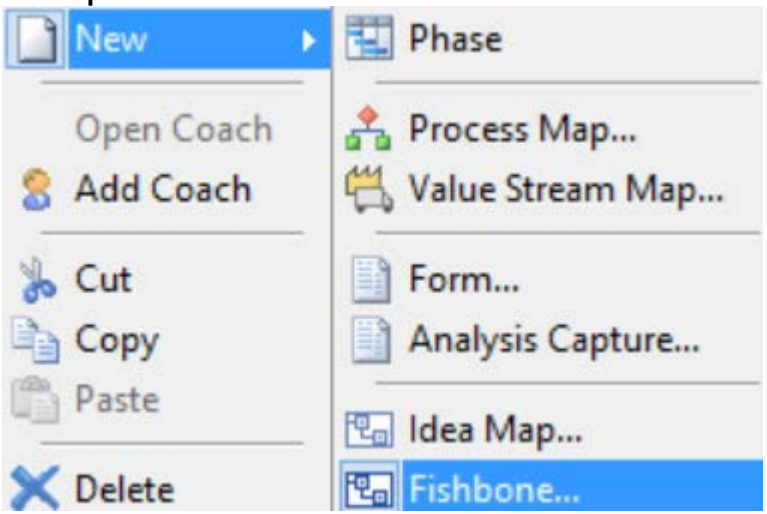
Ford FMEA Working Model



Problem 05
Suggested Solution

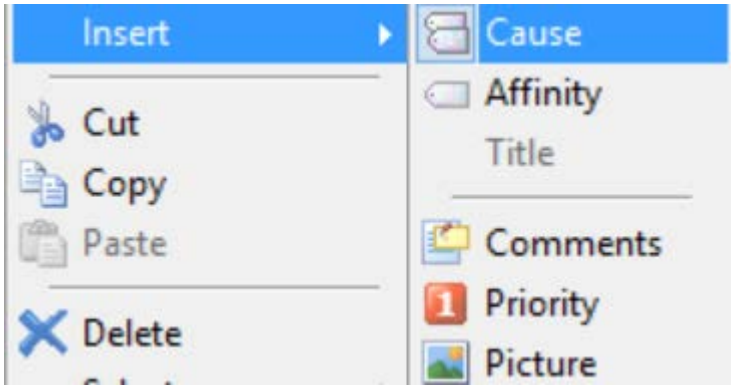
Steps to creating a Fishbone diagram in QC

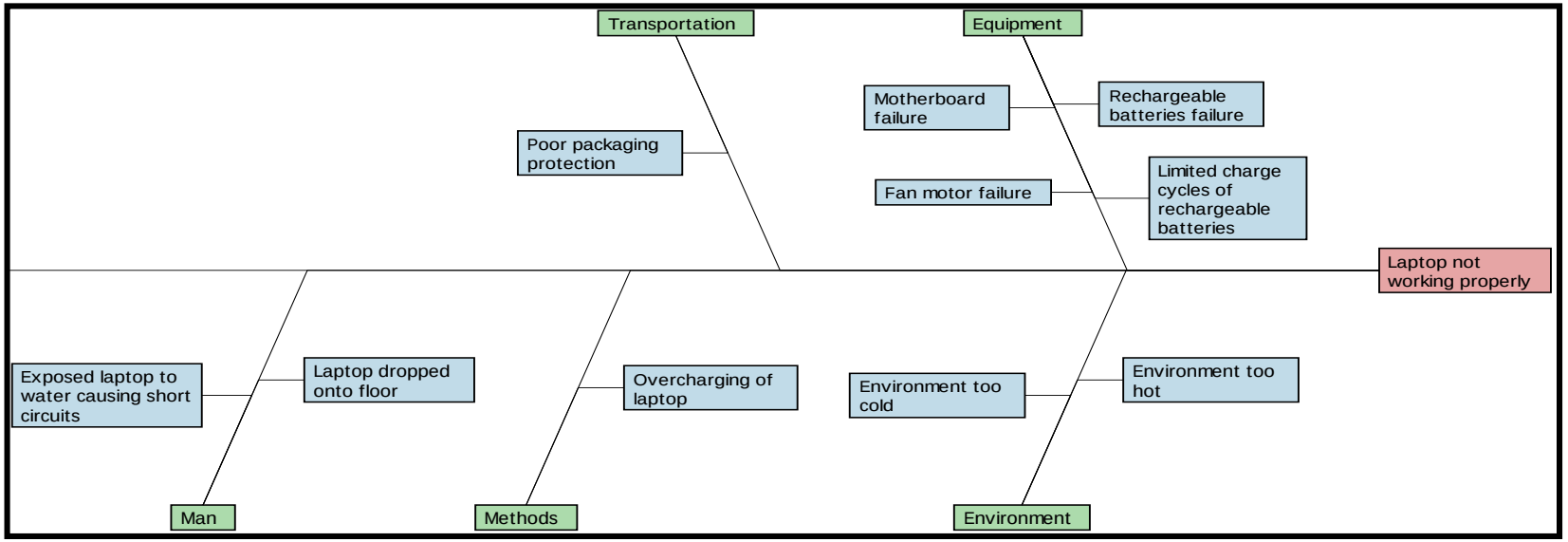
Step1: Add New / Fishbone…



Step2: Right click on fishbone to insert ‘Affinity’

Step3: Right click on affinity box to add ‘Cause’





First-and-Last-Mile Travel Safety – An FMEA Study

- FMEA is an important **risk management tool** commonly used across many industries.
- To ensure first-and-last-mile travel safety, FMEA is applied to identify the potential hazards/risks and prioritize them according to the likelihood of an accident/injury, severity of the accident/ injury, and detectability of the causes.
- The ability to anticipate issues early allows riders, pedestrians and other road users to take actions to eliminate/mitigate these issues and enhance safety.
- The following first-and-last mile travel processes/activities are studied in this FMEA study to identify the potential issues.

Acquiring- Buy, rent, equip accessories, registering	**Charging**- Charge sufficient to power up	**Riding**- Moving along footpaths / shared paths	**Pushing along** Dismount to push, in congested space / to parking	**Parking** Dismount, transfer to MRT ride or walk	**Boarding** Carry along into MRT, bus, vehicle
Affordable, easy process	Charge fast and safely, last long	Arrive destination safely, with ease	Push with ease	Lock safely	Carry with ease

FMEA (Suggested Solution)

FMEA

Project:	Project Leader:
FMEA Project	Phillips
Product/Service:	
Personal Mobility Devices (PMD)	
Process:	Process Owner:
Use of PMD	Wan
	Date:
	14/11/2018

How to fill out the FMEA

Use the tables below to set the cutoff values for color coding the SEV and RPN columns.

Severity (SEV)	Value	Color
If SEV >=	8	
Otherwise		
If SEV <=	5	

Risk Priority Number (RPN)	Value	Color
If RPN >=	350	
Otherwise		
If RPN <=	200	

FMEA# 1

Step#	Process Map - Activity	Key Process Input	Potential Failure Mode	Potential Failure Effects	SEV	Potential Causes	OCC	Current Controls	DET	RPN	Actions Recommended	Responsibility	Target End Date	Actions Taken
1	On-road use	Riding	Pedestrain hit by rider	Pedestrain and rider injury/casualty	9	Reckless riding of rider	7	STOMP; Users update	6	378	[Rules] The maximum speed for a footpath is 15 kilometres per hour	Riders	31/5/2019	Case studies of accidents to be shown when PMDs are sold
2		Riding	Pedestrain hit by rider	Pedestrain and rider injury/casualty	9	Speed limit of PMD modified	4	Speed limit enforcement	9	324	[Rules] The maximum speed of the personal mobility device does not exceed 25 kilometres per hour under all circumstances	Manufacturer	31/5/2019	Manufacturer to put in place in design to restrict modification
3		Riding	Rider fell off PMD	Rider injury	6	Rider Fatigue	4	Training	10	240	[Rules] Minimum age of PMD user is set to 16	Rider	31/5/2019	User to go through training prior purchase of PMD

Note: Criterion for corrective measure is subjective and based on RPN >=350

Recommendations/Actions to Implement

- Based on the top two highest RPN numbers and the failure with the highest severity, the following actions are recommended to ensure first-and-last-mile travel safety:

  - **Riding** – Rider hit pedestrian:
    - [Rules] The speed limit on footpaths will be capped at 15kmh, and at 25kmh on shared paths and cycling paths. Have speed checked, modify back to capped speed.
    - The devices must have a maximum unladen weight of 20kg.
    - Education.

  - **Riding** – Rider fall off:
    - Make wearing helmets mandatory.
    - Educate against long distance travel is not suitable for LTA-compliant e-scooters because it would take an hour to travel 20 to 25km and it's not comfortable.

Learning Objectives

- Explain the purpose of FMEA and the procedure of carrying out FMEA
- Carry out FMEA Process
  - Define Failure Modes, Effects and Causes
  - Employ Severity, Occurrence and Detection Tables for calculation of Risk Priority Number (RPN)
  - Apply Risk indices (RPN) to prioritize failures
  - Use Risk Ranking Table for qualitative risk assessment

Overview of E326 Lean Manufacturing and Six Sigma