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BE CAREFUL

THIS MACHINE
HAS NO BRAIN
USE YOUR OWN

FIRE PREVENTION

Failure Modes and Effects Analysis (FMEA)

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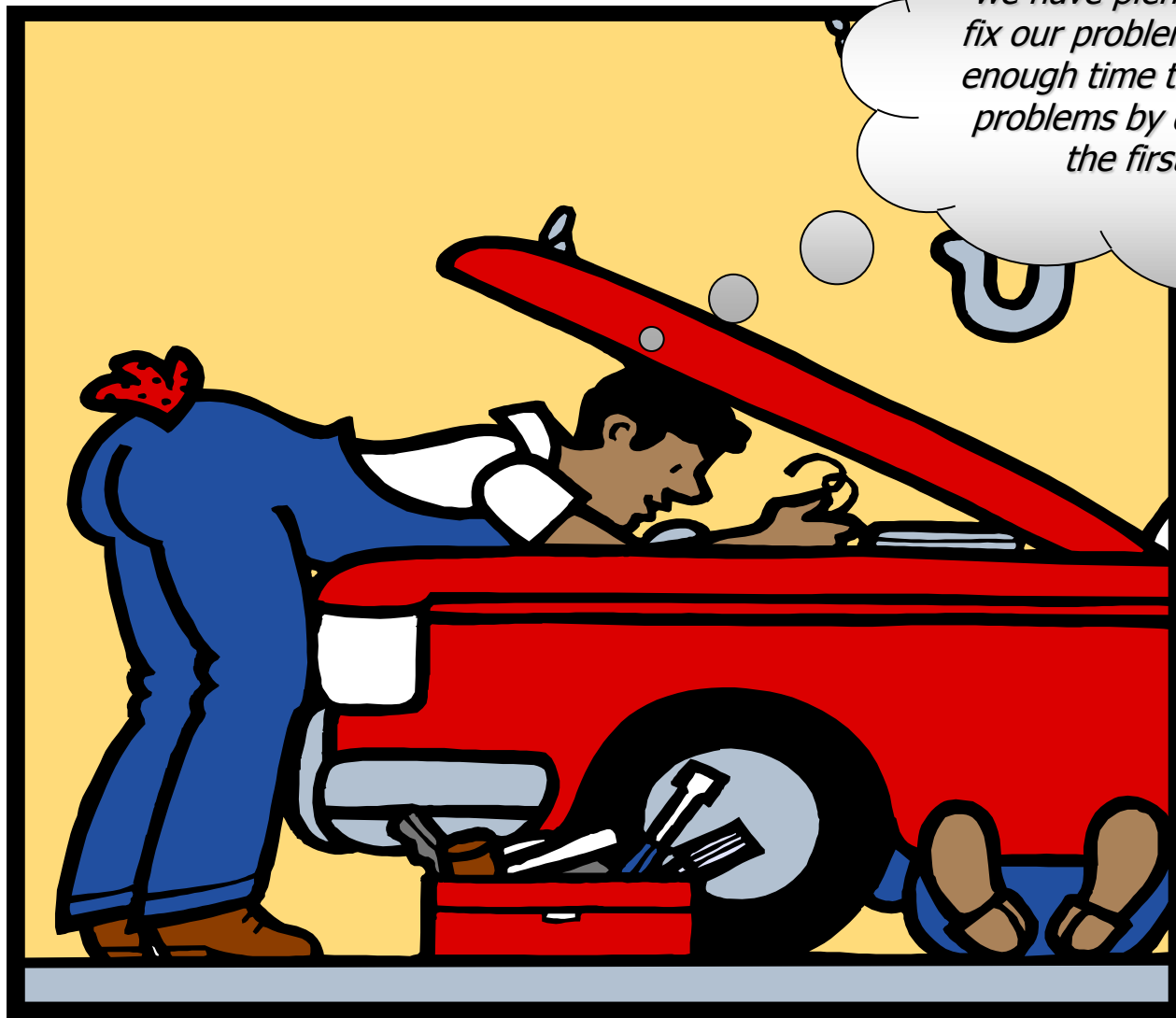
Overview Objectives

- Learn how to Create a Failure Modes and Effects Analysis (FMEA)

- Learn how to incorporate Customer Survey Data into a FMEA

Agenda

- FMEA History
- What is FMEA
  - Definition
  - What it Can Do For You
- Types of FMEA
- FMEA Terminology
- Getting Started with an FMEA
- The FMEA Worksheet
- FMEA Scoring
- Incorporate Customer feedback into a FMEA
- Use Survey Data to Update FMEA
- Celebrate, Reward and Improve

FMEA History

This *"type"* of thinking has been around for hundreds of years. It was first formalized in the aerospace industry during the Apollo program in the 1960's.

➢ Initial automotive adoption in the 1970's.

    ✓ Potential serious & frequent safety issues.

➢ Required by QS-9000 & Advanced Product Quality Planning Process in 1994.

    ✓ For all automotive suppliers.

➢ Now adopted by many other industries.

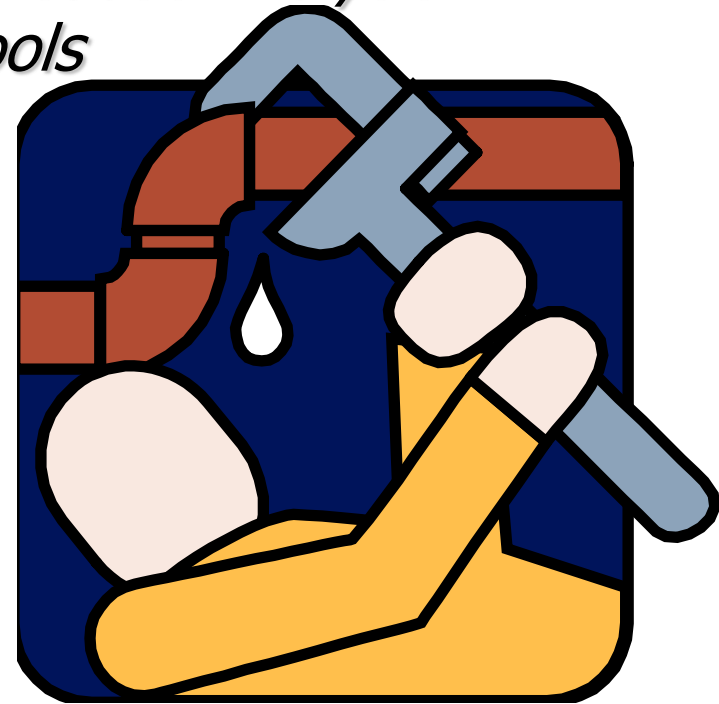   ✓ Potential serious & frequent safety issues or loyalty issues.

What is FMEA ?

IS / IS-NOT, Cause & Effect,
Root Cause Analysis,
Fishbone Diagram
5-Why Etc. = Root Cause Analysis
Tools

Failure Modes and Effects Analysis
= Proactive Documented
Prevention

What is FMEA ?

Definition: FMEA is a tool that:

➢ Helps define, identify, prioritize, and eliminate known and/or potential failures of the system, design, or manufacturing process before they reach the customer. The goal is to eliminate the Failure Modes and reduce their risks.

➢ Provides structure for a Cross Functional Critique of a design or a Process

➢ Facilitates inter-departmental dialog.

➢ Is a mental discipline "great" engineering teams go through, when critiquing what might go wrong with the product or process.

➢ Is a living document which ultimately helps prevent, and not react to problems.

What is FMEA ?

What it can do for you!

1.) Identifies Design or Process related *Failure Modes* before they happen (D = Design & P = Process FMEA).

2.) Determines the *Effect & Severity* of these failure modes.

3.) Identifies the *Causes* and probability of *Occurrence* of the Failure Modes.

4.) Identifies the *Controls* and their *Effectiveness.*

5.) Quantifies and prioritizes the *Risks* associated with the Failure Modes.

6.) Develops & documents Action Plans that will occur to reduce risk.

Types of FMEAs ?

System/Concept "S/CFMEA"- *(Driven by System functions)* A system is a organized set of parts or subsystems to accomplish one or more functions. System FMEAs are typically very early, before specific hardware has been determined.

Design "DFMEA"- *(Driven by part or component functions)* A Design / Part is a unit of physical hardware that is considered a single replaceable part with respect to repair. Design FMEAs are typically done later in the development process when specific hardware has been determined.

Process "PFMEA"- *(Driven by process functions & part characteristics)* A Process is a sequence of tasks that is organized to produce a product or provide a service. A Process FMEA can involve fabrication, assembly, transactions or services.

FMEA Terminology

1.) Failure Modes: (Specific loss of a function) is a concise description of how a part, system, or manufacturing process may potentially fail to perform its functions. Examples of potential failure modes include:

Some Process Failure Modes

-Deliver Wrong Product   -Deliver Wrong Service
-Deliver Poor Product Quality   -Deliver Poor Service
-Customer Gets "Lost" (Walk out)   -Data Gets Lost
-Overcharge   -Undercharge

2.) Failure Mode "Effect*":* A description of the consequence or ramification of a system or part failure. A typical failure mode may have several *"effects"* depending on which customer you consider. Keep in mind the internal as well as the external customer. Examples of failure effects include:

Some Process Failure Mode Effects

-Customer Waits Too Long   -Product or Service Costs Increase
-Customer is Unhappy   -Company Reputation is Damaged
-Customer Injury   -Loss of Business or Market Share
-Legal Issues or Fines   -Death

FMEA Terminology (continued)

3.) Severity Rating (S): (Seriousness of the Effect) Severity is the numerical rating of the impact <u>on customers</u>.

    ✓ When multiple effects exist for a given failure mode, enter the worst case severity on the worksheet to calculate risk.

4.) Failure Mode "Causes": A description of the design or process deficiency (global cause or root level cause) that results
in the failure mode. The causes should be listed in technical terms and not in terms of symptoms.
Examples of potential causes include:

          Some Process Failure Mode Causes

    -Skipped Process Step   -Incomplete / Incorrect Data Collection
    -Poor Communication   -Too Complex or Too Confusing
    -Poor Coordination   -Poor Change Management
-All of the Human Factor Error Precursors (Fatigue, High Work Load, Time Pressure)

    ✓You must look at the causes not the symptoms of the failure. Most failure Modes have more than one *Cause.*

5.) Occurrence Rating (O): Is an estimate number of frequencies or cumulative number of failures (based on experience) that will occur (in our design concept) for a given cause over the intended "life of the design".

6.) Failure Mode "Controls*":* The mechanisms, methods, tests, procedures, or controls that we have in place to *PREVENT* the Cause of the Failure Mode or *DETECT* the Failure Mode or Cause should it occur .

✓Design Controls prevent or detect the Failure Mode prior to engineering release

7.) Detection Rating (D): A numerical rating of the probability that a given set of controls *WILL DISCOVER* a specific Cause of Failure Mode to prevent bad parts leaving the facility or getting to the ultimate customer.

✓Assuming that the cause of the failure did occur, assess the capabilities of the controls to find the design flaw.

8.) Risk Priority Number (RPN): Is the product of Severity, Occurrence, & Detection. Risk= *RPN= S x O x D*

✓Often the RPN's are sorted from high to low for consideration in the action planning step (Caution, RPN's can be misleading- you must look for patterns).

9.) Action Planning: A thoroughly thought out and well developed FMEA With High Risk Patterns that is not followed with corrective actions has little or no value, other than having a chart for an audit

✓Action plans should be taken very seriously.
✓If ignored, you have probably wasted much of your valuable time.
✓Based on the FMEA analysis, strategies to reduce risk are focused on:

➢Reducing the *Occurrence Rating.*
➢Reducing the *Detection Rating.*

Getting Started on FMEA

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What Must be done before FMEA Begins!

Understand your Customer Needs

=Quality Function Deployment (QFD) – Marketing

Develop & Evaluate Product/Process Concepts

=Brainstorming

Create an Effective FMEA Team

=4 to 6 Consensus Based Multi Level Experts

Define the FMEA Scope

= What we are and are not working on

Ready?

Develop and Drive Action Plan 7

Determine "Effects" of The Failure Mode
Severity Rating 3

Determine Product or Process Functions 1

Determine Failure Modes of Function 2

Determine "Causes" of The Failure Mode
Occurrence Rating 4

Determine "Controls"
Detection Rating 5

Calculate & Assess Risk 6

The FMEA Worksheet

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Product or Process	Failure Mode	Failure Effects	S E V	Causes	O C C	Controls	D E T	R P N	Actions / Plans	Resp. & Target Complete Date	p S E V	p O C C	p D E T	p R P N
① Determine Product or Process Functions	② Determine Failure Modes of Function	③ Determine "Effects" of The Failure Mode *Severity Rating*		④ Determine "Causes" of The Failure Mode *Occurrence Rating*		⑤ Determine "Controls" *Detection Rating*		⑥ Calculate & Assess Risk	⑦ Develop and Drive Action Plan					

If a FMEA was created during the Design Phase of the Program, USE IT!
Create an Action Plan for YOUR ROOT CAUSE
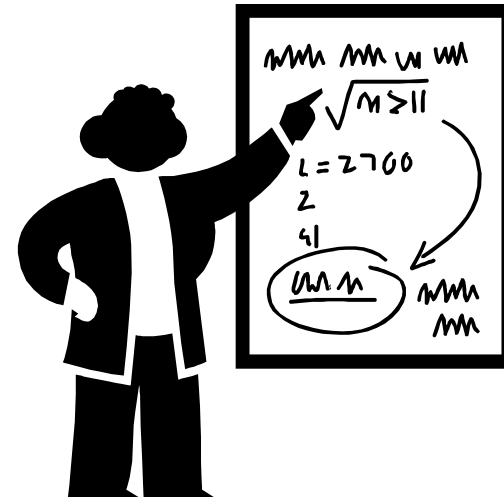and Re-Evaluate the RPN Accordingly

FMEA Scoring

RATING	DEGREE OF SEVERITY	PROBABILITY OF OCCURRENCE	Frequency (1 in …)	ABILITY TO DETECT	Detection certainty
1	Customer will not notice the adverse effect or it is insignificant	Likelihood of occurrence is remote	1,000,000	Sure that the potential failure will be found or prevented before reaching the next customer	100%
2	Customer will probably experience slight annoyance	Low failure rate with supporting documentation	20,000	Almost certain that the potential failure will be found or prevented before reaching the next customer	99%
3	Customer will experience annoyance due to the slight degradation of performance	Low failure rate without supporting documentation	5,000	Low likelihood that the potential failure will reach the next customer undetected	95
4	Customer dissatisfaction due to reduced performance	Occasional failures	2,000	Controls may detect or prevent the potential failure from reaching the next customer	90
5	Customer is made uncomfortable or their productivity is reduced by the continued degradation of the effect	Relatively moderate failure rate with supporting documentation	500	Moderate likelihood that the potential failure will reach the next customer	85
6	Warranty repair or significant manufacturing or assembly complaint	Moderate failure rate without supporting documentation	100	Controls are unlikely to detect or prevent the potential failure from reaching the next customer	80
7	High degree of customer dissatisfaction due to component failure without complete loss of function. Productivity impacted by high scrap or rework levels.	Relatively high failure rate with supporting documentation	50	Poor likelihood that the potential failure will be detected or prevented before reaching the next customer	70
8	Very high degree of dissatisfaction due to the loss of function without a negative impact on safety or governmental regulations	High failure rate without supporting documentation	20	Very poor likelihood that the potential failure will be detected or prevented before reaching the next customer	60
9	Customer endangered due to the adverse effect on safe system performance with warning before failure or violation of governmental regulations	Failure is almost certain based on warranty data or significant DV testing	10	Current controls probably will not even detect the potential failure	50
10	Customer endangered due to the adverse effect on safe system performance without warning before failure or violation of governmental regulations	Assured of failure based on warranty data or significant DV testing	2	Absolute certainty that the current controls will not detect the potential failure	< 50

FMEA Scoring
RPN or Risk Priority Number

The Calculation !

$$S_{everity} \times O_{ccurrence} \times D_{etection} = RPN$$

How can we incorporate Customer feedback into a FMEA?

- *Denise Wymore covered the Net Promoter Score at the AQN January breakfast.*

- In summary
  - On a scale of 0 - 10, how likely is it that you will recommend the (insert your business or service here) to a friend, coworker or family member?
  - What is the primary reason for your score?

- *Transaction Score* = weekly surveys of *key touch points* - Weekly

- *Relationship Score* = random sample of entire customer base - Quarterly

Simplified Survey

Detractor Passives Promoter

How likely is it that you will recommend us to a friend, coworker or family member?	Circle One: ☹ Very Unlikely 😐 Neutral ☺ Very Likely
Why or Why Not?	
Name (Optional)	Phone Number / Email / Address (Optional)

Use Survey Data to Update FMEA

- *Identify your key touch points or customer processes*
  - Going out to a Restaurant
  - Opening a New Account
  - Obtaining a Loan
  - Handling a Customer Call
  - Admitting a Patient
  - Developing Diet and Providing Food
- *Administer Survey (2 questions)*

Use Survey Data to Update FMEA

- *Analyze data weekly*
  - Sort Promoters and Detractors
- *Address Detractor Reasons – What's not working*
  - Group the Detractor primary reasons into affinities
  - Identifies the *Causes* of the Complaints.
    - CAUTION: Causes may need further investigation or Formal Root Cause Analysis (RCA)
  - Review the *Controls* and their Effectiveness.
  - Brainstorm new *Controls*

Use Survey Data to Update FMEA

- *Address Detractor Reasons – What's not working*
  - Identify *Actions* and *Responsibility* and *Target Date*
  - Follow-up and Document *Actions Taken*
  - Revaluate *Occurrence* and *Detection* and *RPN*

Celebrate, Reward, and Improve

- *Address Promoter Reasons – What is working*
  - Highlight the *key touch points or customer processes,* or *Controls* that are *Effective*
    - Celebrate successes
    - Publish wins
    - Acknowledge teams and key individuals
    - Reward "good" behavior
    - Document and instutionalize
    - Acknowledge customers

Failure Modes & Effect Analysis (FMEA)

Questions?

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