Failure Modes Effect Analysis

(FMEA)

Learning Objectives

- To understand the use of Failure Modes Effect Analysis (FMEA)
- To learn the steps to developing FMEAs
- To summarize the different types of FMEAs
- To learn how to link the FMEA to other Process tools

Benefits

- Allows us to identify areas of our process that most impact our customers
- Helps us identify how our process is most likely to fail
- Points to process failures that are most difficult to detect

Application Examples

- Manufacturing: A manager is responsible for moving a manufacturing operation to a new facility. He/she wants to be sure the move goes as smoothly as possible and that there are no surprises.
- Design: A design engineer wants to think of all the possible ways a product being designed could fail so that robustness can be built into the product.
- Software: A software engineer wants to think of possible problems a software product could fail when scaled up to large databases. This is a core issue for the Internet.

What Is A Failure Mode?

- A **Failure Mode** is:
  - The way in which the component, subassembly, product, input, or process could fail to perform its intended function
    - Failure modes may be the result of upstream operations or may cause downstream operations to fail
  - Things that could go wrong

FMEA

- **Why**
  - Methodology that facilitates process improvement
  - Identifies and eliminates concerns early in the development of a process or design
  - Improve internal and external customer satisfaction
  - Focuses on prevention
  - FMEA may be a customer requirement (likely contractual)
  - FMEA may be required by an applicable Quality Management System Standard (possibly ISO)

FMEA

- A structured approach to:
  - Identifying the ways in which a product or process can fail
  - Estimating risk associated with specific causes
  - Prioritizing the actions that should be taken to reduce risk
  - Evaluating design validation plan (design FMEA) or current control plan (process FMEA)

When to Conduct an FMEA

- Early in the process improvement investigation
- When new systems, products, and processes are being designed
- When existing designs or processes are being changed
- When carry-over designs are used in new applications
- After system, product, or process functions are defined, but before specific hardware is selected or released to manufacturing

History of FMEA

- First used in the 1960's in the Aerospace industry during the Apollo missions
- In 1974, the Navy developed *MIL-STD-1629* regarding the use of FMEA
- In the late 1970's, the automotive industry was driven by liability costs to use FMEA
- Later, the automotive industry saw the advantages of using this tool to reduce risks related to poor quality

Types of FMEAs

- Design
  - Analyzes product design before release to production, with a focus on product function
  - Analyzes systems and subsystems in early concept and design stages
- Process
  - Used to analyze manufacturing and assembly processes after they are implemented

FMEA: A Team Tool

- A team approach is necessary.
- Team should be led by the Process Owner who is the responsible manufacturing engineer or technical person, or other similar individual familiar with FMEA.
- The following should be considered for team members:
  - Design Engineers
  - Process Engineers
  - Materials Suppliers
  - Customers
  - Operators
  - Reliability
  - Suppliers

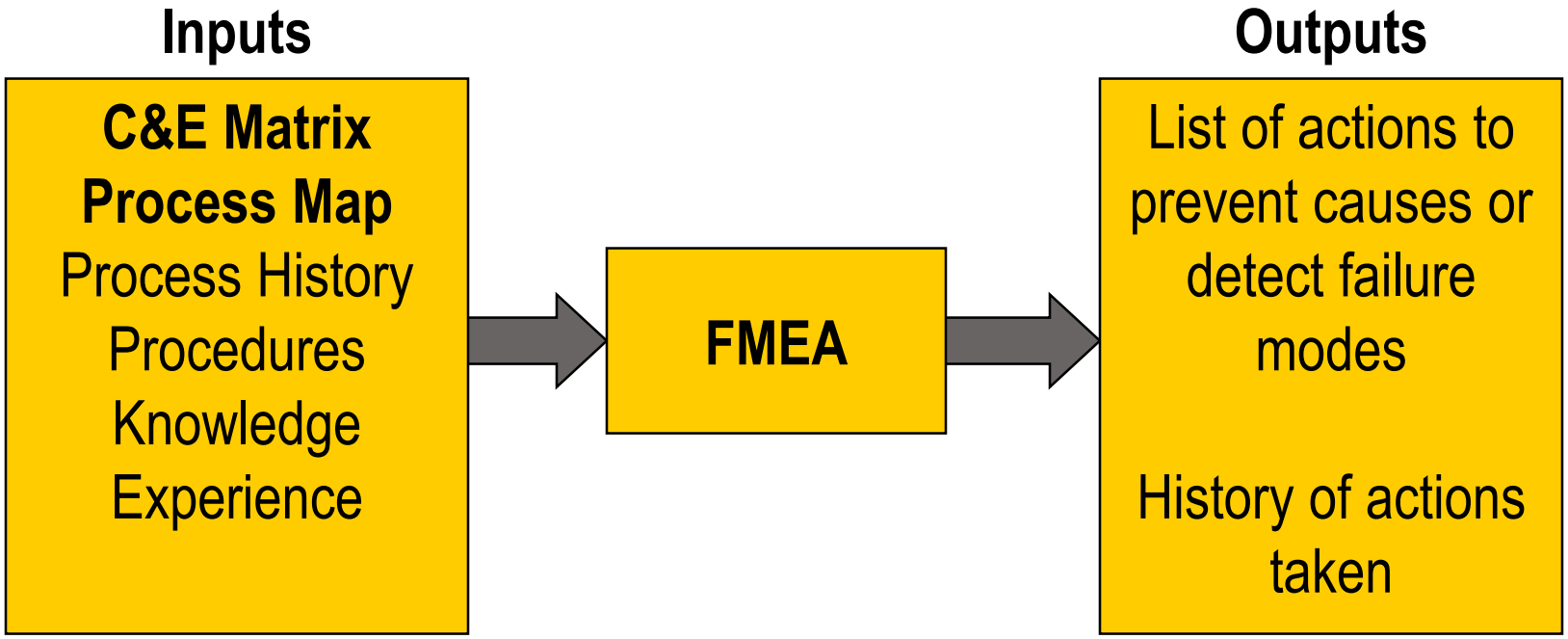
FMEA Procedure

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 (Cont.)

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



Severity, Occurrence, and Detection

- Severity
  - Importance of the effect on customer requirements
- Occurrence
  - Frequency with which a given cause occurs and creates failure modes (obtain from past data if possible)
- Detection
  - The ability of the current control scheme to detect (then prevent) a given cause (may be difficult to estimate early in process operations).

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 may allow 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 = Easy to Detect, 10 = Not easy to Detect

Risk Priority Number (RPN)

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

Summary

- An FMEA:
  - Identifies the ways in which a product or process can fail
  - Estimates the risk associated with specific causes
  - Prioritizes the actions that should be taken to reduce risk
- FMEA is a team tool
- There are two different types of FMEAs:
  - **Design**
  - **Process**
- Inputs to the FMEA include several other Process tools such as C&E Matrix and Process Map.