Critical Thinking & Problem Solving

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How to analyze failure to improve future performance

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

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?				
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Identify failure modes and their effects

Identify causes of the failure modes and controls

Prioritize

Determine and assess actions

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

Team Input Required

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

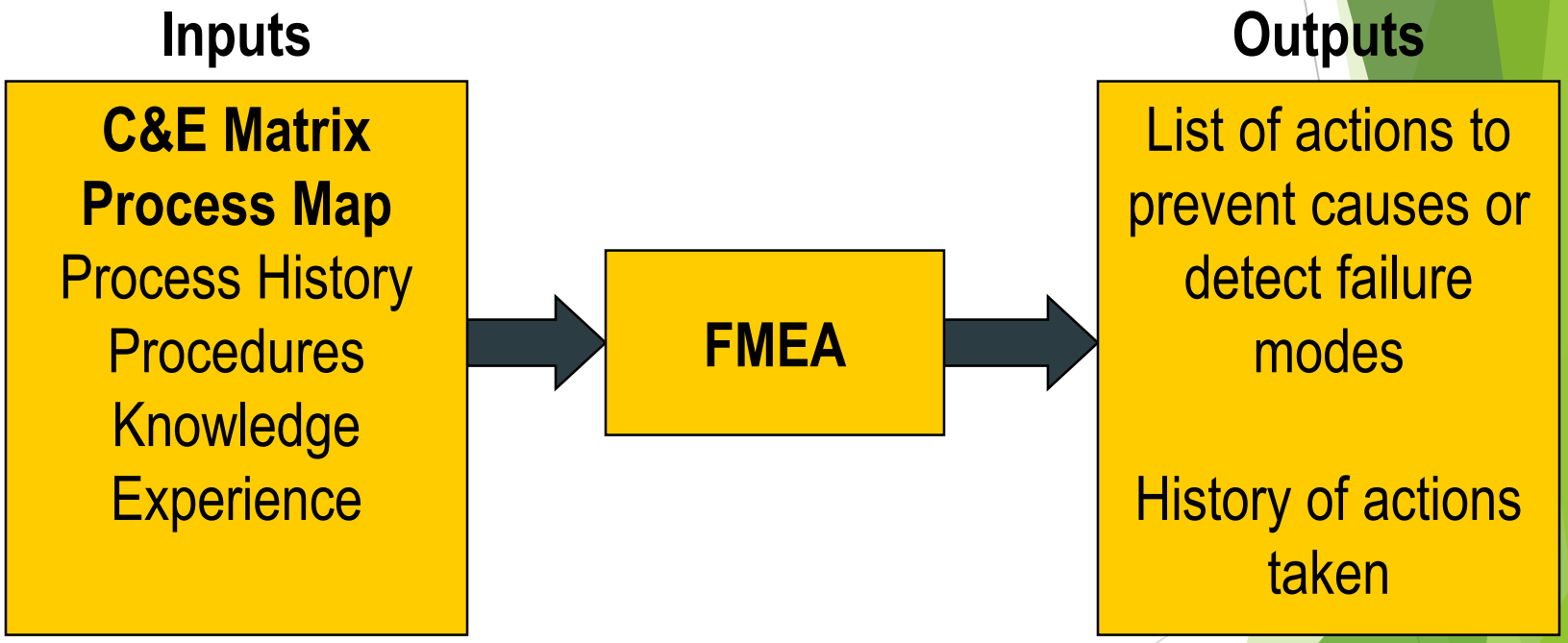
1. For each process input (start with high value inputs), determine the ways in which the input can go wrong (failure mode)
2. For each failure mode, determine effects
   - Select a severity level for each effect
3. Identify potential causes of each failure mode
   - Select an occurrence level for each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

Information Flow

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

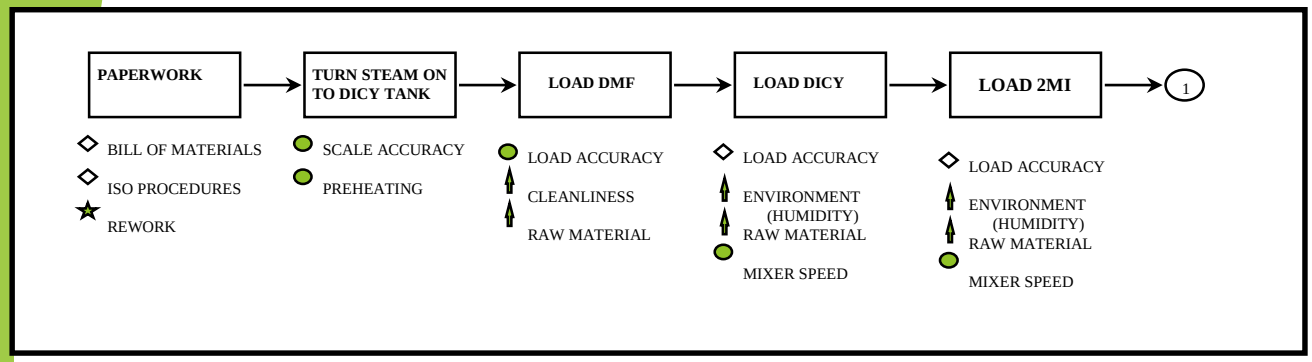
Risk Priority Number (RPN)

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

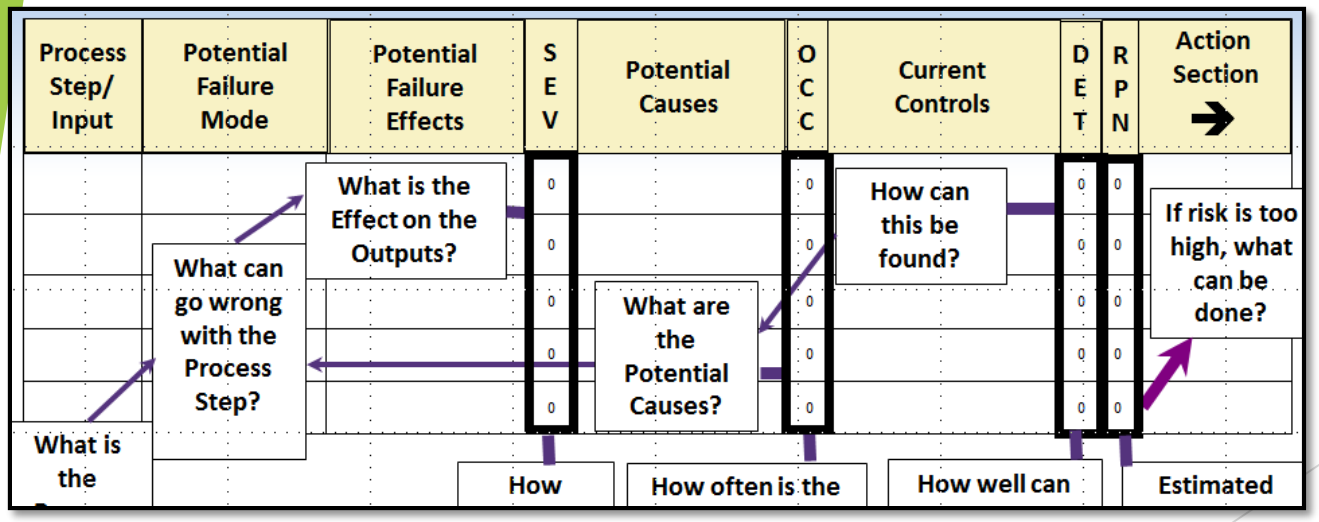
Summary

- 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.

KEY SOURCE MATERIAL FOR AN FMEA



Process Map



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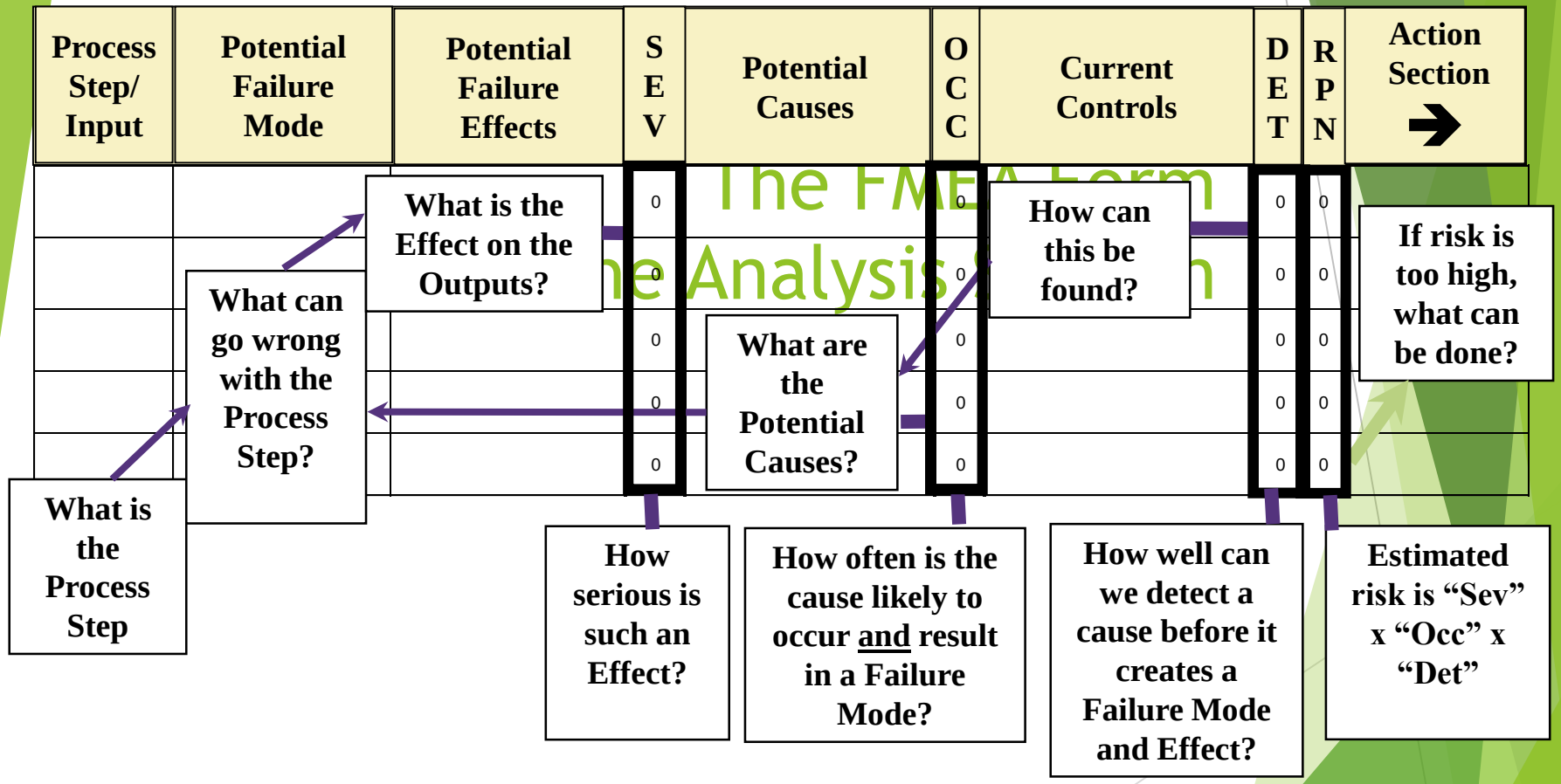
Process Step/ Input
Potential Failure Mode
Potential Failure Effects
S E V
Potential Causes
O C C
Current Controls
D E T
R P N
Action Section
The FMEA Form
he Analysis
What is the Process Step
What can go wrong with the Process Step?
What is the Effect on the Outputs?
How serious is such an Effect?
What are the Potential Causes?
How often is the cause likely to occur and result in a Failure Mode?
How can this be found?
How well can we detect a cause before it creates a Failure Mode and Effect?
If risk is too high, what can be done?
Estimated risk is "Sev" x "Occ" x "Det"

Definition of Terms – Failure Mode

Failure Mode: The way in which a specific process input fails

- ❑ If it is not detected and either corrected or removed, it may cause a negative "Effect" to occur
- ❑ Can be associated with a defect (in discrete manufacturing) or a process input variable that goes outside of specification
  - ✓ Anything that an operator can see that's wrong is considered a Failure Mode
  - ✓ Note 1: Just because a dimension is out of spec (a Failure Mode), it does not imply with 100% certainty that the product will not function (an effect)
  - ✓ Note 2: Just because the process is improperly setup (a failure cause), it does not imply with 100% certainty that the dimension will be out of spec (a Failure Mode)

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- **Effect:** The adverse impact on customer requirements. Generally has an external customer focus, but can also include
downstream processes.
  - A product or process that does not perform satisfactorily to design
- **Cause:** Whatever causes the Failure Mode to occur. How a specific part of the process (operation or component) can cause a Failure Mode.
  - A worn spindle (cause) may cause a dimension to be out of tolerance (mode) which may cause the part to not fit (effect)

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- **Severity:** An assessment of how serious the Failure Effect (due to the Failure Mode) is to the customer
- **Occurrence:** An assessment of the likelihood that a particular Cause will happen and result in the Failure Mode
- **Detection:** An assessment of the likelihood that the current controls will detect the Cause of the Failure Mode or the Failure Mode itself, should it occur, thus preventing the Failure Effect from reaching your customer. The customer in this case could be the next operation, subsequent operations, or the end user

trols

- **Current Controls:** Systematized methods/devices in place to prevent or detect failure Modes or Causes (before causing effects)
  - ✓ Prevention-based controls may include Mistake Proofing, automated controls, setup verifications, Preventive Maintenance, and Control Charts
  - ✓ Detection-based controls may include audits, checklists, inspection, laboratory testing, and Control Charts

Rating Definitions Typical Scales

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

Note : Determine if your company has rating scales and rules. In some companies, rating a “10” on severity may have legal

Risk Priority Number (RPN)

- A key output of an FMEA is the "Risk Priority Number"
- The RPN is a calculated number based on information you provide regarding:
  - ✓ The likelihood of potential causes of Failure Modes
  - ✓ The seriousness of the resulting effects
  - ✓ The current ability of the process to detect the causes of the Failure Modes before they cause an effect to reach a customer
- It is calculated as the product of three (3) ratings, each

RPN = Severity x Occurrence x Detection

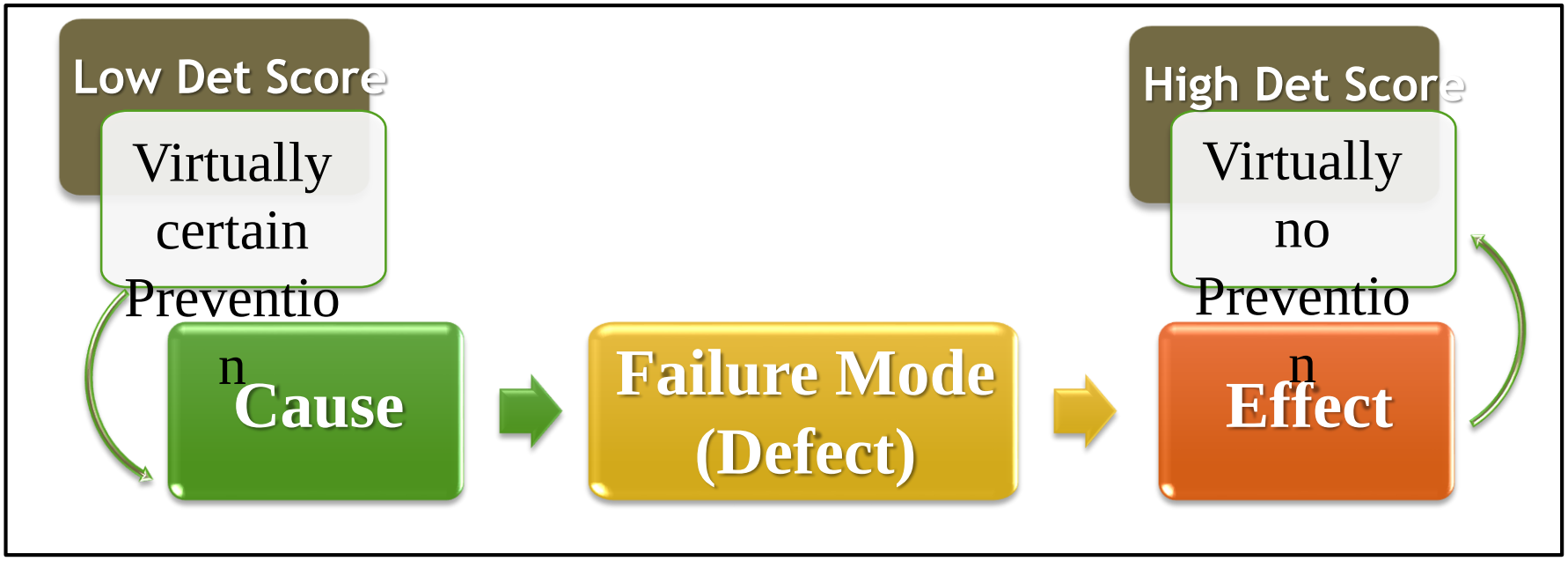
Regardless of RPN, high severity scores should be given special attention.

Risk Priority Numbers (2)

- The Risk Priority Number need not be limited to Severity, Occurrence, and Detection.

Some examples:

- ✓ Add an “Impact” score to estimate the overall impact of the Failure Mode on the process (10 = high, 1 = low)
- ✓ Add an “EHS” rating to a project FMEA to incorporate possible environmental impact (10 = high, 1 = low)
- ✓ Add an “EOC” or Ease Of Completion (10 = easy, 1= hard) to help prioritize/focus projects



- High detection scores imply that we will not easily catch the existence of a Failure Cause until after the resulting Failure Mode creates a Failure Effect. Usually, this means that we detect the effect at the end of the line or, even worse, our customer finds it.
- A very low detection score generally implies that you catch the cause before it creates the Failure Mode

Cause	Mode	Effect
Faculty inverter	Agitator too slow	Extractable too high
High particle count	Pits	Internal opens on printed circuit in clean room
Temp controller out	Temp too high of calibration	Conversion rate too low
Drill not properly	Hole not drilled sharpened	Part will not assemble straight
Part not clamped	Hole not drilled square in fixture	Part will not assemble straight
Drill not properly	Hole not drilled	Part will not assemble to proper diameter

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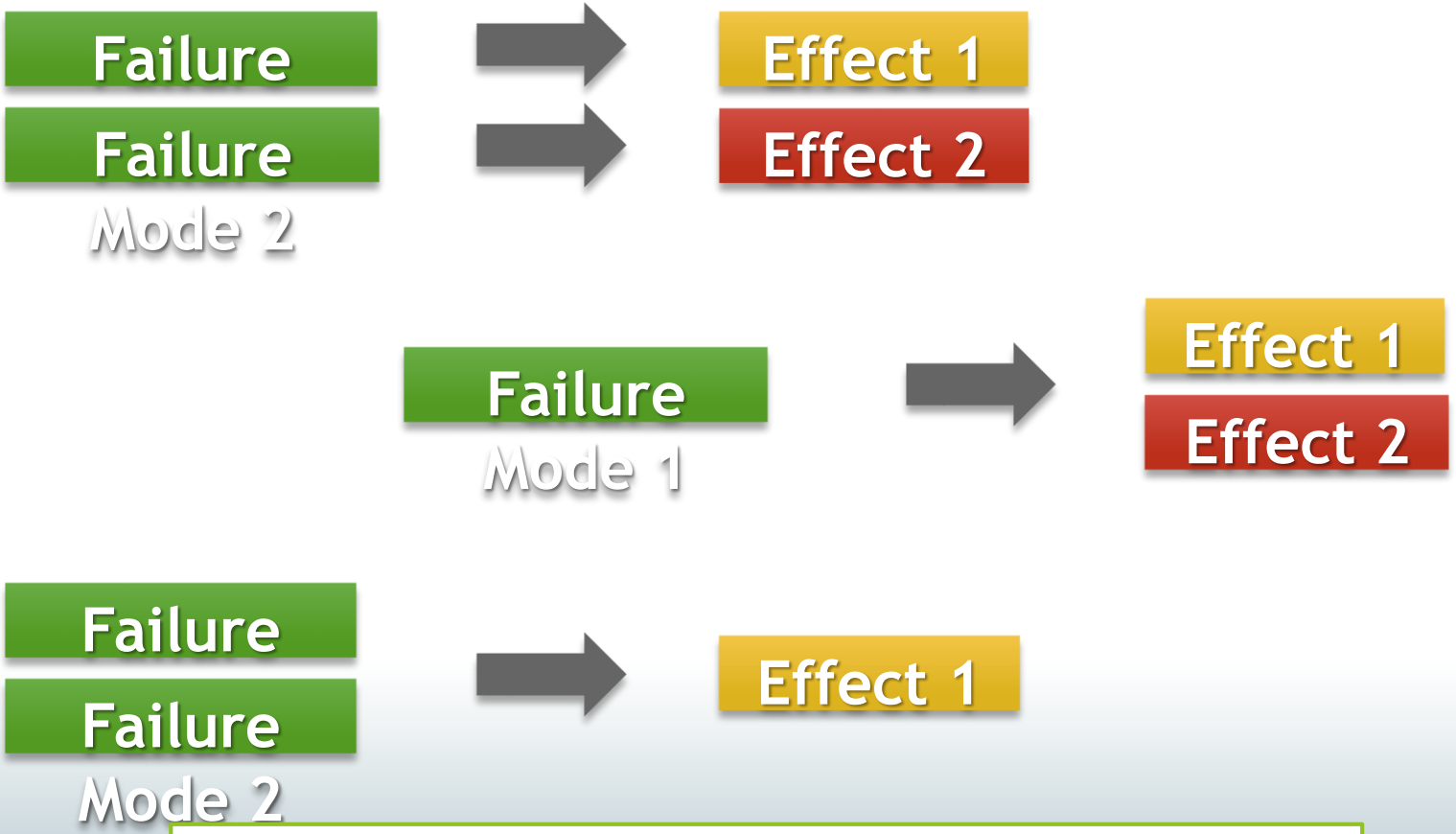

Note that the relationship between the Failure Mode and the Effect is not always 1-to-1.

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Process/Product - FMEA
Failure Modes and Effects Analysis

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

Process Step	Key Process Input	Potential Failure Mode	Potential Failure Effects	SEV	Potential Causes	OCC	Current Controls	DET	RPN
What is the process step	What is the Key Process Input?	In what ways does the Key Input go wrong?	What is the impact on the Key Output Variables (Customer Requirements) or internal requirements?	How Severe is the effect to the customer?	What causes the Key Input to go wrong?	How often does cause or FM occur?	What are the existing controls and procedures (inspection and test) that prevent either the cause or the Failure Mode? **Should include an SOP number.**	How well can you detect cause or FM?	Sev x Occ x Det
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Analysis Section ←	RPN	Actions Recommended	Responsibility	Actions Taken	SEV	OCC	DET	RPN
	Original RPN	What are the actions for reducing the Severity or Occurrence, or improving Detection? **Should have actions only on high RPNs or easy fixes.**	Who is Responsible for the recommended action?	What are the completed actions taken with the recalculated RPN? **Be sure to include completion month/year.**	Revised SEV	Revised OCC	Revised DET	Revised RPN

MEA

1. For each Process Input, determine the ways in which the Process Step can go wrong (Failure Modes)
2. For each Failure Mode associated with the inputs, determine Effects
3. Identify potential Causes of each Failure Mode
4. List the Current Controls for each Cause
5. Assign Severity, Occurrence, and Detection ratings to each Cause
6. Calculate RPN
7. Determine Recommended Actions to reduce High RPNs
8. Take appropriate actions and document
9. Recalculate RPNs

Reference and sources

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