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Corrective Action

Root Cause Analysis and Corrective Action

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Overview Webinar 6: Root Cause Analysis and Corrective Action

- What is Root Cause Analysis (RCA)?
- Why is RCA important?
- When is RCA required?
- Overview of the Corrective Action Process
- Root Cause Analysis Tools:
  - The 5-Whys
  - Ishikawa Cause & Effect (Fishbone) Diagrams
  - Cause Mapping
  - Failure Modes & Effects Analysis
  - Design of Experiments

What is Root Cause Analysis (RCA)?

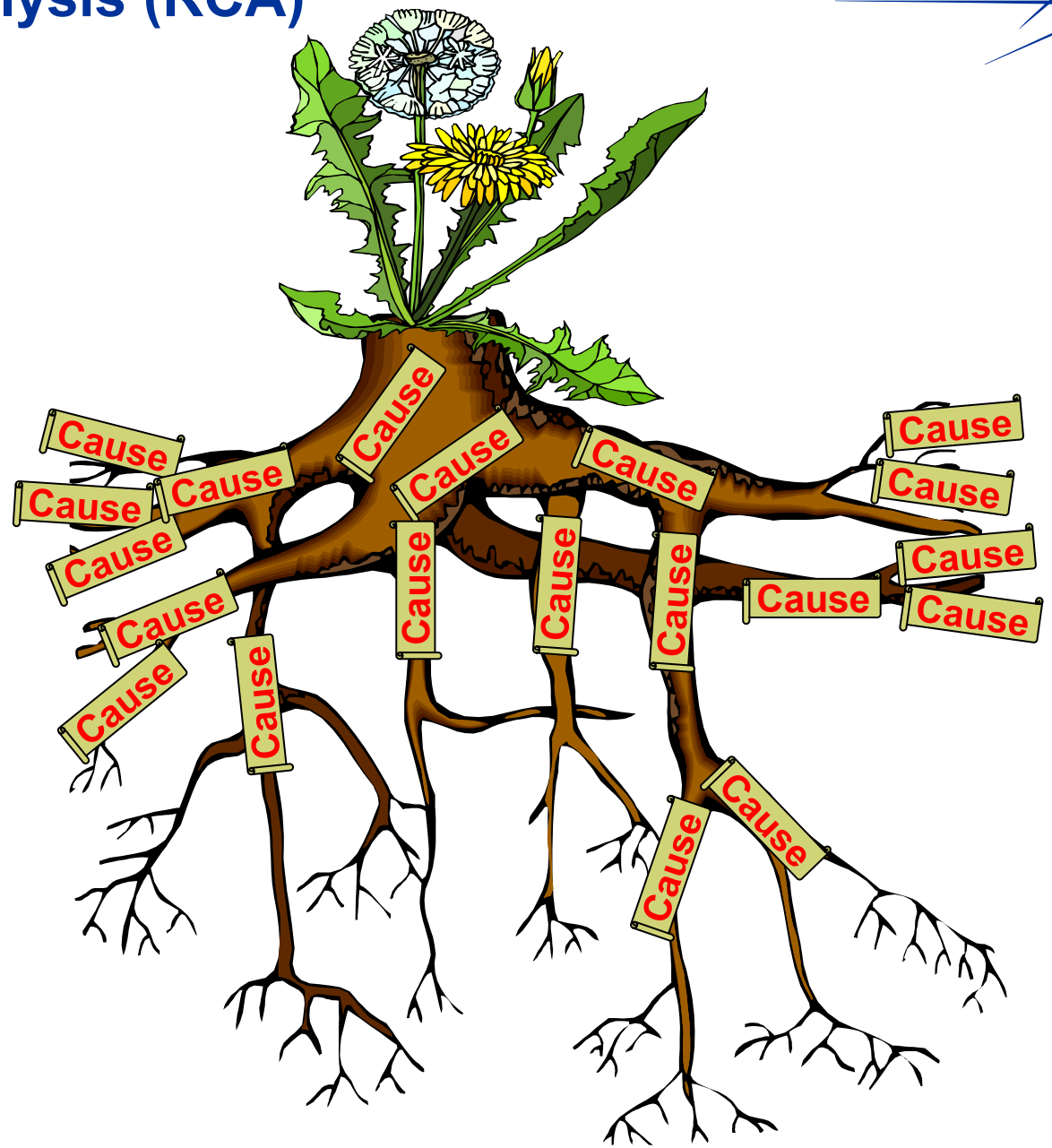
Root Cause Analysis (RCA): The *process* of identifying all the causes (root causes and contributing causes) that have or may have generated an undesirable condition, situation, nonconformity, or failure.

» **IAQG – Root Cause Analysis and Problem Solving April 2014.**

Root Cause Analysis (RCA)

PROBLEM =
Weed
(obvious)

CAUSE = ROOT
(not obvious)



Why Root Cause Analysis (RCA)?

- Helps prevent problems from repeating or occurring.
- Focus on Continuous Improvement throughout the Enterprise.
- Drives Breakthrough Performance.
- Focus on improving processes that actually effect organization performance metrics.

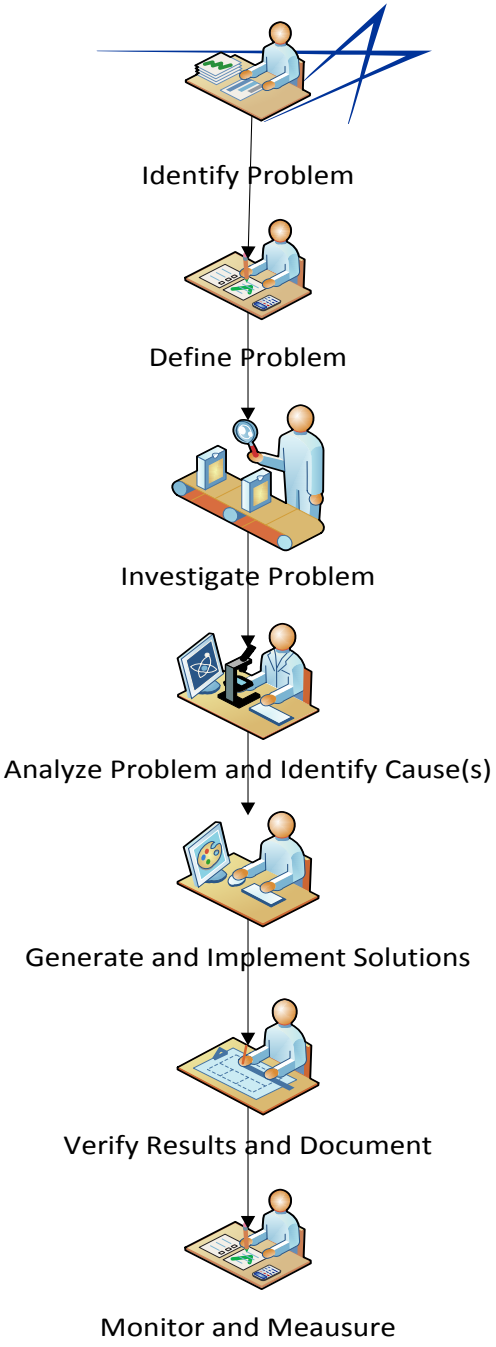
When is RCA required?

- Undesirable condition, defect, or failure is detected
- Safety
- Product strength, performance, reliability
- High impact on Operations
- Repetitive Problems
- Customer Request
- Significant Quality Management System (QMS) issues

» **IAQG – Root Cause Analysis and Problem Solving, April 2014**

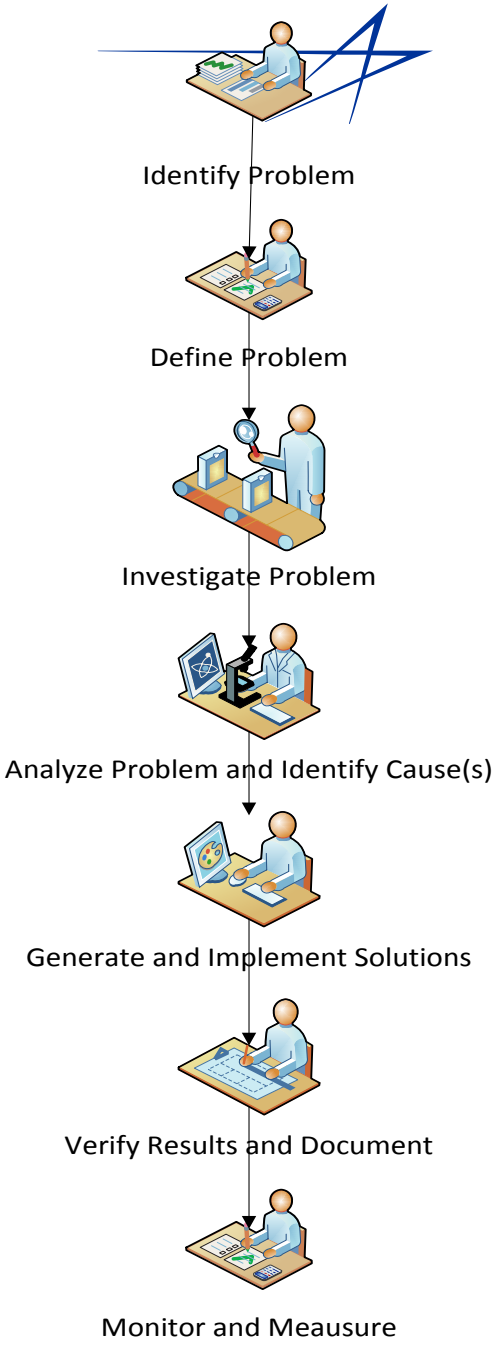
The Corrective Action (CA) Process

- **Objective:** Identify the cause(s) of problems and initiate actions to prevent recurrence.
  - Extent of corrective actions shall be proportional to the effects of the related problems.
  - Corrective action is applicable to the enterprise and not limited to the manufacturing environment.
  - Problems may originate and/or be identified within a product, process, and/or capability in any business area, function, or program.



The Corrective Action Process

- Increased focus on Problem Definition
- Requirement for Evidence-Based Causes
- Requirement to always look for Multiple Causes
- A Corrective Action end state that includes
  - Verified successful mistake proofed solutions
  - Goal of 0% Chance of Recurrence



Overview of the Corrective Action Process

- Step 1: Identify the Problem
- Step 2: Define the Problem
- Step 3: Investigate the Problem (Complete Containment Actions)
- *Step 4: Analyze the Problem & Identify Root Cause (s)*
- Step 5: Generate, Select and Implement Solutions (CA)
- Step 6: Verify the Results and Document
- Step 7: Monitor and Measure Corrective Actions

Corrective Action Process Flow:

Inputs:

Nonconforming Products or Services

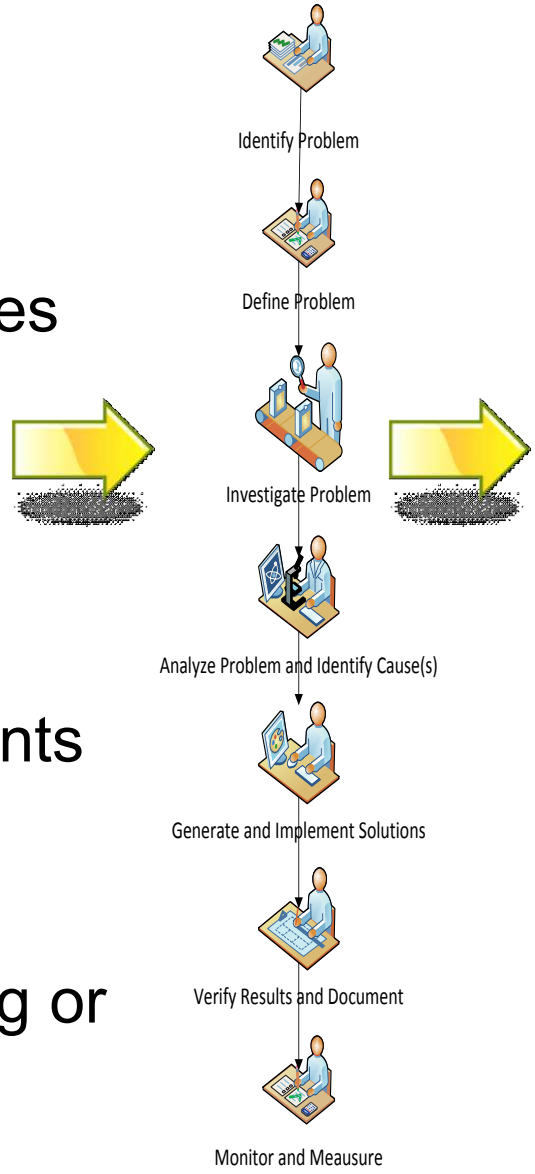
Noncompliant Processes or Capabilities

Audit Findings

Customer Complaints

Management Directives

Program Monitoring or Review



Outputs:

Implemented/Verified CA Plan

Improved Capabilities/Products

Costs Reduced

Schedule Improved

Quality Improved

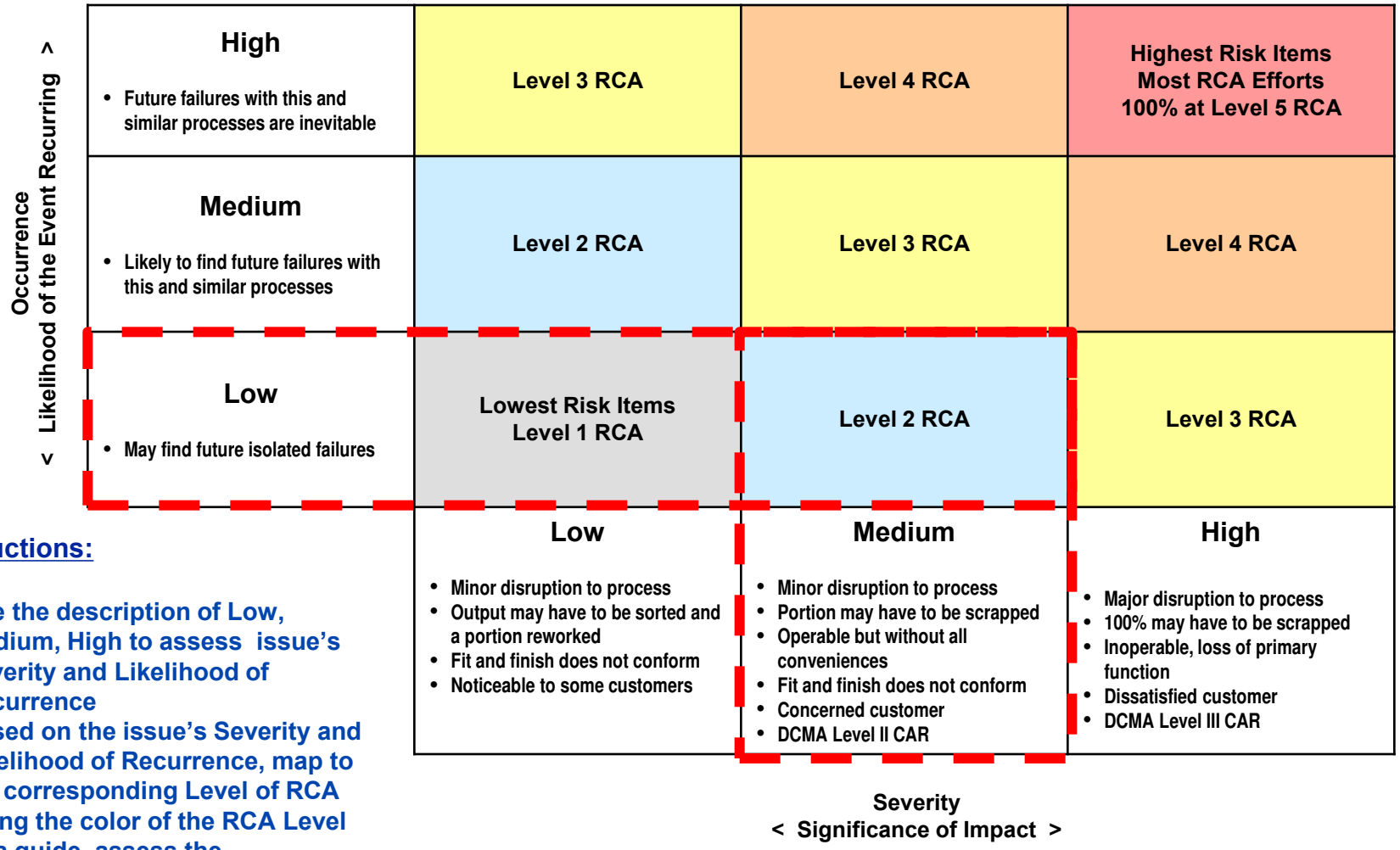
Customer Satisfaction

Record of Corrective Action and Verification

Corrective Action Process

- **7 tools to determine root cause:**
  - The 5 Why's
  - Cause & Effect Diagram (Fishbone)
  - Cause Mapping
  - FMEA: Failure Modes & Effects Analysis
  - Fault Tree Analysis
  - DOE: Design Of Experiments
  - Statistical Process Control
- Perform a Cause/Failure Analysis to determine the cause(s) of the problem. The appropriate root cause analysis tool will be used.
- The RCA tools are utilized and retained/attached as objective evidence to support root cause validation.

Severity/Impact Based RCA Approach



Instructions:

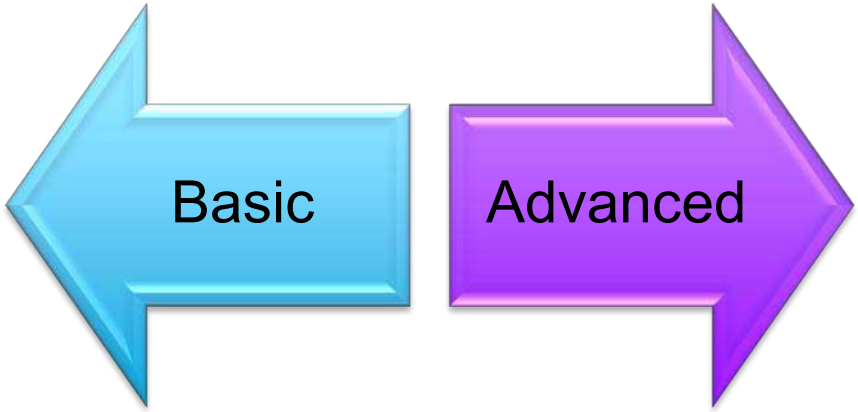
1. Use the description of Low, Medium, High to assess issue's Severity and Likelihood of Recurrence
2. Based on the issue's Severity and Likelihood of Recurrence, map to the corresponding Level of RCA
3. Using the color of the RCA Level as a guide, assess the requirements for that RCA tool

What RCA Tool Should I Use?

RCA Level	Impact	RCA Requirements	Recommended RCA Lead	Typical Analysis Span*	Output Templates	
5	High-High	• Apollo RCA using RealityCharting Tool	• Experienced and Certified Apollo RCA Facilitator	2 – 6 Weeks	1. Summary including Problem Statement 2. RCA Findings and Conclusions 3. RCA Corrective Action Solutions and Measurement Strategy 4. Illustration of Apollo RCA Template	OR… 1. Illustration of Apollo RCA Template
4	High-Medium Medium-High	• RCA using Think Reliability Tool • Apollo RCA using RealityCharting Tool	• Experienced and Certified Apollo or Think Reliability RCA Facilitator	1– 4 Weeks	1. Summary including Problem Statement 2. RCA Findings and Conclusions 3. RCA Corrective Action Solutions and Measurement Strategy 4. Applicable Illustration of RCA Template	OR… 1. Applicable Illustration of RCA Template
3	High-Low Medium-Medium Low-High	• FMEA - Failure Modes Effects Analysis • Apollo Methodology • Apollo RealityCharting • Think Reliability	• FMEA Trained Employee • Apollo or Think Reliability RCA Trained Facilitator or	1 day – 3 weeks	1. Summary including Problem Statement 2. RCA Findings and Conclusions 3. RCA Corrective Action Solutions and Measurement Strategy 4. Applicable Illustration of RCA Template	OR… 1. Applicable Illustration of RCA Template
2	Low-Medium Medium-Low	• 5 Whys • Fishbone Diagram • FMEA - Failure Modes Effects Analysis	• Trained Employee • Green Belt / Black Belt	1 day – 2 weeks	1. Summary including Problem Statement 2. Applicable Illustration of RCA Template	
1	Low-Low	• 5 Whys • Fishbone Diagram	• All Trained Employees	1 – 8 hours	1. Summary including Problem Statement 2. Applicable Illustration of RCA Template	

*** Analysis Span Time for completion of an effective RCA is dependent upon:**
1) Scope of problem; 2) Quality of preparation; and 3) Resources allocated to RCA and problem resolution

Selecting a RCA Leader



- Problem Complexity
- Data type and availability
- Type analyses required
- Individual or team based approach RCA
- Severity of issue/impact to business
- Internal/external engagement

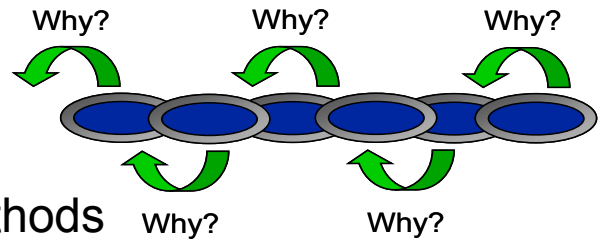
Root Cause Analysis Tools

- The 5-Whys
- Cause & Effect (Fishbone/Ishikawa Diagrams)
- Cause Mapping
- Failure Modes & Effects Analysis
- Design of Experiments

The 5 Why's

- What is a 5 Why?
  - A question based technique used to explore cause-and-effect relationships
  - Determine root cause of a problem
  - Ask Why? *As many times as needed!*

- Advantages
  - Easy to use and teach
  - Identifies more than one cause
  - Useful for minor problems
  - Used to generate causes for use in other RCA methods



- Limitations
  - Linear thinking ignores additional causes
  - Not appropriate for formal investigations
  - Perpetuates the myth of single root cause
  - Does not provide guidance for solutions
- Supporting Tools
  - 5 Why Template - this is a text only approach

5 Whys Template

Instructions: Start with your focused problem and then ask WHY five times.

Focused Problem Statement:

Problem: High reject rate of parts used by downstream aircraft assembly process

Why **There is bare material exposed**

Why **The primer paint coating does not cover the whole part**

Why **The priming process does not ensure full coverage**

Why **The priming process is never done the same way twice**

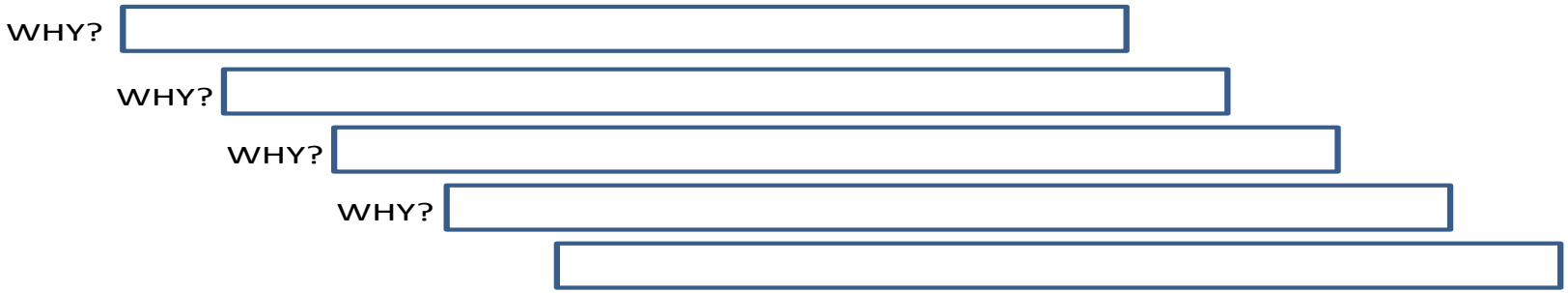
Why **The priming process has always relied on word-of-mouth training and has no standard process defined**

Solution: Create a standard work method that defines the exact sequence and tools for priming the parts. This will significantly improve the process yield.

A New Look at 5 Why Templates

THE SINGLE CAUSE TEMPLATE

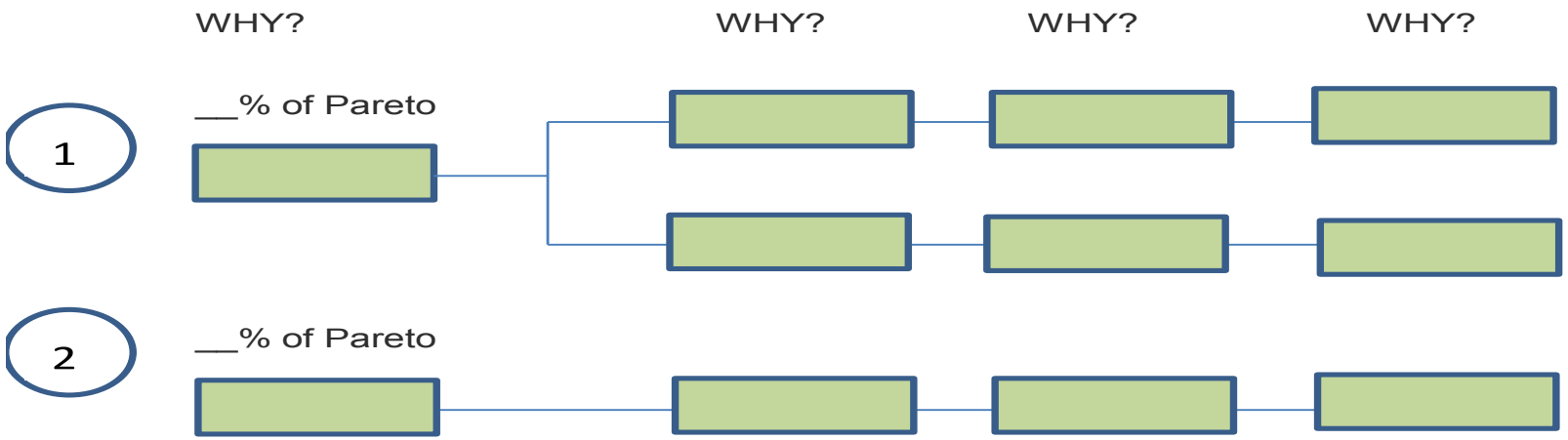
PROBLEM STATEMENT: _____



This example is a typical format for narrow problem statements where one cause-path exists. For problem statements with multiple causes, use the template below.

MULTIPLE CAUSES TEMPLATE

PROBLEM STATEMENT: _____



Proposed Operating Instruction for alternate 5 Why Template

5 Why Operating Instruction

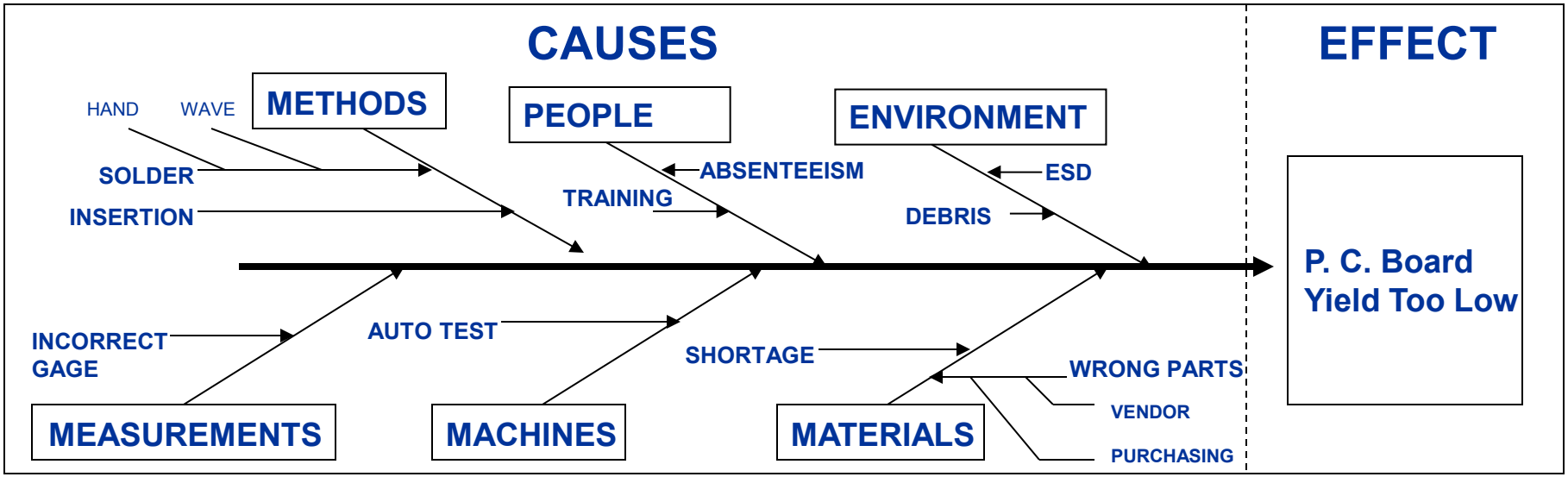
Ishikawa Cause & Effect Diagram (Fishbone)

What is A *Cause and Effect Diagram?*

- A tool used to illustrate the relationship between an effect and the causes that influence the effect

When to Use It?

- Identify causes of a problem (Effect)
- Can be used to prevent future problems



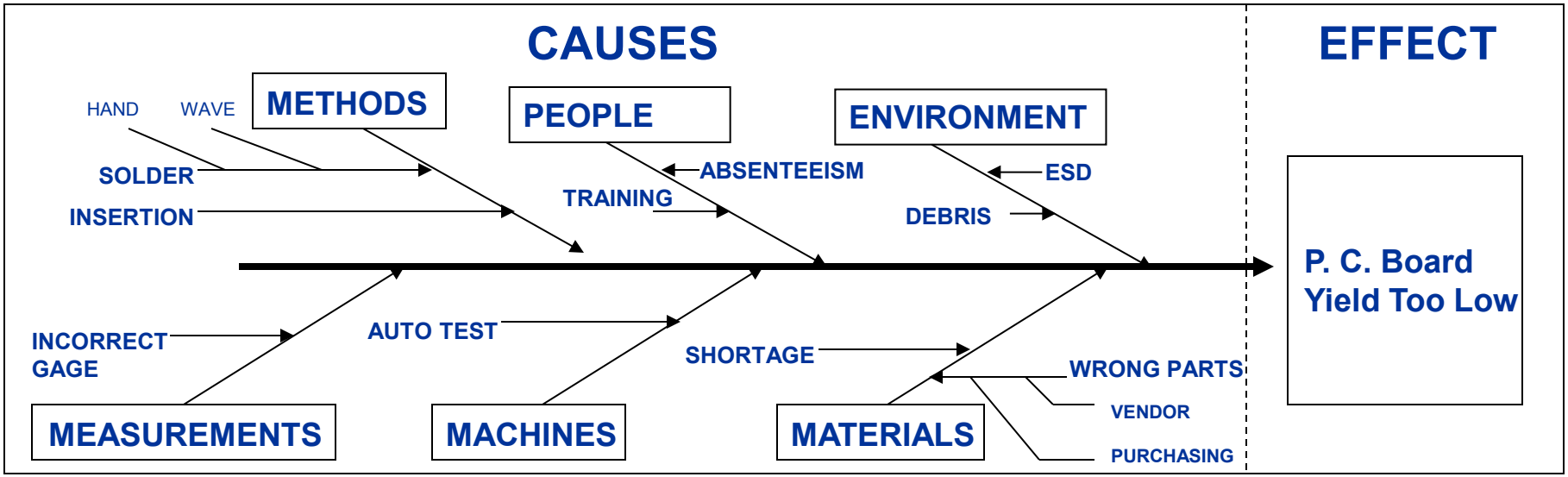
Ishikawa Cause & Effect Diagram (Fishbone)

Advantages

- –Encourages brainstorming
- –Can be used when time is very limited
- –Helps organize many potential causes

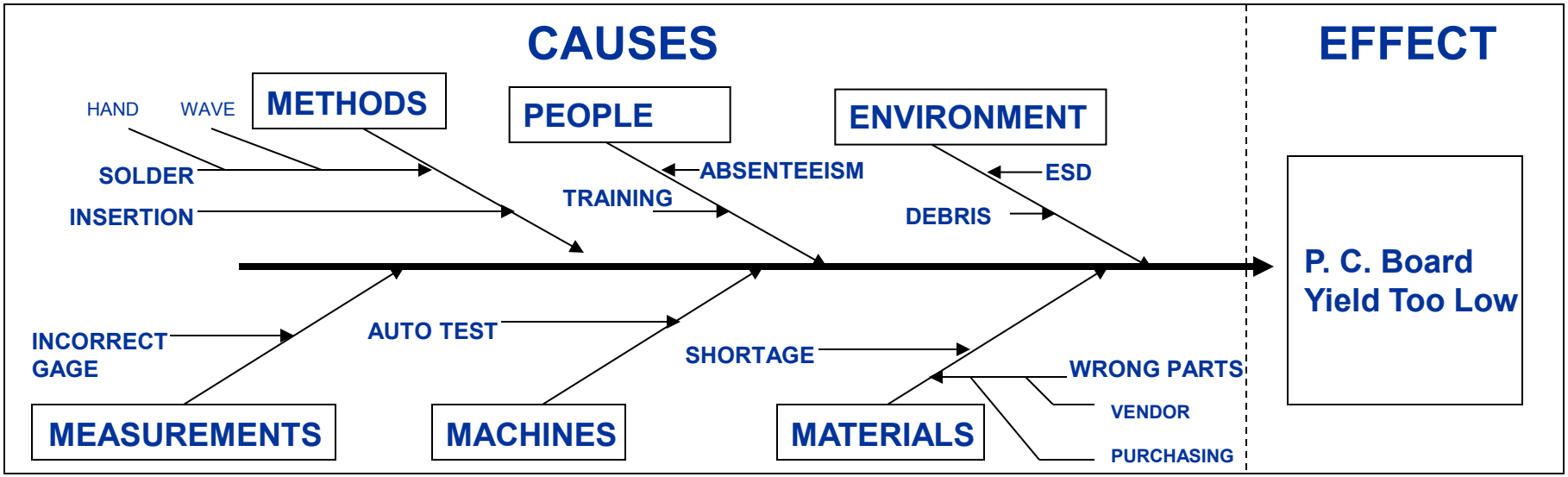
Limitations

- –Categories may cause investigations to stop at "categorical causes”
- –Creates the illusion of equal weight among causes
- –No guidance for prioritizing causes or developing solutions
- –Usually stops at 1 or 2 levels of causes (stops too soon)



Ishikawa Cause & Effect Diagram (Fishbone)

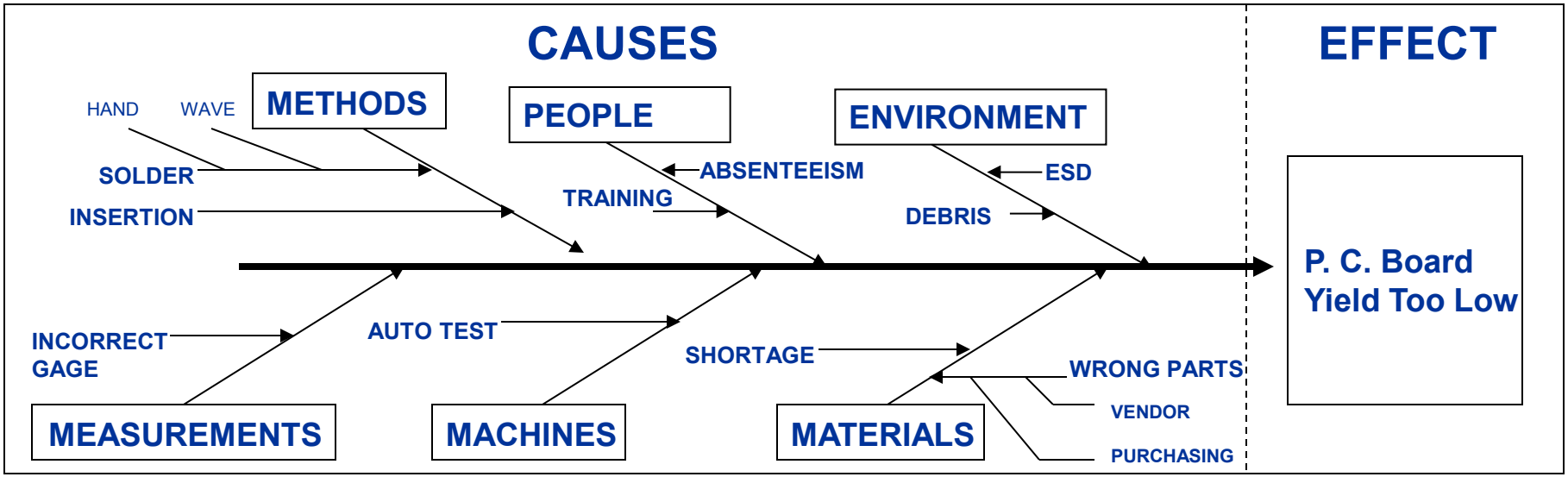
- For every Effect there are likely to be several Major Causes
- Major Causes include: People, Measurements, Machines, Methods, Materials, Environment
- Any major category that helps people think creatively can be used



Ishikawa Cause & Effect Diagram (Fishbone)

- Methods = work instructions, procedures, test methods
- Material = components and raw materials
- Measurements = standards, calibration, gages, data collection
- People = training and staffing
- Machines = tools, equipment, fixtures
- Environment = temperature, humidity, lighting, noise

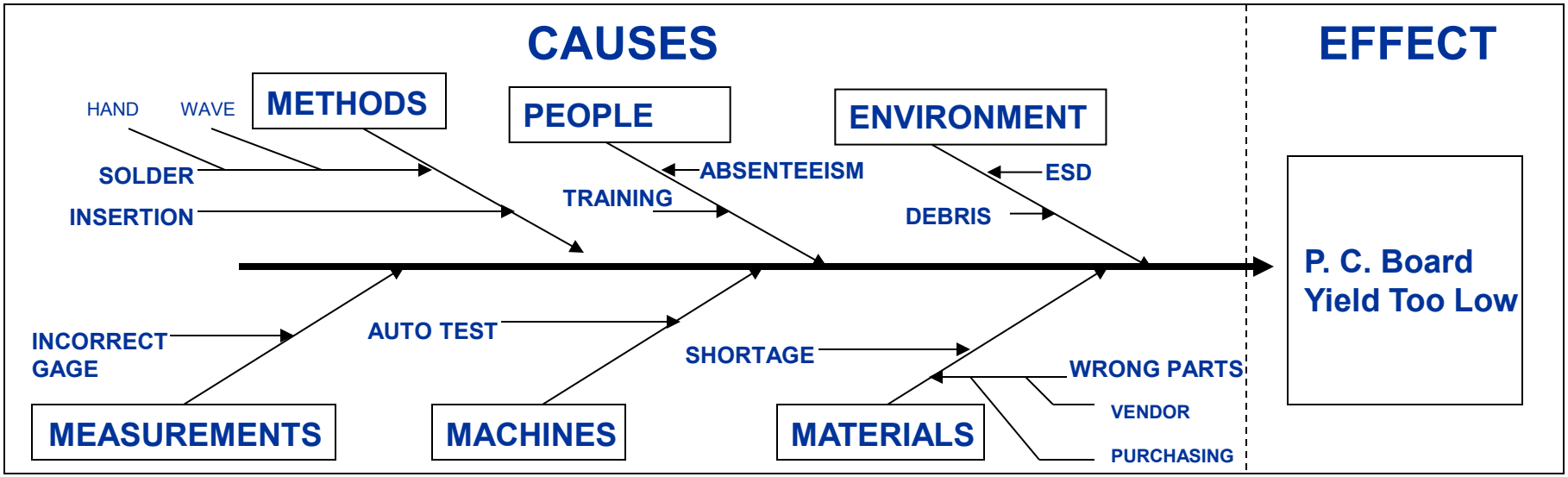
Goal is to discover all possible Causes related to the Effect!



Ishikawa Cause & Effect Diagram (Fishbone)

How to Construct a Cause & Effect Diagram:

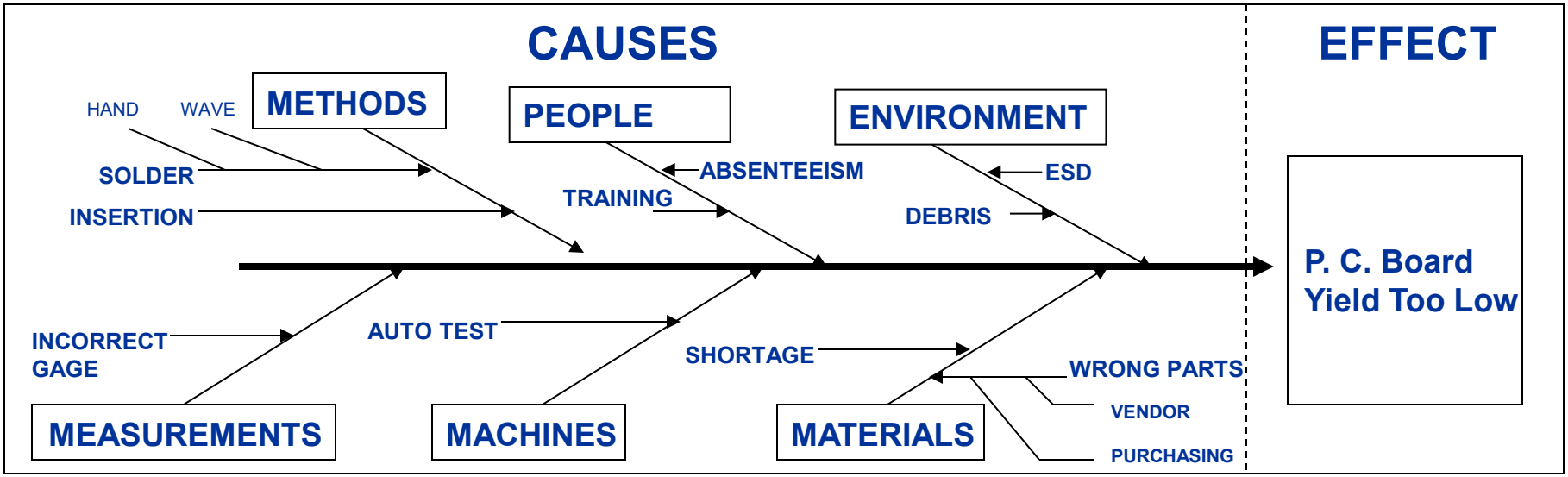
- Brainstorm – include Subject Matter Experts (SME)
- Add the problem to the EFFECT box.
- Add the Major Cause categories
- Place the potential causes in the Major Cause category.
- For each Cause ask, “Why does it happen?”
- List the responses as branches off the Major cause.



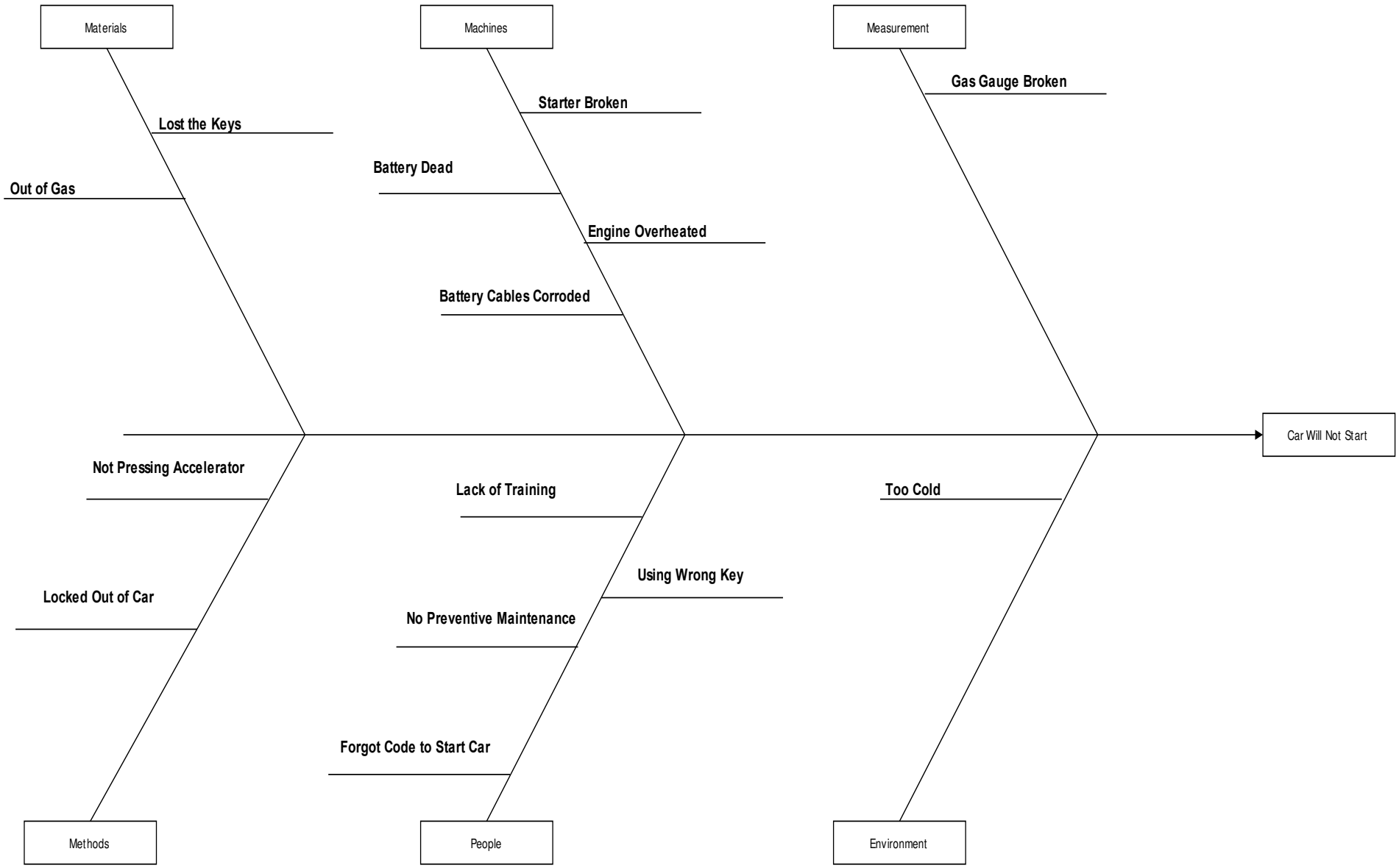
Ishikawa Cause & Effect Diagram (Fishbone)

How to Interpret?

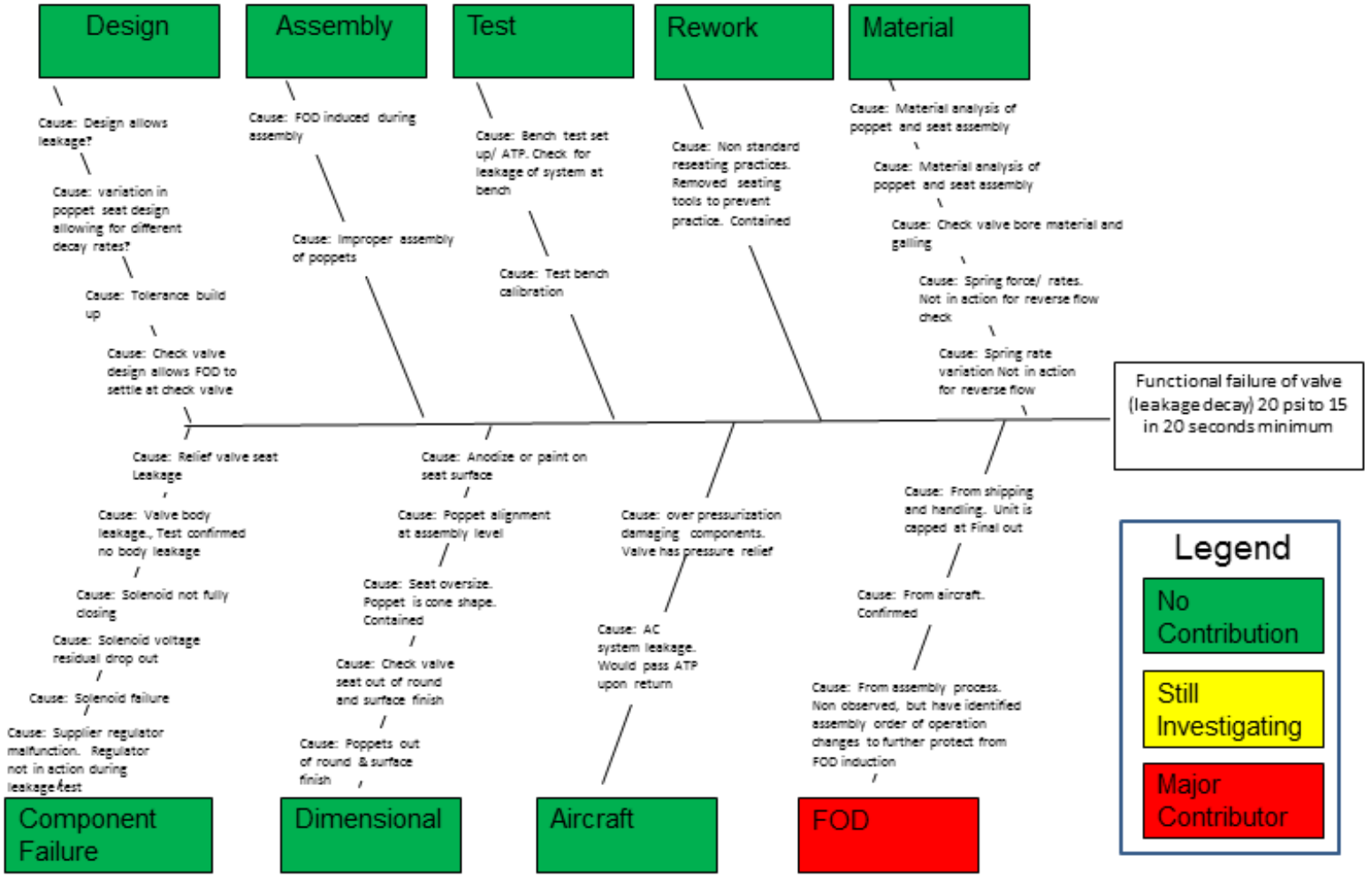
- Look for causes that appear frequently.
- Reach a team consensus.
- Determine the relative frequencies of the different causes.



Example of Cause & Effect Diagram

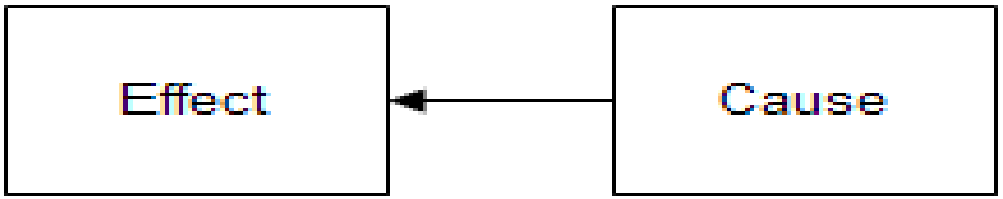


Example C&E Diagram - Canopy Leakage



What is a Cause Map?

- A visual explanation of why an incident occurred
- Connects single cause-and-effect relationships to a system of causes
- A Cause Map can be basic or very detailed



Cause-and-Effect Relationship

"Building Block"

Cause Mapping for Root Cause

Step 1: Problem Statement

- **Identify/Outline the Problem (What, When, Where, Goal)**
- **The Outline explains why time is spent on an issue**

Step 2: Analysis

- **Identify/Breakdown the Causes**
- **This step is where the Cause Map is built**

Step 3: Solutions

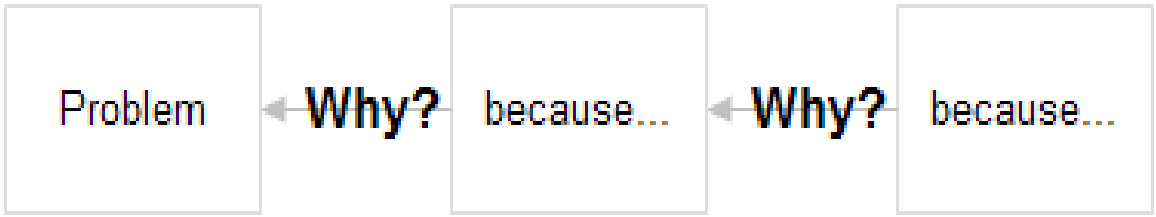
- **Identify Possibilities**
- **Select the most appropriate Solution**
- **Implement specific Corrective Action**
- **Verify/Validate Effectiveness**
- **Document with Objective Evidence**

Cause Mapping - How to read a Cause Map

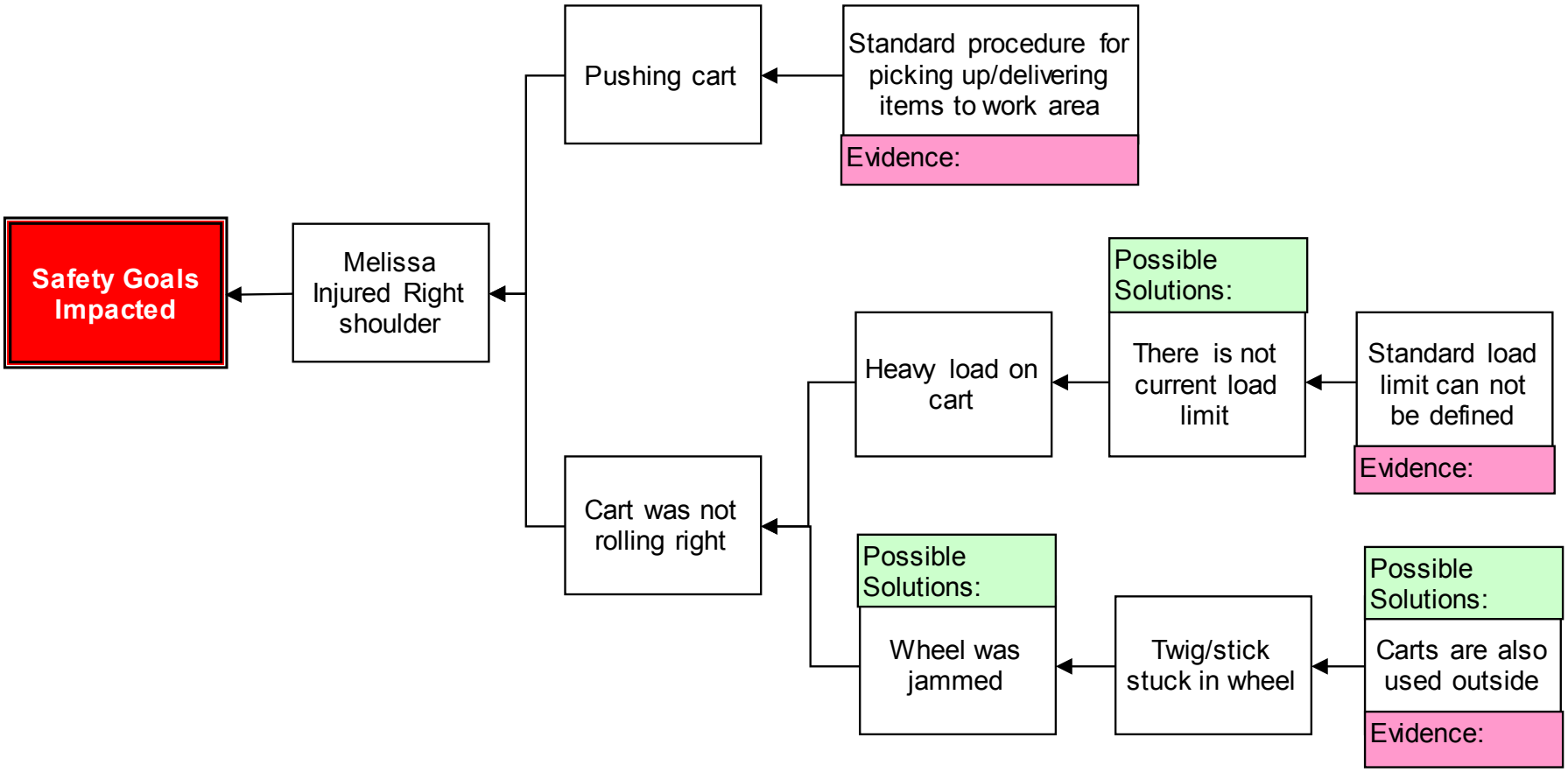
State the Problem

Ask Why Questions - "Why did this effect happen?"

Record Response = Cause (or causes)



Cause Map Example

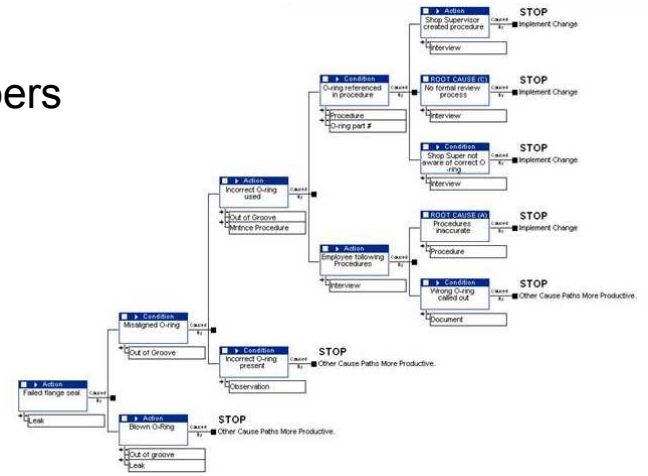


Cause Mapping

- **When to Use It:**
  - Use to develop an effective solutions to prevent recurrence of undesired effects
  - Use when you want to fully understand causes of success
  - Use to reveal the entire system of causes
  - Use it when you need to dive deeper into a problem

- **Advantages:**
  - Reveals the entire system of causes and effects
  - Focuses on cause-effect relationships
  - Emphasizes effective solutions to prevent recurrence
  - Mitigates the hazards of using categories or checklists alone to drive analysis
  - Focuses attention on events and conditions rather than people

- **Limitations:**
  - Does not prioritize causes or solutions
  - Has a learning curve for facilitators and team members
  - Lengthier process than other tools
  - Does not lend itself to proactive problem solving



Failure Mode & Effects Analysis (FMEA)

What is FMEA?

A systematic method for identifying, analyzing, prioritizing, and documenting potential failure modes and their effects on a system, product, or process and the possible causes of failure.

Where Is FMEA Used?

Used extensively in safety oriented and aerospace businesses.

Why FMEA?

- Reduce development cost by early risk identification
- Documented evaluation of risk
- Minimize product failures
- Track process improvements
- Develop efficient test plans

Failure Modes and Effects Analysis (FMEA)

- **When to Use FMEA:**
  - Identify and eliminate known or potential failures or errors from a product or a process
    - Engineering – mitigate risk in product design
    - Manufacturing – reduce and eliminate product defects
    - Transactional – reduce and eliminate process errors
  - Use when identification of the root cause may be complex

- **Advantages**
  - Provides quantitative rankings with defined scale for prioritizing based on severity, occurrence, and detection of current controls
  - Analyzes potential causes
  - Can be used proactively (risk management)
  - Can be used to assess current mitigation plans
  - Provides a structure for developing and prioritizing solutions

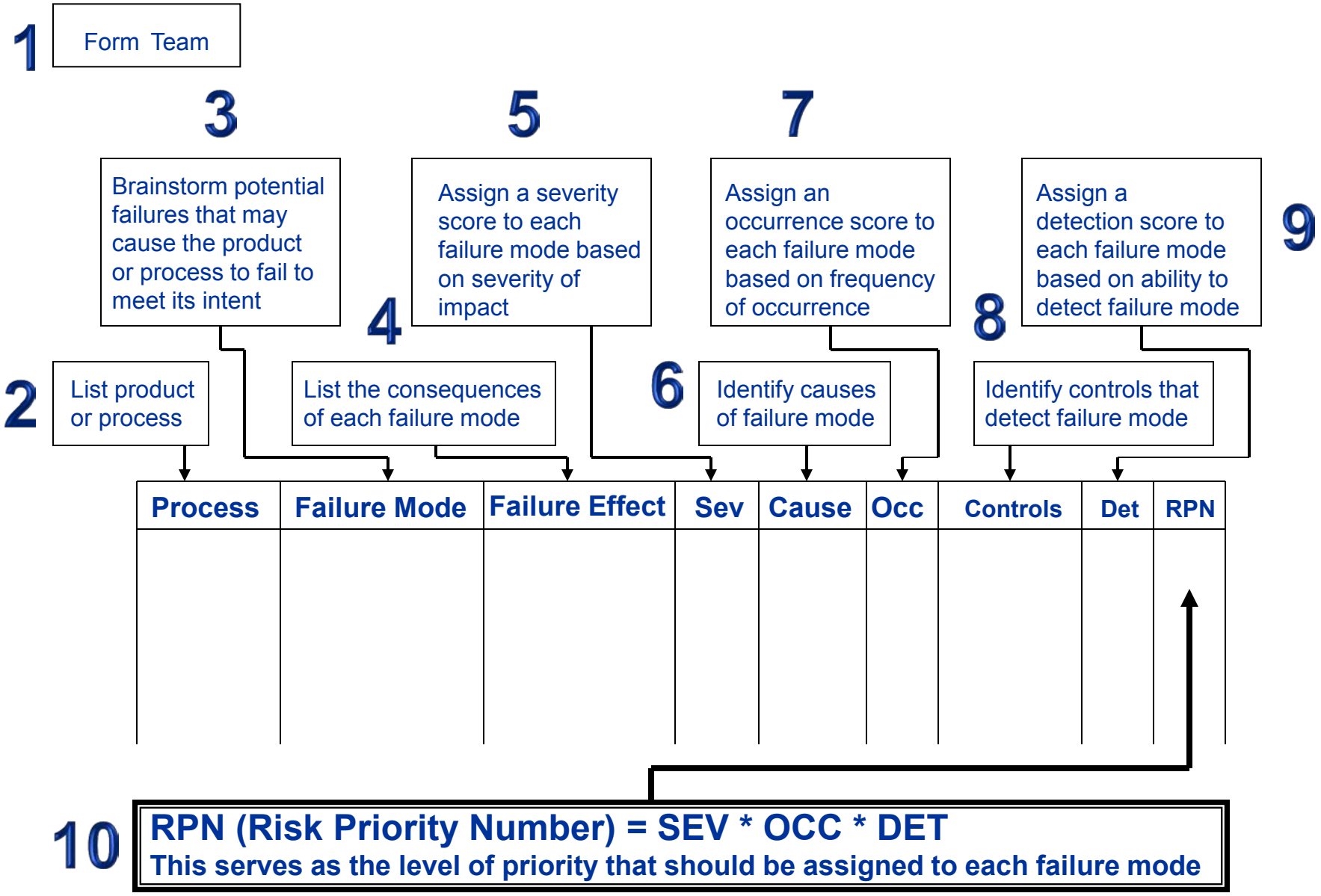
- **Limitations**
  - Does not delineate causal relationships
  - Does not require supporting causes with evidence
  - Addresses specific failure modes individually without taking a systems view

Failure Mode & Effects Analysis (FMEA)

Types of FMEAs

- **Process:** Used to analyze processes and identify potential failure modes
- **Design/Product**: Used to analyze products and identify potential failure modes early in the development cycle
- **Defect:** Used to analyze and prioritize defects to prevent recurrences in products and processes

Failure Mode & Effects Analysis (FMEA) Tool



Design of Experiments (DOE)

Why Use DOE?

- Can be used to help improve the capability of a process by identifying the process and product variables that effect the mean and the variance of the quality characteristics of a product.

- Can be used as a powerful tool to achieve manufacturing cost savings by minimizing process variation, reducing rework and reducing scrap

- Use DOE when more than one input factor is suspected of influencing an output.

Design of Experiments (DOE)

When Can I Use DOE?

- When you want to find the input settings that optimize the output of a process
- When you want a mathematical model relating the outputs and / or variance of a process to the inputs
- When you want to identify the most important input factors that influence the mean output or the variance of the output
- When you want to determine the cause of a product failure

Design of Experiments (DOE)

Where Can I Use DOE?

- Any process with measurable quantitative or qualitative inputs and quantitative outputs is a potential application for DOE
- In engineering design, to find component values and tolerances that optimize the response
- In production, to optimize the yield of a machine or assembly process
- In testing, to ensure the fullest coverage of possible inputs with a minimum number of tests

DOE Applications Are Limited Only By The Imagination

Summary

- Root Cause Analysis is not easy!
- Be diligent in the pursuit of Root Cause
- Address the Cause not the Symptom
- The RCA Tools presented today will help ensure:
  - Thorough Investigations
  - Identification of Root Cause
  - Effective Corrective Actions

Root Cause + Effective Corrective Action = Problem Elimination!

Summary

- **Root Cause Analysis** is the process of applying the cause and effect principle to solve problems. A root cause analysis program should be a systems approach to finding effective solutions to prevent problems from occurring or recurring.
- **RCA Tools** provide a means to conduct systematic analysis of a problem to identify cause and effect relationships and identify appropriate solutions to eliminate nonconformances
- **Corrective Action**: Action(s) taken to eliminate the cause of nonconformances in order to prevent recurrence
- **Root Cause Analysis** helps ensure:
  - Continuous improvement
  - Efficient use of resources
  - Focus on actions that are most impactful

Root Cause + Effective Corrective Action = Problem Elimination!

Root Cause Analysis References

- IAQG – Root Cause Analysis and Problem Solving (aligned with IAQG 9136 draft) www.iaqg.org/scmh
- The Memory Jogger 2 – Tools for Continuous Improvement and Effective Planning
- The Lean Six Sigma Pocket Tool Book
- Think Reliability www.thinkreliability.com