

# **Non-Conformance Management & Corrective and Preventive Action**

## **Part 2 – Effective CAPA Investigation Methods, Correction Action Development**

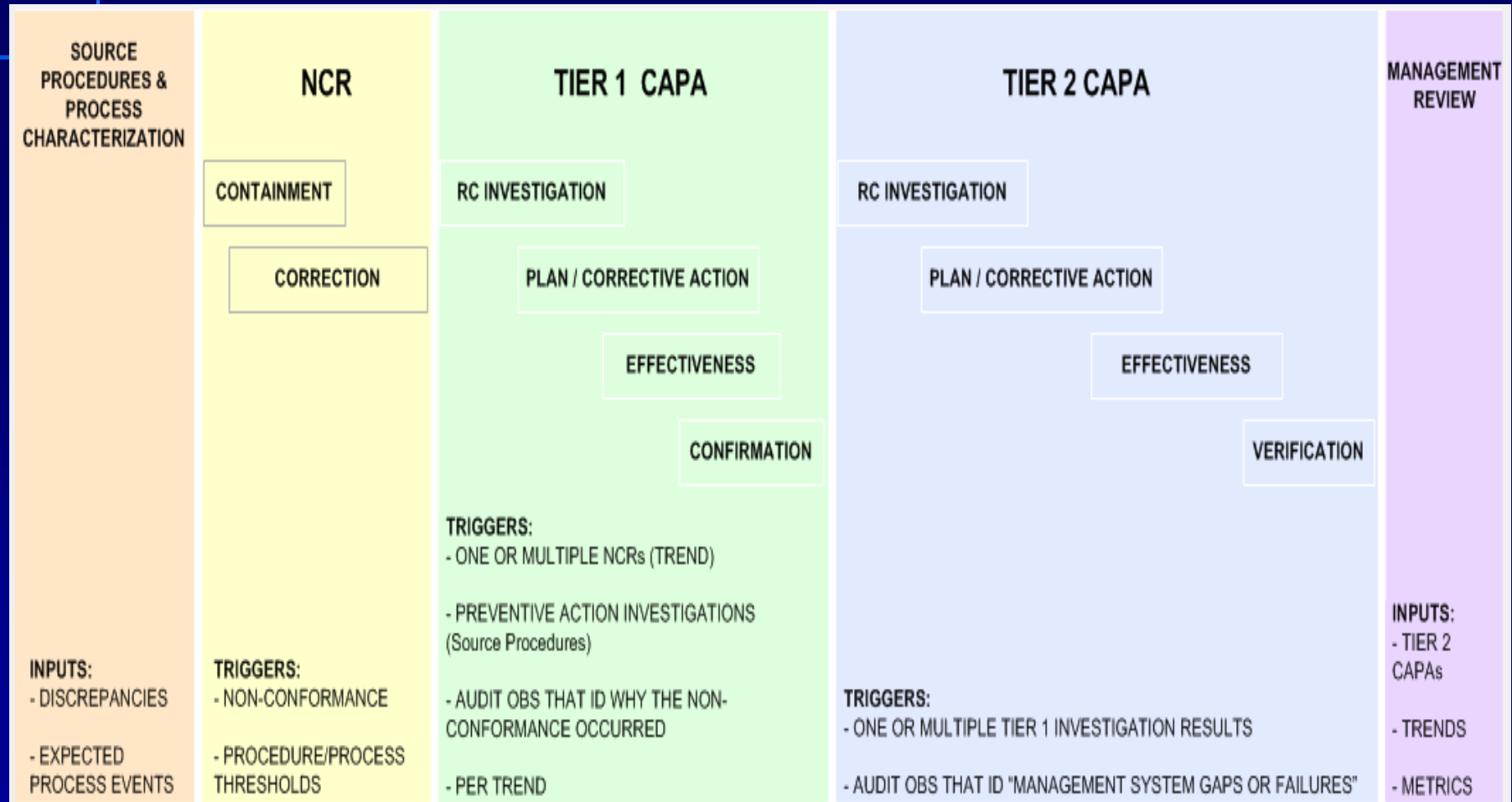
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# Recap

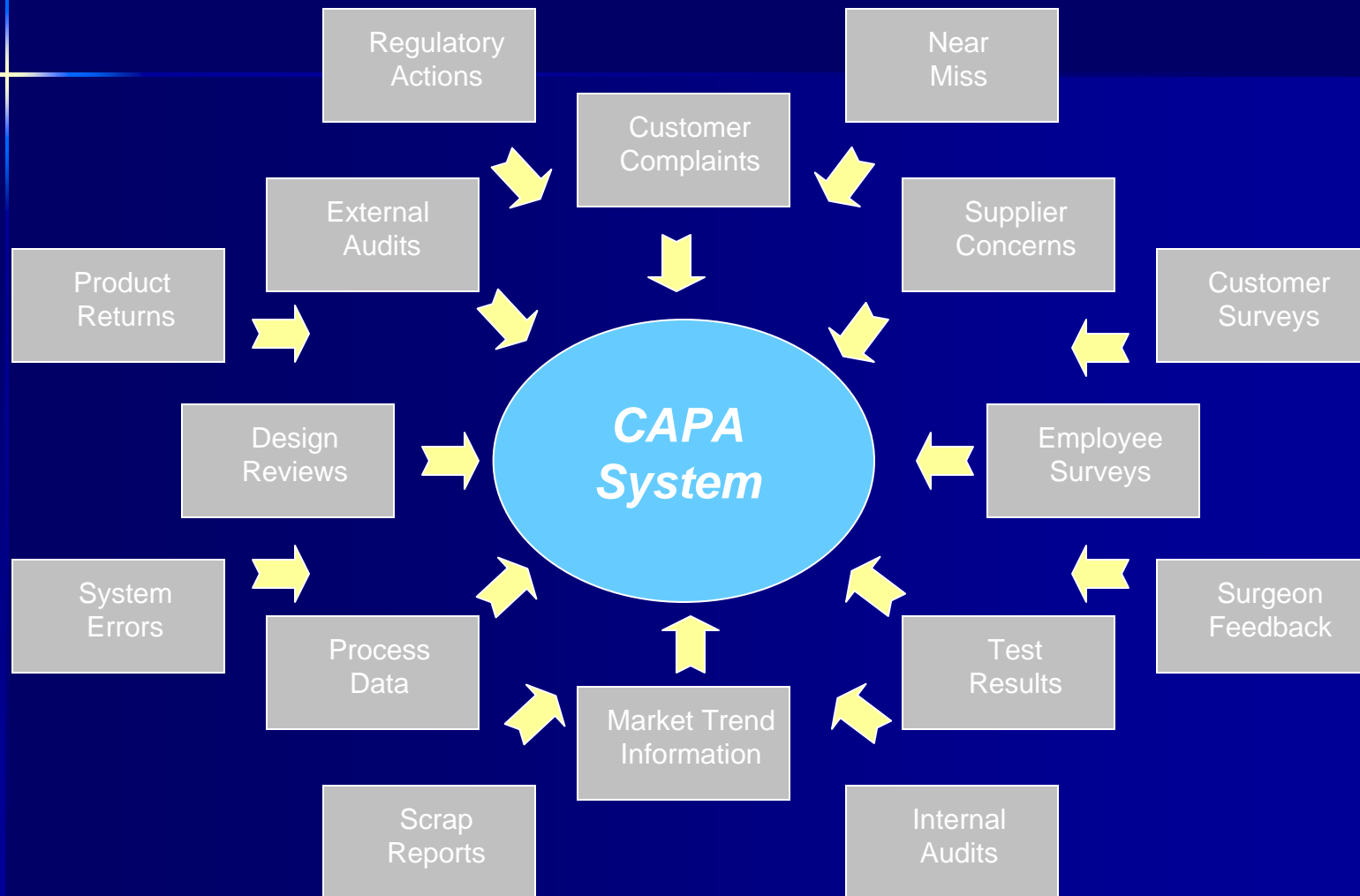
## **Non-Conformance Management & Corrective and Preventive Action**

### **Part 1 – Definitions, Detection, Management & CAPA Escalation**

# Elements of a CAPA System



# Feeds to NC Management



# Definitions

**Conforming** – An expected observation, event or characteristic. Fulfillment of a requirement.

**Non-conformance** – An unexpected observation or event. Non-fulfillment of a requirement.

**Discrepancy**– An expected observation not meeting a requirement.

i.e.: A Pre-identified (Expected) Non-conformance with frequency within process capability.

# Definitions

**Correction** – Action taken to eliminate a detected non-conformance. These actions may involve process or product changes, (e.g., rework or repair). Corrections are fixes that correct the act that caused the non-conformance to exist.

**Corrective Action (CA)** – Action taken to eliminate the causes of a non-conformance, defect, or other undesirable occurrence and prevent recurrence. The distinction between a Correction and Corrective Action is that the former relates to the elimination of an existing non-conformance, whereas a Corrective Action relates to the elimination of its cause.

# Definitions

**Preventive Action** – Action taken to eliminate the cause of a potential non-conformity, defect or other undesirable condition in order to prevent its occurrence.

**Root Cause** – The factor associated with or relating to the reason for the observed symptom's existence.

**Source Procedure** – Any document that identifies a standard, requirement or expectation. Source procedures clearly identify the methods used to gather data on non-conformances and potential non-conformances and the threshold for initiation of a preventive action.

# Definitions

**Effectivity/Effectiveness** – The measure of the ability of the implemented Corrective or Preventive Actions to objectively demonstrate successful elimination of the identified Root Cause(s). Effectiveness checks shall also be defined to establish that the original issue identified was eliminated or reduced to acceptable levels.

Detection by the customer (e.g. use of complaint searches) shall not be the sole Effectiveness check. Effectiveness shall be detected at the earliest part of the process prior to arrival in the hands of the customer.

# Expectations

Many Management System Regulations and Standards have similar requirements

For Example:

FDA 21 CFR Part 820

ISO 9001

ISO 13485

Expectations are similar among them

# Data Reporting

- Data (Process/Product) is reported at intervals to support effective Preventive Actions to minimize product or process non-conformance
- Data (CAPA System Performance) is reported to demonstrate the state of Product and / or Process Performance at Management Review

# Non-Conformances Management

Non-Conformances and Suspect Non-Conformances are documented and processed in accordance with a procedure designed to Control and Correct Non-Conformances; inclusive of containing the non-conforming process or product.

# CAPA Identification

CAPAs are Non-conformances that are identified and prioritized through the use of Risk Assessment for investigation of Root Cause, Corrective or Preventive Action

## Risk Based Approach

- **Ensures Effective Use Of Resources**
- **Results In Focus On Investigations Benefiting Customers and Your Business**
- **Avoid Unnecessary Investigation Costs**

## **Part 2**

**Effective CAPA Investigation  
Formal Methods**

**Correction Action Development  
and Bottom Line Improvement**

**Bottom Line Improvement and  
Sustainability**

# CAPA Investigations

Corrective Action

= Cost / Loss Elimination

Preventive Action

= Cost / Loss Avoidance

# Benefits of Using Formal Investigation Methods

*“In God we trust; all others must bring data.”*

W. Edwards Deming

1986

# Benefits of Using Formal Investigation Methods

- Discovery of what is really happening
- Prevents exclusion of data that does not fit our mental model (paradigm)
- Prevents erroneous inclusion of data that is part of our model but not part of the data set

# Benefits of Using Formal Investigation Methods

- Higher Probability of Positive Identification of the Actual Root Cause
- Eliminates Unlikely Root Cause Candidates
- Does Away With Use of Conjecture, Hearsay, Circumstance

# Benefits of Using Formal Investigation Methods

Use of formal method includes examination of historical data

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*"The farther backward we look, the farther forward we are likely to see."*

**Sir Winston Churchill**

# Root Cause Generation

## Tools

- Brainstorming
- Fishbone Analysis
- Cause and Effect Diagrams
- Logic Tree Analysis (Why/Why)

# Root Cause Generation

*Facts and Data* are essential to understanding an event (opinions may be useful later in formulating solutions)

# Root Cause Generation

- Observations often are not facts, but lead us to them
- Much of what is heard is a mixture of fact and opinion
- Use of Formal Methods permits identification of *facts* out of opinions and observations

# Process Data and Records - *Facts*

- ✓ *Process Logs*
- ✓ *Test results*
- ✓ *Inspection data*
- ✓ *Scrap reports*
- ✓ *Design records*
- ✓ *Mfg. records*
- ✓ *Customer Service logs*
- ✓ *Financial records*
- ✓ *HR records*
- ✓ *Help Desk data*
- ✓ *Surveys*
- ✓ *Complaints*

# Defining the Issue

## What was observed?

**Be specific about what happened**  
Include information which would help describe the problem

# Defining the Issue

**Where did the observation take place?**

**Be specific about where the problem occurred; department, customer, plant floor location...**

# Defining the Issue

**When did the observation take place?**

**Be specific about date, time, shift, relationship to other events, i.e.: after PM, before break, start up,...**

# Defining the Issue

**Who made the observation?**

**Be specific about name function, role of the person(s), internal, external, employee, customer, supplier, auditor, investigator...**



# Root Cause Identification

*Without knowing the root cause, you may not be able to identify a solution which successfully solves the problem*

- Determine and Verify the real reason(s) the problem occurred – the “root cause.”

**How Are Root Causes  
Identify And Determined?**

# Investigation

## Data, Data, Data,...

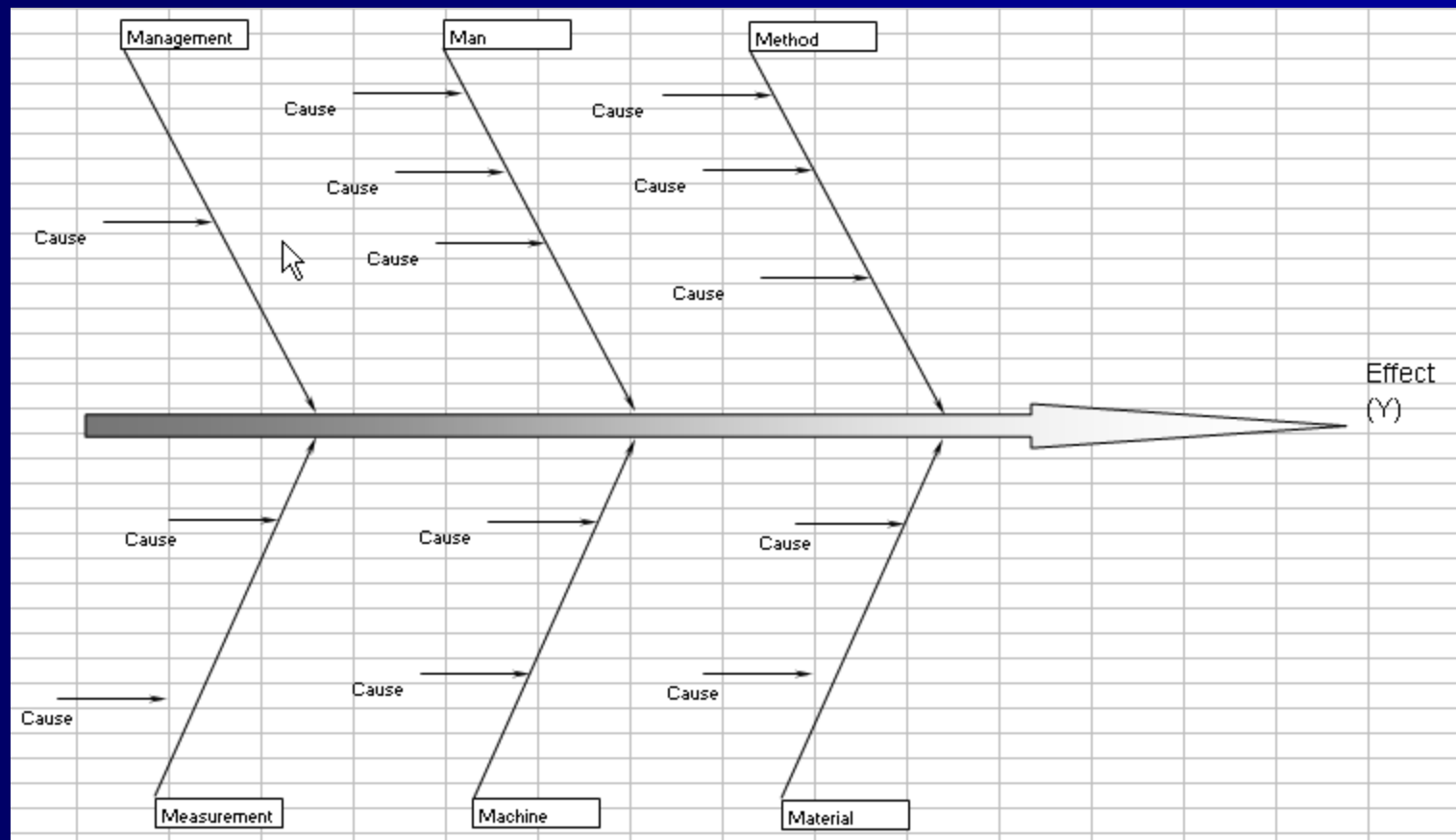
- Design History
- Manufacturing Records
- Inspection / Test Reports
- Related Topic Data – Industry Research
- Product Samples
- Returned Product
- Experimentation

# Determining Causes

## Commonly Used Tools

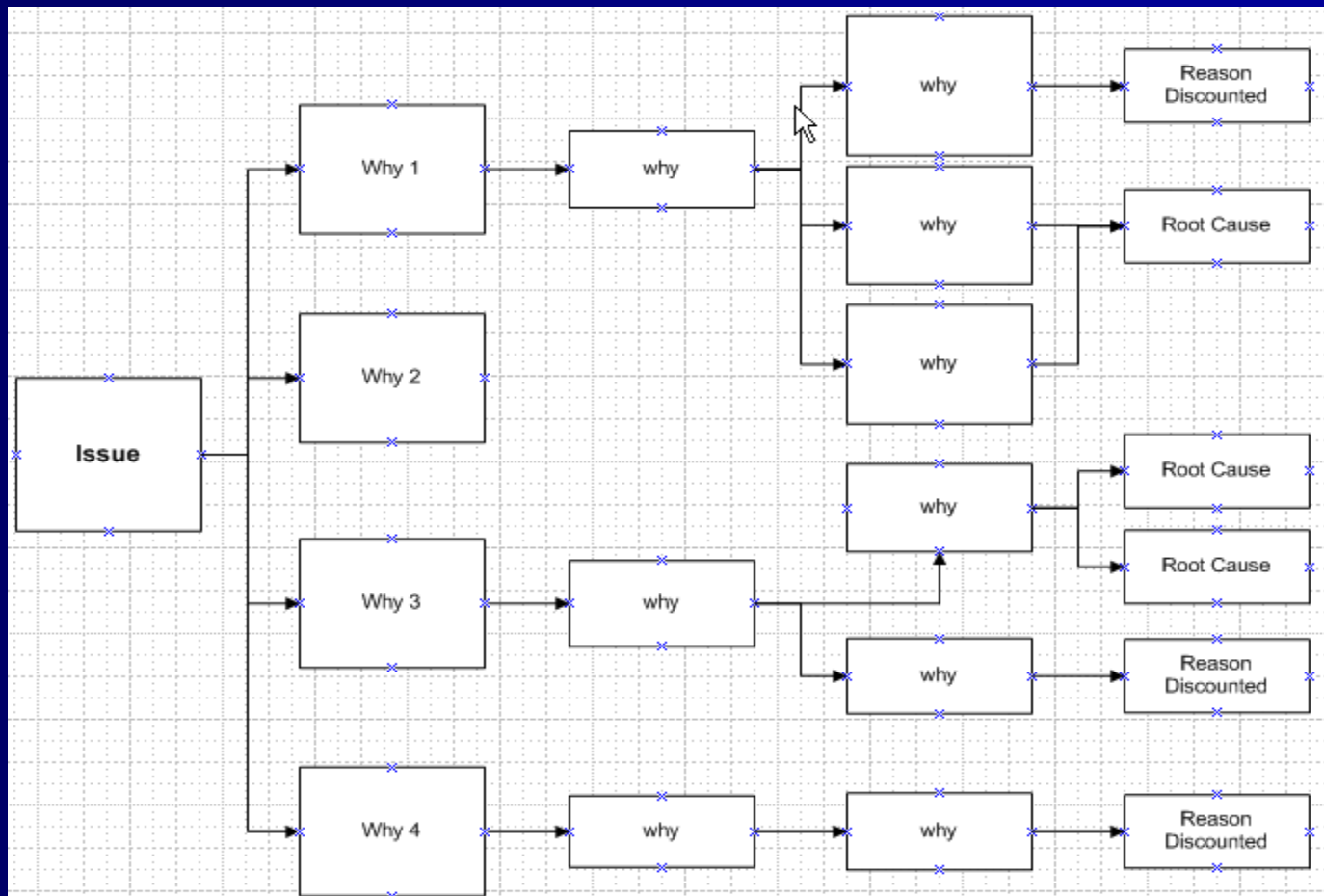
# Determining Causes

## Fishbone Diagram



# Determining Causes

## 5 Whys



The key is to ask "why?" for each cause until there are no new answers.

# Determining Causes

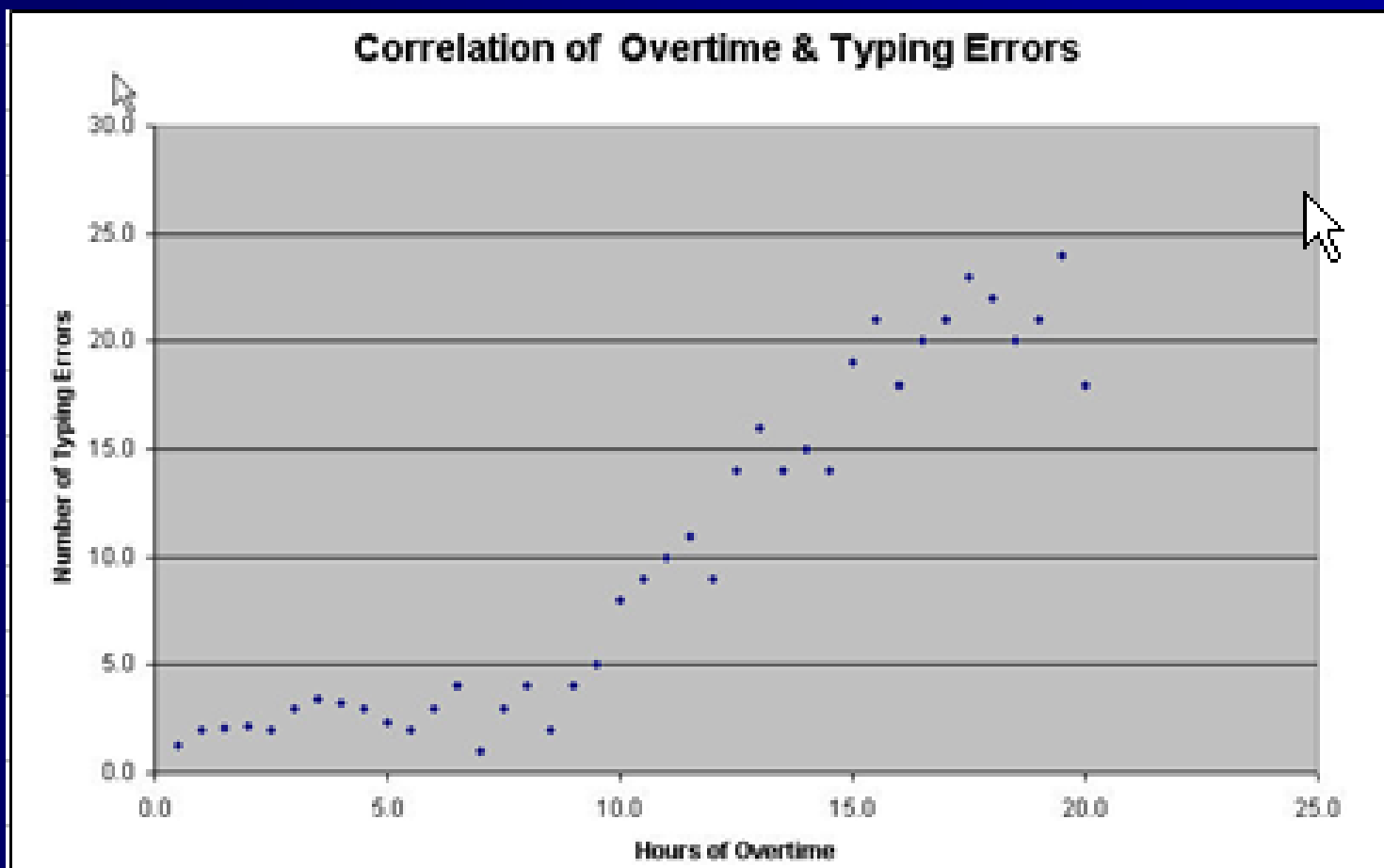
## Traceability Matrix

<b>Problem Statement:</b>	Lack of an effective system to manage ECA incidents resulting in untimely and incomplete investigations.			
<b>Root Cause Category:</b> (based on Fishbone)	<b>Actual/Potential Root Cause(s)</b>	<b>Analysis:</b> (Rule out or acceptance based on data, trends, evaluation of controls (barrier analysis), actions taken )	<b>Containment/ Corrective/ Preventive Actions Needed?</b>	<b>CAPA Plan Reference #</b> (Number actions included in CAPA plan and correlate to root causes )
Method	TI-ENVC-01, ENVC01-01, ENVC01-02			
	Roles & Responsibilities are unclear			
	Form ENVC01-01 flow not in accordance with process			
	Time required for documentation not defined in procedure			
	Lack of defined monitoring & trending requirements			
	Form lacks space to document date			
	Form missing information (i.e. product being manufactured, reference to MAXIMO WO when corrections are made)			
	Differential Pressure not considered in reporting			
	Duration of event not considered in procedure (i.e. power dip vs power outage)			



# Determining Causes

## Scatter Diagram



# Determining Causes

## Impact Analysis

Problem Title:

Date:

Revision Level:

Team Leader:

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*DESCRIBE PROPOSED SOLUTIONS*

Description of Proposed Solutions				
Solution #1		Solution #2		Solution #3

# Determining Causes

## Impact Analysis (Continued)

### ANALYZE SOLUTIONS

Category	Weight (1-10)	Solution #1		Weight (1-10)	Solution #2		Weight (1-10)	Solution #3	
		Rating (1,3,5)	Wt. x Rating		Rating (1,3,5)	Wt. x Rating		Rating (1,3,5)	Wt. x Rating
Capable			0			0			0
Reliable			0			0			0
Simple			0			0			0
Low Cost			0			0			0
<b>Total</b>			-			-			-

Rating: High = 5 pts, Medium = 3 pts, Low = 1 pt

# Checking Your Work

## ASK:

- Are all possible causes identified?
  - If not, Seek Outside Opinions
- Are all causes well-defined and specific?
  - If not, Reword or Add Further Definition
- Are all causes categorized?
  - If not, Define Additional Categories

# Checking Your Work

## ASK:

- Are solutions listed rather than possible causes ?
  - If not, Write Possible Solutions Down and Save Them For Later.
- Do the causes relate to the problem?
  - If not, Eliminate Irrelevant Material.

# Select Most Likely Cause(s)

Often there will be data already available that can eliminate some causes from further evaluation.

# Select Most Likely Cause(s)

There is no "correct" number to pick; the goal is to rule out any causes that are very "unlikely" based on available *data*

The remaining causes are *potential causes* that cannot be eliminated; these should be evaluated

# Evaluate the Possible Causes

For each cause selected, drill down to make sure the Level I (*Specific*) and Level II (*Systemic*) root causes have been reached

# Root Cause Verification

You have discovered a Root Cause when you identify a *cause (or causes)* that could be changed, eliminated, or controlled in such a way that the *problem will not occur again*

# Root Cause Verification

**There must be adequate data available to confirm or eliminate the possible root cause**

- If not, additional data must be collected

# Selecting Actions

## Initial Actions

- “Band-Aid” solutions, not sustainable or practical over time
- May be necessary if the permanent action will take too long to identify or implement
- Can be part of Containment

# Selecting Actions

## **Permanent Corrective Actions**

- Resolve the *specific* problem permanently by eliminating the Cause(s) of the problem

## **Systemic Corrective Actions**

- Resolve this systemic problem permanently by eliminating the Root Cause(s) of the problem to prevent recurrence of this type of problem

# Final Check

*Verification before Implementation!*

Verify selected solutions before implementing them to make sure they eliminate the problem

The best proof is when the symptom can be made to reappear when the solution is removed

# Questions

*Thank You*

