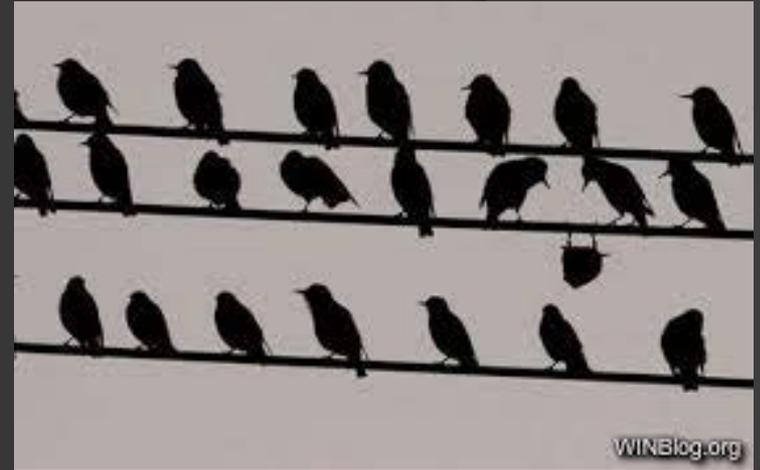


**PREVENTIVE ACTION /  
CORRECTIVE ACTION /  
ROOT CAUSE ANALYSIS**

# Nonconformance



- Non fulfillment of a specified requirement

This could be a Standard Requirement or an SOP

# Preventive Action



- Action to eliminate the cause of a potential nonconformity or a needed improvement.
- It is a proactive process to identify opportunities for improvement rather than a simple reaction to identified problems or complaints.
- Something new added to a Management System or a change implemented to address a weakness.

# Correction

- ⦿ Action to eliminate a detected nonconformity;
- ⦿ The immediate action taken to correct a problem, usually to allow data to be reported to a customer
- ⦿ Examples include
  - Making an adjustment
  - Fixing a mistake
  - Repeating analysis



# Corrective Action

- ① Action to eliminate the cause of a detected nonconformity;
- ② Must establish a root cause
- ③ Must address the root cause

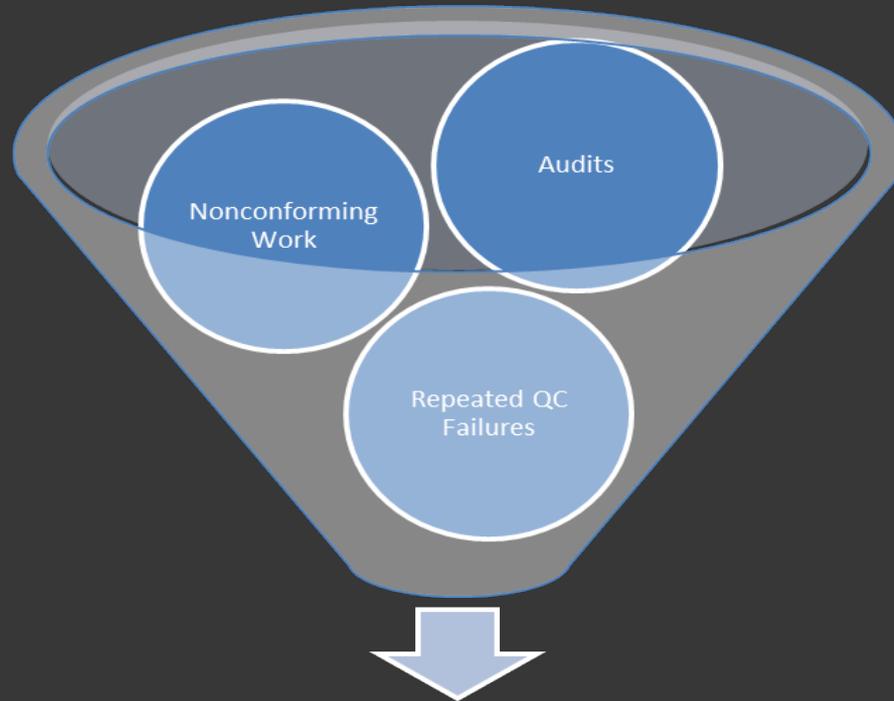
# Preventive vs. Corrective Action

- ⦿ **Preventive Action:** taken to prevent occurrence
- ⦿ **Corrective Action:** Action taken to prevent recurrence

# Correction vs. Corrective Action

- ⦿ **Correction:** Action taken to eliminate the nonconformity
- ⦿ **Corrective Action:** Action taken to eliminate the cause of the nonconformity

# Corrective Action Funnel

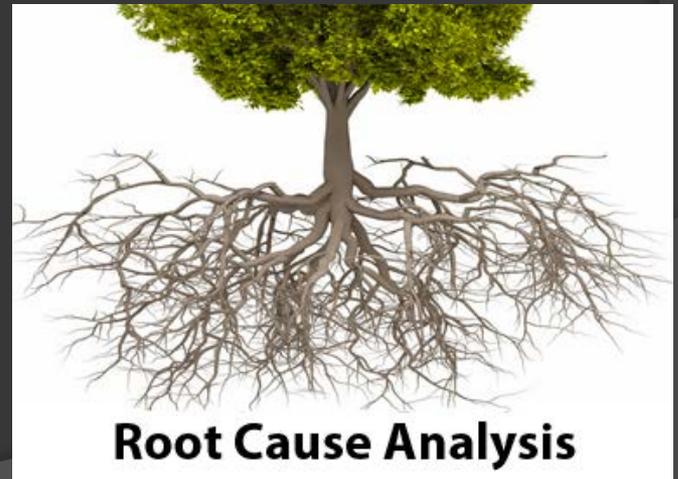


Corrective Action

Changes to the  
Management System

# Root Cause Analysis

- A problem-solving process or the process of asking the “why” question relative to the identified problem to determine the bottom-line causal factor(s) and to use that analysis to improve the process



**Root Cause Analysis**

# Root Cause Analysis

## ⦿ Asks questions

- **What** is the problem? (this is the issue that we want to stop from happening again)
- **When** did it happen? (when did the primary effect occur)
- **Where** did it happen? (the location of the primary effect)

# Root Cause Analysis

- To get to the root cause, we must look at the systems and how they can be changed to make the process easier on everyone.
- We won't ask the question “**Who?**”
- This is not the place for blame.
- What looks like a people problem is often a system problem.

# Root Cause Analysis

- Root Cause Analysis encourages brainstorming by ALL who are involved
- There is no judgement and no wrong answers
- We are encouraged to find multiple root causes, and pick the most appropriate
- We are encouraged to find multiple corrective actions and pick the most appropriate

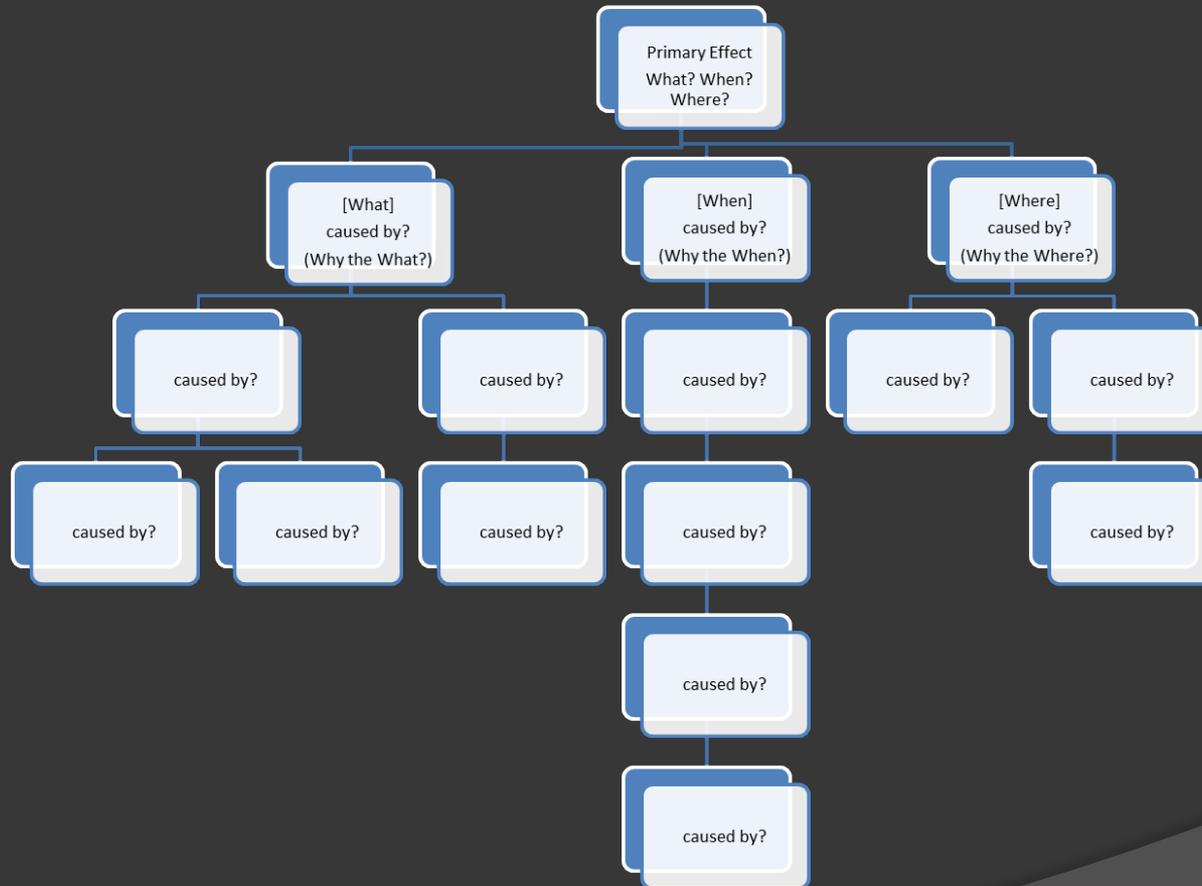
# 2005 Stale Popcorn Study

Moviegoers were served stale popcorn in  
Large and Medium Size Buckets



Moviegoers who were served popcorn in the  
Large Buckets ate 34% more than those who  
were served in the Medium Buckets

# Root Cause Analysis



# Example of asking the question “Why?” for Root Cause Analysis

## ⦿ Problem or Primary Effect: Flat Tire



- Why? Nails on garage floor
- Why? Box of nails on shelf split open
- Why? Box got wet
- Why? Rain thru hole in garage roof
- Why? Roof shingles are missing

# Unacceptable Root Causes

- ⦿ Human Error
- ⦿ Mistake
- ⦿ Distraction

# Unacceptable Corrective Actions

- Reminded employees
- Retraining
- Instructed to pay more attention

# Challenges

- ⦿ Staff might think it is overkill. “Why take so much time to discuss something that is obviously a simple mistake.”
- ⦿ Too much work
- ⦿ “I don’t have the time”
- ⦿ “It’s obvious that someone just doesn’t know how to follow directions.”
- ⦿ We want to skip to the solution when we really haven’t defined the problem.

# Goals

- Take an active approach. Having employees simply read and sign a procedure is often not enough.
- Improve procedures and worksheets to make the system more effective
- Communicate the new process through training
- Evaluate the new process through Internal Audits

# Corrective Action Request Form (CAR)

Corrective Action Request (CAR) Form		
Step 1	Initiated By:	Date:                      Number:
Step 2	Source:	
	Complaint <input type="checkbox"/> Audit <input type="checkbox"/> QC Failure <input type="checkbox"/> PT Failure <input type="checkbox"/> Nonconformity <input type="checkbox"/>	
	If Complaint, Identify Person:	
Step 3	Description of the Issue:	
Step 4	Decision Matrix	
	1. Has a requirement not been met?	<input type="checkbox"/> Yes – Continue with CAR <input type="checkbox"/> No – Consider a PAR
	2. Has a customer questioned a result? Do repeated test results confirm original?	<input type="checkbox"/> Yes – Re-analyze the Sample <i>if possible</i> <input type="checkbox"/> Yes – Consider a PAR <input type="checkbox"/> No – Continue with CAR
	QAO Approval:	Date:
Step 5	Statement of the Requirement:	
	Statement of the Evidence:	
	Redefine Problem as Needed:	
	QAO Approval:	Date: CAR Due Date:
Step 6	Correction (Immediate Fix):	
	QAO Approval:	Date:
Step 7	Root Cause Analysis Results:	
	QAO Approval:	Date:
Step 8	ID Potential Corrective Actions	
	QAO Approval:	Date:
Step 9	Select Best Corrective Action	
	QAO Approval:	Date:
Step 10	Change/Update SOP or Method	
	QAO Approval:	Date:
Step 11	Implement Corrective Action	
	QAO Approval:	Date:
Step 12	Monitor Corrective Action	
	QAO Approval:	Date:
Step 13	Close out Corrective Action	
	QAO Approval:	Date:

# Preventive Action Request Form (PAR)

Preventive Action Request (PAR) Form		
Step 1	Initiated By:	Date:                      Number:
Step 2	Source:	
	Customer Feedback <input type="checkbox"/>	Management Review <input type="checkbox"/>
	Staff or Other <input type="checkbox"/>	
	If Feedback, Identify Customer:	
Step 3	Opportunity for Improvement	
Step 4	Decision Matrix	
	Is Proposed Preventive Action Appropriate?	<input type="checkbox"/> Yes – Continue with PAR
		<input type="checkbox"/> No – Discontinue the Process
	QA Group Manager Approval:	Date:
Step 5	Root Cause Analysis Results:	
	QAO Approval:	Date:
Step 6	ID Potential Preventive Actions	
	QAO Approval:	Date:
Step 7	Implementation Plan:	
	QAO Approval:	Date:
Step 8	Implement Preventive Action	
	QAO Approval:	Date:
Step 9	Monitor Preventive Action	
	QAO Approval:	Date:
Step 10	Develop/Change/Update SOP, Method, Requirements, etc.	
	QAO Approval:	Date:
Step 11	Close out Preventive Action	
	QAO Approval:	Date:

# Final Statements

- Quality Assurance Officers work with the teams to provide guidance and establish due dates.
- All CAR's and PAR's are signed by management and QA.



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