

PREVENTIVE ACTION, CORRECTIVE ACTION AND ROOT CAUSE ANALYSIS

QUALITY IMPROVEMENT FORUM CALL
AUGUST 20, 2015
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Nonconformance



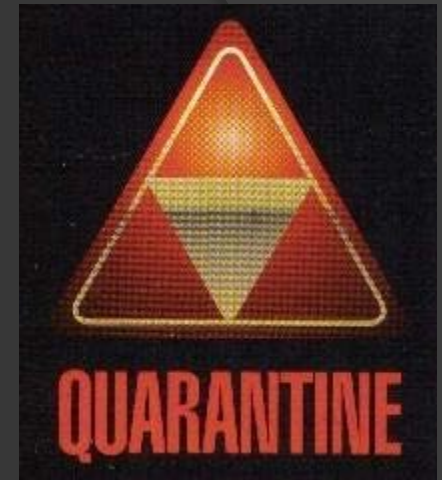
- Nonfulfillment of a specified requirement
This could be a Standard Requirement or a SOP

Preventive Action

- ① Action to eliminate the cause of a potential nonconformity or a needed improvement.
- ① It is a proactive process to identify opportunities for improvement rather than a simple reaction to identified problems or complaints.
- ① 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

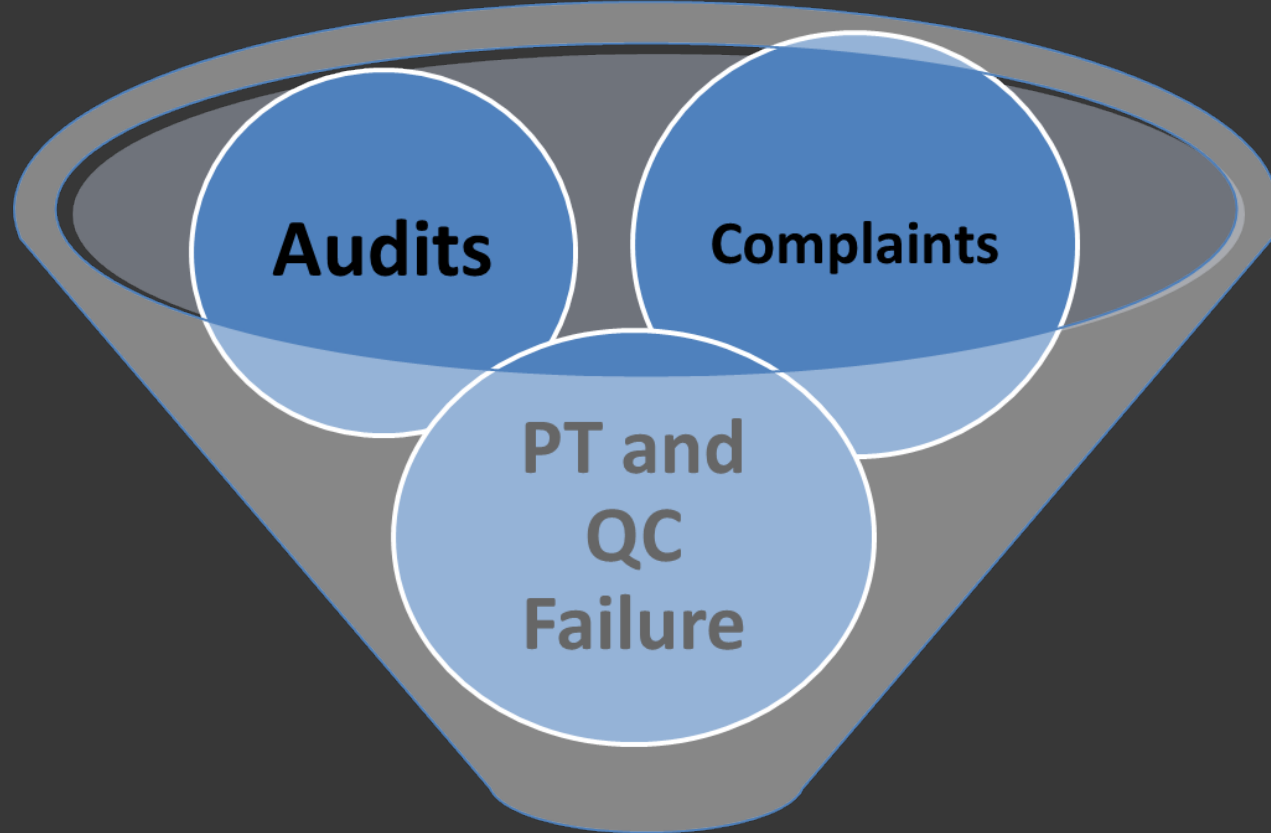
- ⦿ **Preventive Action:** Action taken to prevent occurrence
- ⦿ **Corrective Action:** Action taken to prevent recurrence

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



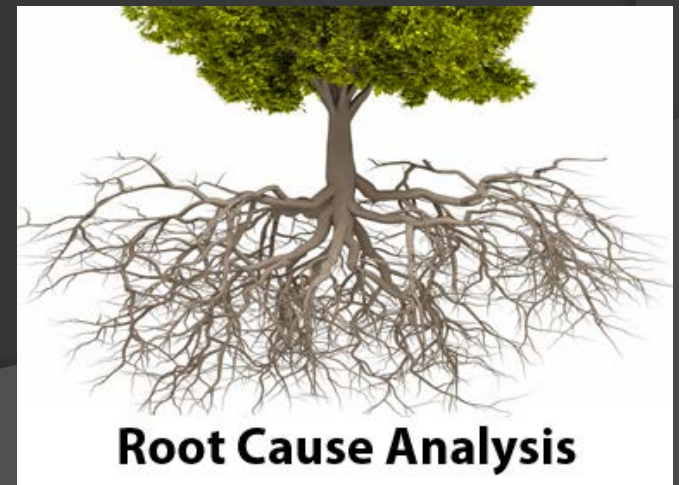
Corrective Action



**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

Asks Questions

- ① **What** is the problem? (this is the issue that we want to stop from happening again)
- ② **When** did it happen? (when did the primary effect occur)
- ③ **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 judgment 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.

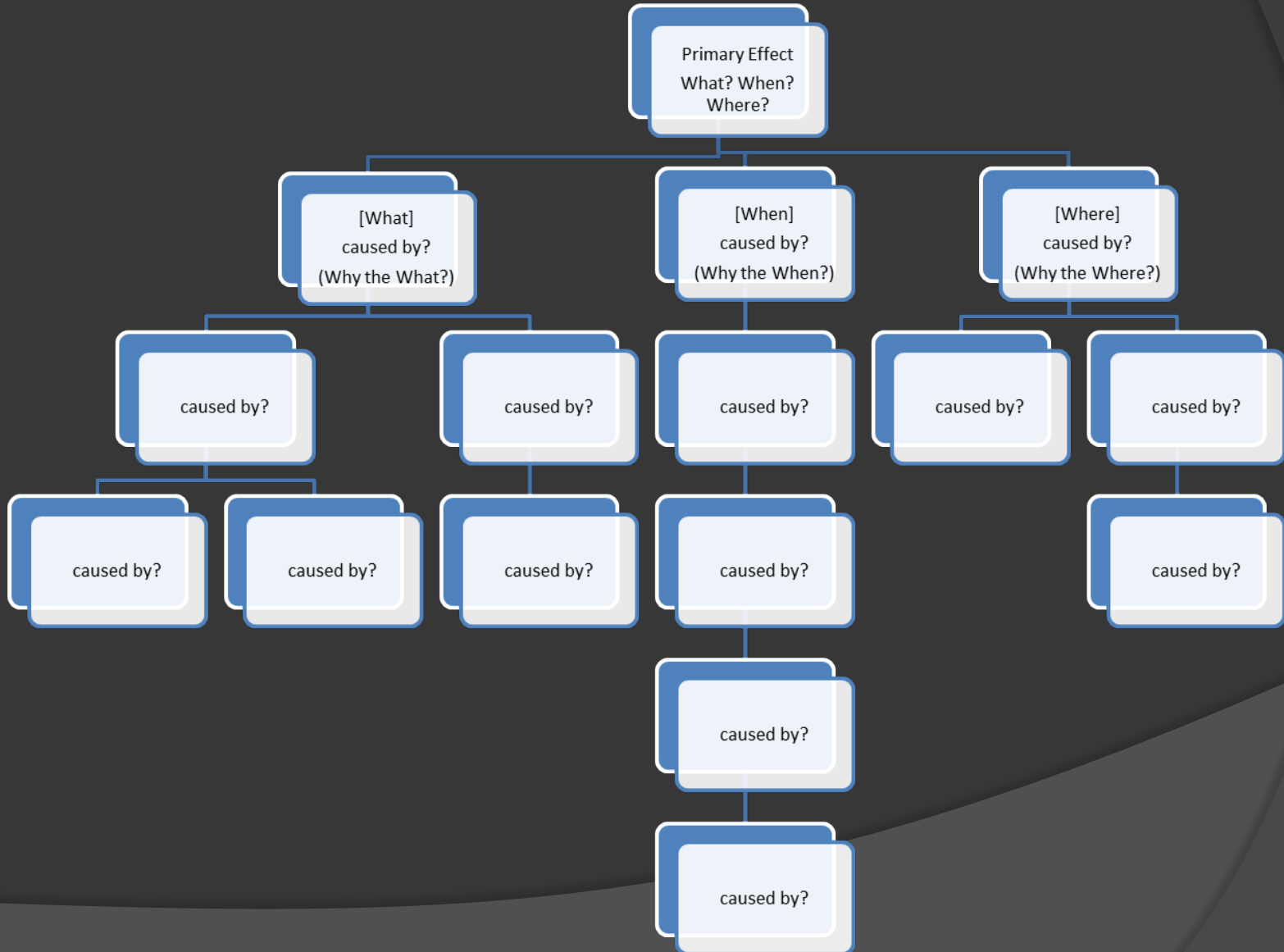
2005 Stale Popcorn Study

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

Some Challenges

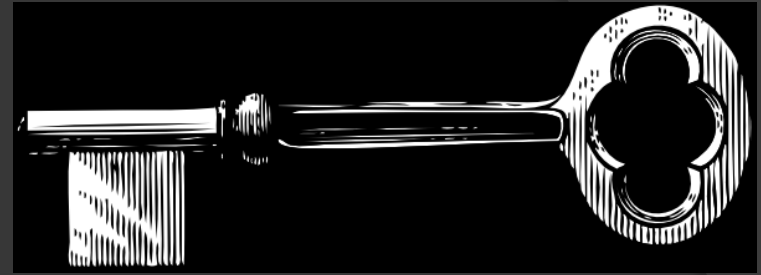
- ⦿ Staff might think too much work is involved.
- ⦿ Skipping to the solution when the problem hasn't been clearly defined.
- ⦿ Staff responses:
 - “If they would just pay attention, we wouldn't have this problem.”
 - “That's QA's Job!”

Biggest Challenge



Taking the WHO out of it

Keys to Success



- 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
- Repetition is the key to learning
- Implement the new process through quizzes
- Evaluate the new process through Internal Audits

13 Step Corrective Action Process

1. Identification of initiator and date
2. Source: Nonconformity, Audit, PT Failure, QC Failure, Complaint
3. Description of the issue
4. Has a requirement not been met?
5. Statement of the requirement
6. Statement of the evidence

13 Step Corrective Action Process

7. Correction
8. Root Cause Analysis Results
9. Potential Corrective Actions
10. Best Corrective Action
11. Update documents
12. Implement Corrective Action
13. Monitor Corrective Action – typical monitoring phase at least 30 days

Corrective Action Case Study

Step 1: Initiator/Date **Anyone in the lab can initiate a CAR**

Step 2: Source **Nonconformity**

Step 3: Description of the Issue

When working on inventory in the lab, Reagent XYZ, which is used daily, was discovered to be expired as of 7/25/2015.

Corrective Action Case Study

Step 4: Has a requirement not been met? **Yes**

Step 5: Statement of the Requirement

Laboratory Policy for Expiration Dates-221, page 2 Section V/D/1. States:

“Testing materials with an expiration date established by the manufacturer must be discarded when they reach the expiration date... Manufacturer’s expiration dates cannot be extended.”

Corrective Action Case Study

Step 6: Statement of the Evidence

When working on inventory in the lab, Reagent XYZ, which is used daily, was discovered to be expired as of 7/25/2015.

Step 7: Correction

Reagent XYZ was removed discarded. Inventory was updated.

Corrective Action Case Study

Root Cause Analysis - brainstorming

What?

Where?

When?

Corrective Action Case Study

Root Cause Analysis - brainstorming

What?

Expired Reagent

Where?

Refrigerator

When?

During Inventory

Corrective Action Case Study

Root Cause Analysis - brainstorming

What?

Expired Reagent

Why?

Not checked prior to using for testing

Why?

No place to record the information –
assumption that the reagent was good for use

Corrective Action Case Study

Step 8: Root Cause Analysis Results

- ⦿ No place to record expiration dates on the worksheet.
- ⦿ Improper usage of inventory data for purchasing purposes.

Step 9: Potential Corrective Actions

- ⦿ Create a space on the worksheet to record expiration dates.
- ⦿ Improve inventory/purchasing process.

Corrective Action Case Study

Step 10: Best Corrective Action

Update the worksheet to include a place to record expiration date.

Step 11: Update Documents

Worksheet ABC-220 was updated and approved on 8/19/2015.

Corrective Action Case Study

Step 12: Implement Corrective Action

- All performing employees have electronically signed the new revision in the online document control system.
- Training has been completed.

Step 13: Monitor Corrective Action

9/18/2015 -Spot check of the area identified that the worksheet is being used with no issues and there was no evidence of expired reagents in the lab.

Final Statements

- ① Changing a process like this takes a culture shift and a new way of thinking.
- ① Quality Assurance Officers provide guidance and approvals in each step of the process.



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