CORRECTIVE ACTIONS AND ROOT CAUSE ANALYSIS

Corrective action:

Corrective action: Action taken to eliminate the causes of non-conformities or other undesirable situations, so as to prevent recurrence

As result of Non Conformity
NC: Non fulfillment of requirements

EXAMPLE

Differences between correction, corrective action and preventive action

Correction
Put fire out
(at the time)

Corrective Action
What caused fire
and how to prevent
recurrence
(after event)

Preventive Action
Stop fire from
happening
(before event)

INCIDENT SPECIFIC CORRECTION / CONTAINMENT ACTIONS

Correction / Containment

►These are actions taken related to the incident →“Incident Specific Actions”
►Correction / containment actions are **important**

►Should be taken immediately to protect the internal or external customer

-Start immediately after the report is issued

►Are generally of three types

1. “We corrected the certificate” or “We completed the form”
2. We corrected and reissued all applicable certificates
3. We added additional inspection to catch any further occurrence

CORRECTION / CONTAINMENT

Record what you did in the correction:

- Be specific and include data
- What was done about it, when, by whom

►Record the results of any actions

►Has containment been documented, implemented, and verified to be effective?

►Is relevant process data being collected during containment actions

►Have customers (internal and external) confirmed effectiveness of containment?

SYSTEMIC ROOT CAUSE ANALYSIS

A proper root cause analysis answers this question: “What in the **system** failed such that the problem occurred?”

►The focus is on the system, not the incident

►Root Cause Analysis requires effective problem solving

- Keep the method simple
- Don’t use lots of approaches
- Learn and use one or two →**recommendation 5 Why’s**

5 WHY'S

Step 1: Start with the Problem Statement
•Step 2: Ask Why #1, record possible answers
•Step 3: For each answer, ask Why #2.
•Step 4: Record possible answers
•Step 5: Repeat Steps 3 and 4 until Why #5 is reached
–This will almost always be a systemic root cause
!!! Sometimes your answers to a 5-Why question may give you multiple answers. It's okay to branch off in more than one direction as long as you follow each branch to the root cause. !!!

EXAMPLE

. **Why** were you late for work this morning?
–Answer: My car wouldn’t start.

•2. **Why** wouldn’t your car start?
–Answer: The starter wouldn’t turn the engine over.

•3. **Why** wouldn’t the starter turn the engine over?
–Answer: The battery was too weak to engage the starter. I had to get a friend to jump start my car.

•4. **Why** was the battery too weak to start the car?
–Answer: The alternator was not producing enough energy to keep the battery charged.

•5. **Why** was the alternator output low?
–Answer: The alternator drive belt was slipping.

EXAMPLE

1. **Why** were the audit days inadequate?
–Answer: The employee headcount in our database was incorrect.

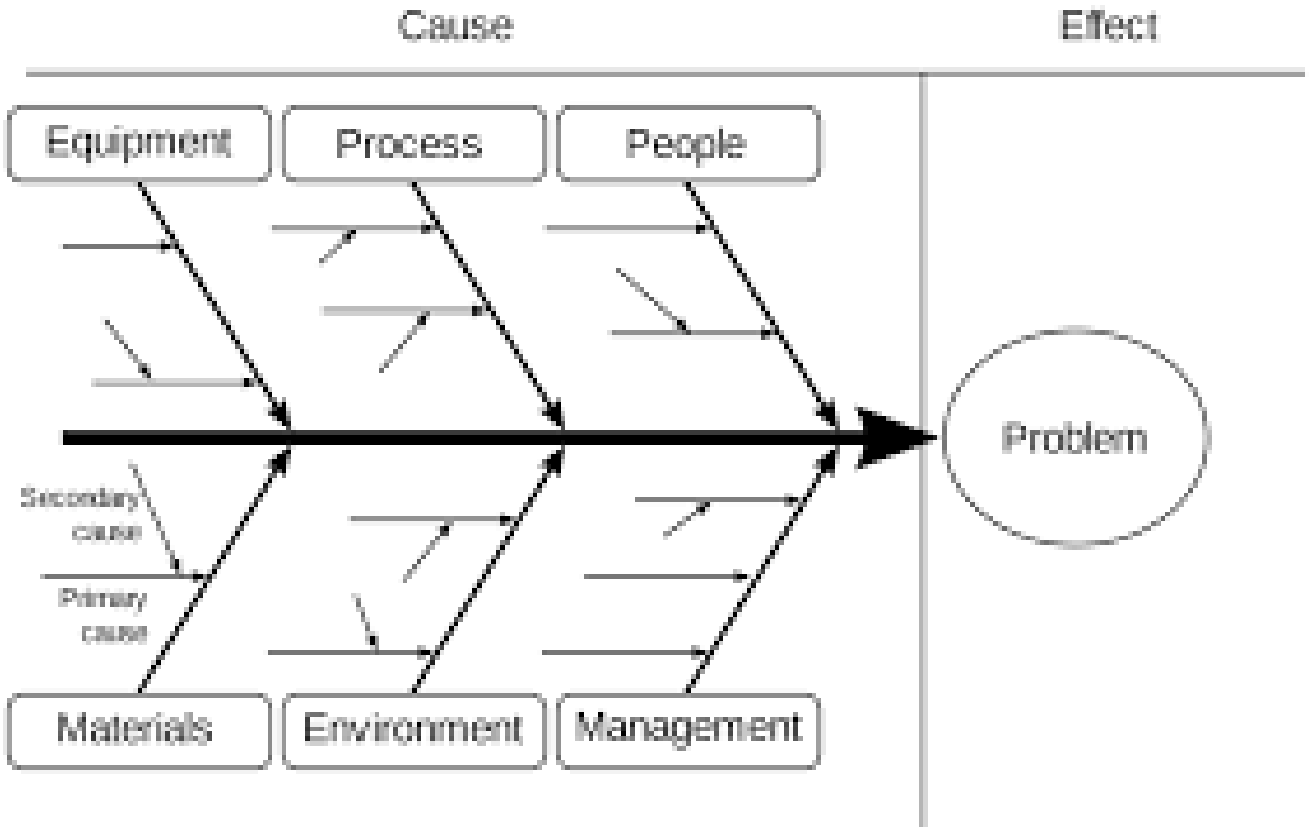
•2. **Why** was the employee headcount incorrect?
–Answer: The number was old and had not been updated.

•3. **Why** had the number not been updated?
–Answer: The auditor did not verify the number in the past.

•4. **Why** didn’t the auditor verify the number?
–Answer: The auditor was not aware of our process.

•5. **Why** wasn’t the auditor aware of the process?
–Answer: We did not include it as a requirement in the auditor work instruction.

FISH BONE ANALYSIS



ROOT CAUSE ANALYSIS-VARIOUS APPROACHES

Various Approaches for Root Cause Analysis:

- Nominal Group Technique (NGT)
- 5 Why’s
- Ishikawa Diagram (Fishbone Diagram)
- Multivoting

ROOT CAUSE ANALYSIS

Look for Root Causes in Two Areas:

●Technical

•What problems with the process caused the failure?

►Many Root Causes restate the incident or include Correction / Containment Actions→This is not acceptable

►Some problems may have multiple root causes →list each one

►A proper root cause analysis answers this question: “What in the system failed such that the problem occurred?” →The focus is on the system, not the incident. Blaming the employee / auditor will not be accepted as the only root cause.

►In addition to your process, don’t forget to investigate the strength of your documentation (i.e. work instruction, form, template, etc) to determine if it was part of the problem

►If the same incident repeat after you thought it was resolved →refer to the previous NCR for history

CORRECTIVE ACTION(S)

Addresses the Root Cause(s)

►Should, therefore, address the question, “What in the system failed such that the problem occurred?”

►Explains the changes to the system that have been tested and then implemented to prevent further recurrence

►Not only addresses the system, but actions should be “irreversible”

- Should involve a **change** in the **system**
- Training is generally nota system change
- Publishing a newsletter is generally nota system change
- Incident specific actions are not irreversible
- Should include an addition or revision to documentation

►Many NCRs give Correction / Containment Actions for the Corrective Action →not acceptable

►Some NCRs identify multiple root causes, but do not give corrective actions for all the root causes →not acceptable

CORRECTIVE ACTION(S)

There should be at least 1 corrective action for each root cause that was identified

►For each corrective action:

- Is the responsibility defined?
- Is it clear how the results will be validated?
- Have Procedures, Work Instructions, Training, etc. been updated?
- Have procedures not only been written, but actually implemented?
- Does the customer agree that the problem has been eliminated?

►For a corrective action to be implemented, the verb tense used should be the past tense. The work instruction wasrevised

►An action in the future tense is one that has not been implemented! The work instruction will be revised. For actions planned for the future, always include the timing

Move Forward with Confidence