



QMS Quick Learning Activity

Root Cause Analysis & Corrective and Preventive Actions ISO/IEC 17025 Clauses 4.11 and 4.12

What will be covered in this training?

- Root Cause Analysis
 - What it is
 - Who performs it
 - Sample methods for root cause analysis
- Corrective Action & Preventive Action
 - What is the difference between them
 - When each applies



Definitions

- **Continual Improvement:** recurring activity to increase the ability to fulfill requirements
- **Correction:** immediate action to eliminate a detected nonconformity
- **Corrective Action:** action to eliminate the cause of a detected nonconformity or other undesirable situation
- **Effectiveness:** extent to which planned activities are realized and planned results achieved
- **Nonconformance:** nonfulfillment of a requirement
- **Preventive Action:** action to eliminate the cause of a potential nonconformance or other undesirable potential situation



Root Cause Analysis

- Root Cause Analysis/Investigation
 - A type of problem solving method aimed at identifying the root cause(s) of a problem (nonconformance)
 - The goal is to prevent recurrence of the nonconformance
 - Is not a quick and easy process that can always be accomplished in an office or conference room
 - Generally requires talking to the people involved who best know the process



Root Cause Analysis

- Takes place after the immediate correction of a nonconformance.
- Required when a nonconformance is significant (could recur, casts doubt on a laboratory operation's compliance with procedures)
- Required for nonconformances identified through audits and for failing proficiency test reports.



Laboratory SOP Must Define Authorities and Responsibilities

- ✓ Responsibility and authority for the management of nonconformances
- ✓ Actions to be taken when nonconforming work is identified
 - ✓ This may include halting of work and withholding of test reports or calibration certificates
- ✓ Who evaluates the significance of the nonconforming work
- ✓ Who decides about the acceptability of the nonconforming work
- ✓ Who notifies the customer and recalls work, if necessary
- ✓ Who is responsible for authorizing the resumption of work
- ✓ Designate authorities for implementing the corrective action procedure when required



Process of Root Cause Analysis

- Root cause analysis—
Using different problem solving methods to identifying the underlying causes of problems or incidents
- **Who should work on root cause analysis?**
 - **It is best if it is those who are closest to the work on a daily basis**
- What's the problem?
(DEFINE)
- Sometimes “Why” isn't the starting question
 - What is it?
 - When did it happened?
 - Where did it happen?
 - How were overall goals affected?
 - Keep it simple—make an outline
 - People see problems differently
- Why did it happen?
(ANALYZE)
- What will be done?
(PREVENT)

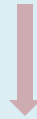


Examples of Types of Causes/Root Causes

- QC out of control—What could be the:
 - Cause?-incorrect dilution
 - Immediate cause?-pipette on incorrect setting
 - Root cause?-pipette not checked before pipetting began
- Skinned knee—What could be the:
 - Cause?-fell down
 - Immediate cause?-bike hit a bump
 - Root cause?-didn't wear protective gear
- Water on the floor—What could be the:
 - Cause?-leaking freezer
 - Immediate cause?-door left open
 - Root cause?-freezer not organized
 - Items are not easily found
 - Takes too long to find items

Root cause means digging deeper for an answer.

Why did this happen?



Cause (first response)



Ask "why" again..

Immediate cause (next response)



Ask "why" again..

Root cause (upon further thought)

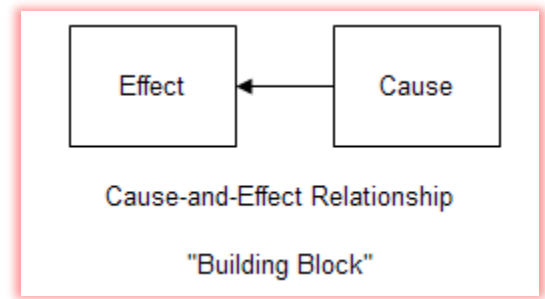


Start with a New Mindset

- People are generally not the ultimate cause of problems
- People implement processes
- Most people do not come to work planning to sabotage their own work
- Don't waste time looking at surface issues
- Use passive voice to avoid "blame game"
 - Bob didn't complete the form X correctly (WRONG)
 - Form X lacks spaces for all the information
 - Form X lacked necessary review and approval (CORRECT)

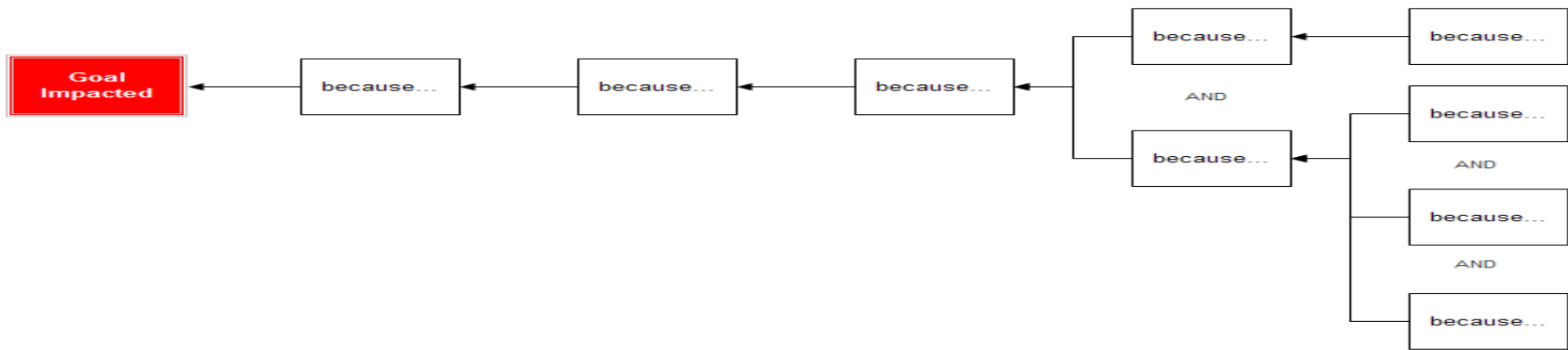


One method of Root Cause Analysis: Cause Mapping (5 Whys)



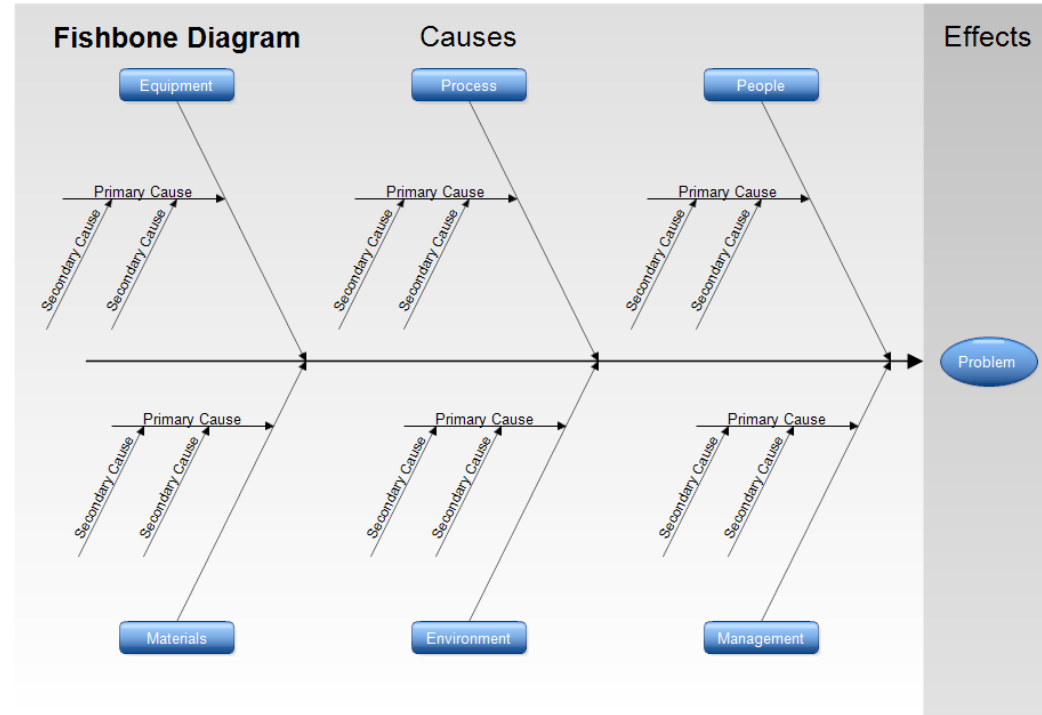
Ask: “Why did this happen?” Write down the response, then ask the question again. Write down the response. Ask the question 5 - 6 times and you may get to the “root cause” of the problem. May ask what and when questions, too:

- Why was there water on the floor?
- What could be the cause(s)?
- Why would that happen?
- When could that happen?



Another method of Root Cause Analysis: Diagramming (Fishbone)

- People (manpower)
 - Training, verbal miscommunication, lack of communication, staff changed mid-project
- Process/Methods
 - Procedures, workflow,
 - Measurement (Calibrations performed, but were they appropriate?)
- Equipment (machines)
 - Defective, not maintained, not calibrated, overloaded
- Management
 - Reviewed annually?
- Environment
 - Temperature, humidity, work area, distractions
- Materials
 - Incorrect, degradation, certificates of analysis



Root Cause Analysis → Corrective Action

- Once the root cause is identified, you must implement a fix (corrective action) to prevent it from happening again.
 - Identify potential corrective actions
 - Select and implement the action most likely to eliminate the problem and prevent recurrence
 - Corrective actions are appropriate to the magnitude and risk of the problem



Corrective Action

- Once implemented, the laboratory monitors the results of the corrective action to ensure it was effective.
 - If effective, close the Corrective Action.
 - If not effective, select another Corrective Action or revisit the root cause.



Preventive Action

- Pro-active process of continual improvement
- Goal:
 - Improvement of the quality management system
 - Improvement of technical operations
 - Elimination of potential nonconformities

System improvement stems from rigorously correcting problems, and learning to foresee potential problems.



Identifying Preventive Actions

- May be identified as:
 - A result of normal work
 - Observations
 - Nonconformities
 - Analysis of data
 - Proficiency tests
 - Suggestions for continuous improvement
- May be identified for laboratory documents, quality system or laboratory processes



Addressing Preventive Actions

- Develop an action plan
 - Specify what situation needs preventive action
 - Define what changes/actions need to occur
 - Assign responsibility
 - Implement the preventive action
- Monitor the action
 - After implementation gather observations or data to determine whether the preventive action was effective.

➤ If effective, close the Preventive Action.

➤ If not effective, select another Preventive Action



Summing It Up

- Quality management system SOPs define responsibilities and authorities for the root cause investigation process.
- Root cause investigation is a problem solving activity focused on the system, not the personnel.
- Root cause investigation leads to corrective action, which is intended to prevent recurrence of nonconformance.
- Preventive action is a pro-active process intended to prevent occurrence of nonconformance.



Reference

ISO/IEC 17025:2005 *General requirements for the competence of testing and calibration laboratories*

- <https://www.iso.org/standard/39883.html>

