

QMS Quick Learning Activity

Nonconforming Work, Root Cause Analysis, Corrective Actions, and Opportunities for Improvement

ISO/IEC 17025:2017

Clauses 7.10, 8.6, and 8.7

What will be covered in this training?

- Root Cause Analysis
 - What it is
 - Who performs it
 - Sample methods for root cause analysis
- Corrective Action
 - What is it?
- Opportunities for Improvement
 - Customer Feedback



Definitions

- **Continual Improvement:** recurring activity to increase the ability to fulfill requirements
- **Correction:** immediate action to eliminⁱⁿate 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
- **Nonconforming work:** when work does not conform to the laboratory's procedures or agreed requirements with the customer)



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

Section 7.10.3

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



Laboratory SOP Must Define Authorities and Responsibilities

Section 7.10.1

- ✓ Responsibility and authority for the management of nonconformances
- ✓ Actions to be taken when nonconforming work is identified
 - ✓ This may include halting or repeating of work and withholding of test reports
- ✓ 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



Laboratory SOP Must Define Authorities and Responsibilities

- ✓ Where the evaluation indicates that the nonconforming work could recur, or that there is doubt about the conformity of the laboratory's operations with its own management system, the laboratory shall implement corrective action.
- ✓ First step: React to the nonconformity
 - ✓ Take action to control and correct it
 - ✓ Address the consequences
- ✓ Next step: Root Cause Analysis for the cause



Nonconforming Work and Next Steps

Sections 7.10 and 8.7.1

- ✓ Where the evaluation indicates that the nonconforming work could recur, or that there is doubt about the conformity of the laboratory's operations with its own management system, the laboratory shall implement corrective action.
- ✓ First step: React to the nonconformity
 - ✓ Take action to control and correct it
 - ✓ Address the consequences
- ✓ Next step: Root Cause Analysis for the cause of the nonconformity.



Next Steps

- ✓ Evaluate the need for action to eliminate the cause(s) of the nonconformity so that it does not recur
 - ✓ Review and analyze the nonconformity
 - ✓ Determine the cause
 - ✓ Determine if similar nonconformities exist or could potentially occur



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)

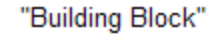


Start with a New Mindset

- 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)

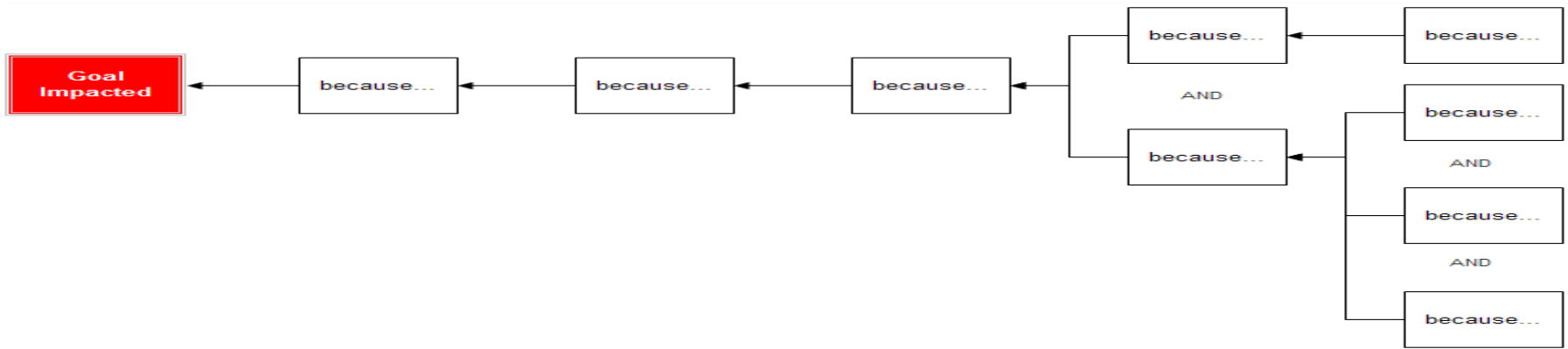


One method of Root Cause Analysis: Cause Mapping (5 Whys)



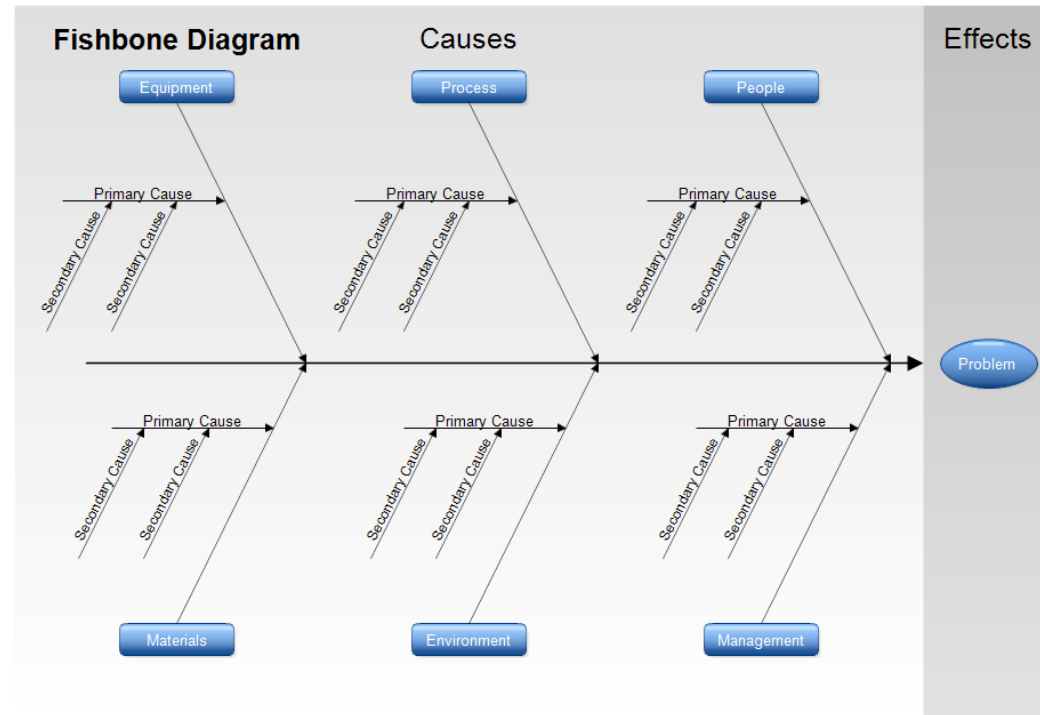
Ask: “Why did this happen?” Write down the response, then ask the question again. Write down the response. Ask the question 5 - 6 times and you may get to the “root cause” of the problem. You may ask what and when questions, too:

- 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

Section 8.7.2

- 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.
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- If effective, close the Corrective Action.
 - If not effective, select another Corrective Action or revisit the root cause.



Corrective Action

- Update any risks and opportunities determined during planning, if necessary
- Make changes to the quality management system, if necessary



Improvement

Section 8.6

- Proactive 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.



Opportunities for Improvement

- May be identified through the review of:

• Operational procedures • Use of the policies • Overall objectives • Audit results • A result of normal work • Observations • Corrective actions	• Analysis of data • Proficiency tests • Management review • Suggestions from personnel • Risk assessment • Analysis of data
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- May be identified for laboratory documents, quality system, or laboratory processes



Addressing Opportunities for Improvement

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



Seeking Feedback from Customers

- Seek feedback, both positive and negative, from customers.
- Analyze the feedback to improve:
 - The quality management system
 - Laboratory activities
 - Customer service
- Examples include customer surveys, records of communication, and review of reports with customers.



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.
- Improvement is a proactive process intended to prevent occurrence of nonconformance and improve the laboratory
- Seek customer feedback for improvement areas.



Reference

ISO/IEC 17025:2017 *General requirements for the competence of testing and calibration laboratories*

- <https://www.iso.org/standard/66912.html>

