

## Root Cause Analysis & Corrective and Preventive Actions

### APHL Quality Management System (QMS) Competency Guidelines

The participant will understand

\* Root Cause Analysis

- What it is
- Who performs it
- Sample methods for root cause analysis

\* Opportunities for Improvement

- How to identify them
- How to address them

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

*Once the root cause is identified, you must implement a fix (corrective action) to prevent it from happening again.*

### 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 nonconformity
- 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

Public health laboratory competency guidelines:  
Quality Management System (QMS) domain

QMS 10.00 Nonconforming event management: ensures that processes are in place for detecting and managing nonconforming events

QMS 10.01. Management of nonconforming events (NCEs)



QMS 10.03. Investigation and root cause analysis

QMS 12.00 Continual quality improvement (CQI): ensures mechanisms for continuous quality improvement

QMS 12.02. CQI activities

QMS 12.03. Corrective action process

QMS 12.04. Preventive action

General (GEN) domain

GEN 1.05. Troubleshooting

Informatics (INF) domain

INF 1.02. Electronic data exchange regarding test requests

INF 14.03. Tracking corrective actions and reports

Microbiology (MCB) domain

MCB 6.01. Nonconforming event (NCE) tracking

Chemistry (CHM) domain

CHM 6.01. Nonconforming event (NCE) tracking

Safety (SAC) domain

SAC 3.02. Incident reporting

## 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

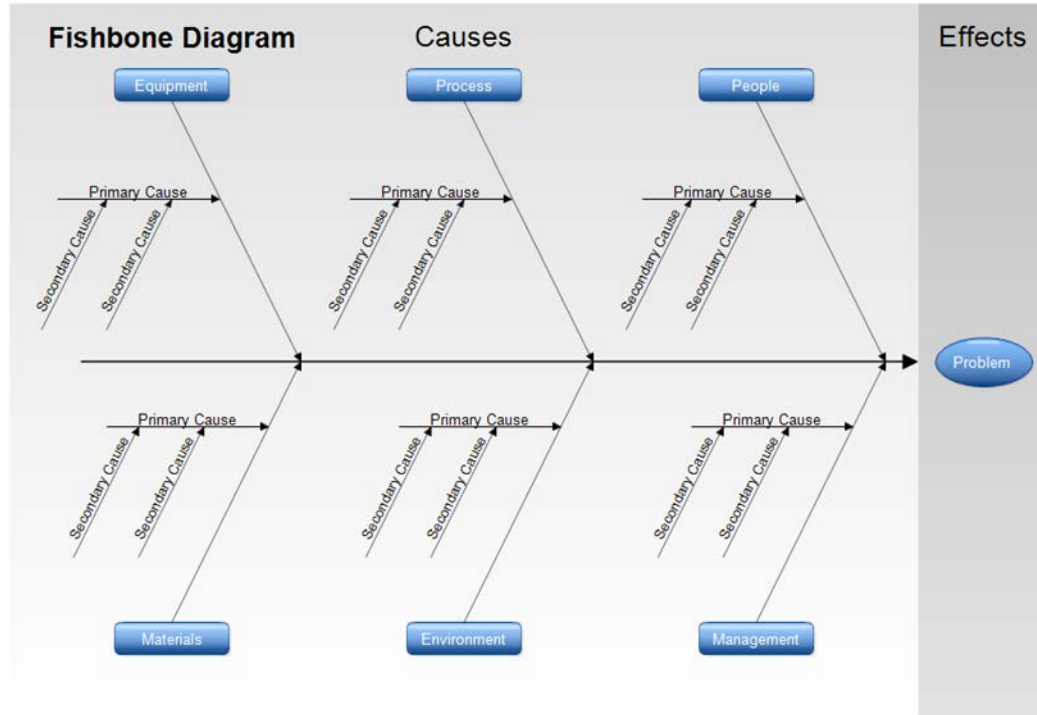
**Effectiveness:** extent to which planned activities are realized and planned results achieved

**Nonconformance:** nonfulfillment of a requirement



# Tools

- 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.



## Five Whys

