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
* Corrective Action & Preventive Action
  - What is the difference between them
  - When each applies

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.

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

**Preventive Action**: action to eliminate the cause of a potential nonconformance or other undesirable potential situation
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.
- Preventive action is a pro-active process intended to prevent occurrence of nonconformance

Five Whys