Public Health Laboratory Model Practices for QMS11-A:

Nonconforming Events

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APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES®

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INTRODUCTION

Scope

The CLSI guidelines provide a broad framework for the approach on managing nonconforming events (NCEs). This document was developed by applying that framework through the examples of model practices implemented throughout the Public Health Laboratory (PHL) community. NCEs occur when any aspect of laboratory activity, including safety or security aspects, do not conform to laboratory procedures. When an NCE occurs, the laboratory must take action to control and correct it in a timely manner, address the consequences, and evaluate the need for action to eliminate the cause to prevent recurrence. Actions and resolutions must be documented.

NCEs may be identified through customer complaints, external and internal audits, proficiency testing results (internal and external), demonstration of competency, and encompass all laboratory functions including pre-analytical, analytical, and post-analytical workflows, as well as safety and security incidents.

NCEs are documented by the laboratory in written or electronic form. Documentation systems vary in specific nomenclature, and so only generalized fields will be used in this document.

Purpose

This procedure provides direction for identifying, analyzing, correcting and documenting NCEs in a laboratory environment using model practices developed throughout the PHL community.

Definitions

Standardized terminology is critical for clarity in communication, both within the laboratory and with external partners. The following terms and definitions were compiled by various public health laboratory personnel in the development of their respective protocols, and definitions may vary by entity. Terms with multiple definitions were standardized in this document.

Accident

An event which results in or might have resulted in some level of material damage, injury or exposure to a hazardous substance. The term may also describe the loss of a specimen due to breakage or mishandling by the laboratory.

Action (Within NCE Report)

Describes specific steps taken to address a non-conforming event.

Action Completed

Labels a NCE action: *completed* or *outstanding*.

Action Status

Reflects the current state of a NCE action: *not started, in progress* or *completed*.

Anomaly

EPA/FDA term for nonconformance.

Complaint

Expression of dissatisfaction made to the laboratory related to a product or service, or the complaints-handling process itself where a response or resolution is explicitly or implicitly expected.

Conformance / Compliance

Actions, results, documents and records that meet regulatory, accreditation or internal laboratory requirements for normal or standard operating procedures.

Controls
Measure that maintains and/or modifies risk. Controls include, but are not limited to, any process, policy devise, practice, or other conditions and/or actions which maintain and/or modify risk.

Correction
Initial fix or containment action taken to eliminate or rectify a nonconformity.

Corrective Action (CA)
An action to eliminate the cause of a detected nonconformity or other undesirable situation, such as when an error or out of specification result is detected prior to the release of test results to prevent recurrence (ex., when the quality control (QC) results for a run are out of range due to double-pipetting of control material, the corrective action is to re-run the batch with the proper amount of control material).

Documentation
Material records that provide written proof of an action. For example, field service records provide documentation of instrument repair or a printed or PDF file of an email thread discussing an action taken with a regulator provides documentation of regulator contact and response.

Exposure, Biological
According to the US Occupational Safety and Health Administration (OSHA), an exposure incident is a specific eye, mouth, other mucous membrane, non-intact skin or parenteral contact with blood or other potentially infectious materials, as defined in the standard that results from the performance of a worker's duties.

Exposure, Chemical
OSHA sets enforceable permissible exposure limits (PELs) to protect workers against the health effects of exposure to hazardous substances, including limits on the airborne concentrations of hazardous chemicals in the air. Most OSHA PELs are eight-hour time-weighted averages, although there are also Ceiling and Peak limits, and many chemicals include a warning against skin contact. Approximately 500 PELs have been established, which can be viewed in the OSHA PEL tables.

Frequency
The rate at which something occurs or is repeated over a particular period of time or in a given sample.

Hazard Identification
Reporting of a material or condition that could cause potential injury or exposure (ex., water spill in corridor).

Incident
Any condition outside of normal operations related to testing, building/environmental conditions, physical plant, security or safety. All incidents are reported using using an NCE documentation system.

Index Number
The unique identification number for each entered NCE or Incident report.

Likelihood
Chance of something happening.

Near Miss
An incident where there was a chance of exposure or injury only if additional steps were taken (ex., a package containing a rabies specimen was opened, but the sealed secondary packaging was not opened and therefore no exposure to the specimen occurred).

Nonconforming Event (NCE)
A deviation from the standard operating procedure or conditions required to accurately complete testing and report an accurate test result.

Nonconforming Work / Nonconformance / Nonconformity

Any work which does not conform to the laboratory's methods, procedures, policies or the agreed requirements of the customer. A nonconformance is a quality event where the laboratory fails to meet a requirement of the Quality Management System, regulations, or accreditation standards. These may include unusual occurrences and unexpected or adverse outcomes. A nonconformance is also referred to as an issue, incident, problem, departure, quality event, NCE, or deficiency.

NCE Report

Documentation used for capturing detailed information about quality events such as nonconformances. Includes risk evaluation based on frequency and impact, and corrective, remedial and/or preventive actions.

Organizational Unit

The individual testing units.

Preventive Action

A proactive process to identify opportunities for improvement or to prevent the occurrence of a nonconformity or other potentially undesirable situation before it happens. An action to address risks and opportunities.

Regulatory / Statutory Requirement

Obligatory requirement specified by an authority mandated by a legislative body.

Risk

Effect of uncertainty on objectives.

Remedial Action

Action taken to address any nonconformity which has already occurred or if something is expected to result in a nonconformity. For testing, it is any action taken following the release of a test result (ex., instrument calibration error found after test results reported for a sample batch).

Some remedial actions would be to notify submitters, correct the calibration error, retest the samples and issue corrected reports. Another example would be actions taken when it is known that recalibration or required maintenance will not occur within the required time frame. Remedial actions do not usually correct the root cause.

Root Cause Analysis

Investigation to determine the fundamental cause as to why an incident occurred. Root causes are grouped in broad categories, such as *personnel, methods, measurement, instruments, materials* or *environment*.

A root cause investigation looks at all probable causes of failure and not just the most obvious or superficial events. Repeated incidents of the same type should be investigated using root cause analysis.

Severity

Degree to which an incident caused harm: *minor* (i.e., superficial cut), *moderate* (i.e., deep cut or ankle sprain) or *severe* (i.e., broken bone, unconsciousness).

Status

The state of completion of actions taken to resolve a nonconforming event.

Type

The description of actions taken: *preventative, corrective* or *remedial*.

Review

In documentation system, the review of incidents and actions by management and the laboratory director.

NCE REPORTING PROTOCOL CRITERIA

NCE reporting policies are needed to establish a consistent response from all staff. Written protocols set a clear process for response which, in turn, will establish an environment of quality throughout all processes, from analytical testing, IT, building management, administrative support (fiscal, purchasing, billing), as well as employee safety and security.

Protocol Development

The following are general criteria for NCE protocol development:

- All NCEs are reported to laboratory management (supervisors, managers, etc.) using the established procedures developed by the laboratory.
- NCE reports are used to drive continuous quality improvement within the laboratory through the process of review and procedural changes.
- NCE reports are not used to document personnel issues. Job titles, such as 'analyst' and 'section supervisor', etc. are used to record roles when required.

Reporting

Reporting of NCEs includes, but is not limited to:

- Pre-analytical, analytical and post-analytical testing incidents
- Proficiency test (PT) failures or results of < 100% acceptable (regardless of PT provider's pass level)
- Building environmental conditions out of range
- Instrument/equipment failures
- LIMS/IT failures
- Reagent/kit lot failures
- Inability to obtain needed reagent(s) or supplies
- Incorrect reports or reports sent to wrong submitter
- Exceeding monitor thresholds
- Repeated QC failures in a test system
- Turn-around time or hold time exceedances
- Deviations from SOPs or plans
- Safety and security failures

Documentation

Documentation of all NCEs should be initiated as soon as possible following discovery. The following are key things to remember during this process:

- Any laboratory staff member may initiate NCE reports.
- Management must review or delegate the review of all NCE reports prior to closure of the report and document this review.
- The laboratory or quality director may request revisions to the report or that additional actions be taken for reported NCEs.
- Completed and reviewed NCE reports are printed and filed or maintained electronically. The College of American Pathologists requires that any incidents for specific personnel be placed in the training binder of personnel in the appropriate accredited laboratory testing areas (ex., document in CAP areas, EPA areas, etc.) These binders are maintained securely in designated offices.

Timeline

Actions to resolve NCEs are to be completed in a pre-determined timeframe. Suggested timeframes are as follows:

- All incidents are reviewed and closed after 30 days, or an interim progress report added.
- High-impact or high-severity incidents will have a shorter resolution times as determined by the laboratory director or quality director/manager.

ROLES AND RESPONSIBILITIES

Public health laboratory personnel play a critical role in implementing the processes to ensure identification and reporting of NCEs, understand root causes and take appropriate actions and interventions, as well as monitor trends. Below are the essential roles and their key responsibilities. Using a QA committee structure to develop and implement the quality management system (QMS) provides an avenue to collaboratively engage personnel at all levels of the organization, support inclusion and alignment of programs and services, improve communications and embed continuous quality improvement practices.

Note: This is a generalized section, as each laboratory has its unique organization.

Figure 1. NCE Roles and Responsibilities Matrix*

Responsibility	Role				
	Lab Director & Associate Directors	Quality System Manager	Safety Officer	Supervisors & Managers	All Staff
Ensure implementation of the NCE system	X				
Establish and maintain the NCE system		X			
Final review/approving authority to determine acceptability (validation)	X	X	X		
Assign actions based upon risk levels	X	X	X	X	
Approve resumption of work as necessary		X	X		
Train and assist staff with NCE process, procedure, and forms		X			
Track and trend NCE data and information		X			
Present data and analysis to leadership for review and appropriate action		X			
Set NCEs as compliant but not final validation				X	
Document when a client requests a departure from laboratory procedures, if allowable. This will not be considered a NCE requiring corrective action.					X
Assist staff to resolve or identify the root cause of NCEs		X	X	X	
Inform clients when results may be delayed or recalled due to questionable data				X	
Resume work when appropriate action has been taken to identify the root cause and corrective actions are in place				X	
Identify and report using the NCE system					X
Complete assigned actions					X

* Figure 1 is based on the State Hygienic Laboratory at University of Iowa's *NCE Management, Version 8*, September 20, 2020.

All Staff

- Participate in a workplace culture that encourages reporting of NCEs, security and safety incidents.
- Comply with established policies and procedures.
- Recognizing NCEs that affect the laboratory's testing work, the results of this work, and its staff.
- Recognize safety or building/facility issues that may affect the laboratory and its general operation.
- All staff members have the authority to halt their work when a nonconformance is identified and are responsible for notifying their supervisor or the Quality Manager and documenting the event, and completing any actions as assigned.
- Provide documentation of, and input on, NCEs as required.

Supervisors/Managers

- Maintain and support a workplace culture that encourages reporting of nonconformances, security and safety incident.
- Ensure that staff adhere to policies and protocols.
- Direct analysts to report all nonconformances to laboratory management and/or the quality manager.
- Ensure that nonconformances are documented appropriately and completely, and make revisions or updates as required.
- Be actively involved in the halting or management of nonconforming work, evaluation of the significance of the nonconformance, contacting the customer when appropriate and withholding test reports.
- Ensure that laboratory staff have the time, equipment and supplies needed to document and perform follow-up actions for nonconformances on which they are involved.
- Review and verify that preventative, remedial and/or corrective actions are completed within established time frames.
- Participate in the investigation of nonconformances.
- Ensure any staff assessments required to correct nonconformances are documented using established protocols.
- Authorize the resumption of work and to follow up on actions taken within their departments.
- Provide follow-up monitoring to ensure the effectiveness of actions taken, and document using established procedures.

Quality Managers/Quality Assurance Officers

- Maintain and support a workplace culture that encourages reporting of nonconformances, security and safety incidents.
- Responsible for the overall implementation and management of the Quality Assurance Program.
- Maintain documentation in NCE system.
- Direct that NCEs be reported or revised and assist in resolution actions as needed.
- Contribute to incident reporting, investigation and closing in NCE system.
- Enter and/or track NCE actions and assist in resolution as needed.
- Facilitate and document root cause analysis discussions.
- Maintain electronic and hard-copy files of NCEs.
- Review and close completed NCEs.
- Monitor Actions to ensure effectiveness.
- Ensure that NCEs are tracked and discussed in quality assurance meetings.

Laboratory Director

- Ensures implementation of the NCE system.
- Set goals for the Quality Assurance Program to foster a culture of continuous quality improvement and compliance.
- Maintain and support a workplace culture that encourages reporting of nonconformances, security, and safety incident.
- Reviews and approves all completed NCE reports and associated follow-up actions taken.

Quality Committee

Committee includes the director, quality manager and supervisor/manager/other representation from each unit. The Quality Committee regularly reviews NCEs within the laboratory and their resolution. The focus of these reviews is to ensure that appropriate actions were taken to prevent future incidents of the same type, and to identify laboratory-wide problems with the information management or operations systems. NCE Review/Corrective/Preventative Action review is a standing item on the Quality Committee meeting agenda. Minutes from these meetings are documented and available for review.

NCE PROCEDURAL PROCESS

In order for NCEs to be identified, evaluated and remediated, it is important that the process is done consistently by all staff and documented through established written protocols. The following is a generalized process for the development of a written protocol from identification, processing, risk assessment, root cause assessment, documentation and closure.

Identification

NCEs may be identified through various methods. These include customer complaints, proficiency results, quality control failures, instrumentation failures, safety failures and/or security concerns. The event can be either a complete failure or a near-miss situation.

Process

Recognition

Once it is discovered that a nonconformance has occurred:

- Report to the appropriate supervisor and provide any details and/or relevant documentation.
- Supervisor (or other personnel, as tasked) begins documentation of the incident.

Notification

- Bring all NCEs, other than routine QC monitoring, to the attention of the laboratory director and any relevant staff in a timely manner.
- High-impact events: Conduct meetings with appropriate staff (ex., supervisors, management, laboratory director and quality director/manager(s)) to determine root cause and coordinate follow-up actions. Examples of such events might include a second failed PT, the discovery of significant procedural deviations or a media-related incident.
- Low-impact events: Discuss at regularly scheduled laboratory QA meetings. An example of a low-impact event might be when QC monitors exceed their threshold.
- Discuss NCEs related to specimen receipt, availability of reagents, instrument/equipment failures, and environmental failures with the appropriate department personnel (ex., fiscal, maintenance, specimen receiving, etc.) to coordinate actions.
- Action, Monitoring & Documentation: Document all action taken to resolve the NCE and include any documentation as an attachment to the NCE report.

- Determine the staff member responsible for completing the NCE report and ensuring actions are completed.
- Supervisors/managers ensure all short- and long-term actions or monitoring are tracked and completed as stated, or that the record is modified to reflect any changes.
- Take actions based on assessment of the risk.
- Actions may include:
    - Halting/repeating of work
    - Withholding reports
    - Review of impact on previous results
    - Determination of the acceptability of nonconforming work
    - Notification of the submitter/customer
    - Responsibility for authorizing the resumption of work.
- Take preventative action when an evaluation indicates that recurrence of the nonconforming work is likely.
- Include a review of the effectiveness of actions or monitoring in the documentation system. Quality managers/QA coordinators act as a secondary monitor of all bureau NCEs and may assist in follow-up actions as appropriate.

Incident Review

When all actions are completed:

- Supervisor: Initiate review of the completed NCE report.
- Reviewers: Approve or provide feedback on the NCE report.
- Laboratory director: Review and approve all NCE reports and request revisions as necessary.
- Quality manager/director: Review all submitted NCE reports and submit a summary annually.

Monitor NCE Trends

Review NCE summaries for the past year for each laboratory area at the first quarterly QA meeting of the following year to identify any trends and pursue preventative actions as indicated.

Risk Assessment

Risk assessment is the overall process of risk identification, risk analysis and risk evaluation.

Risk Identification

The purpose of risk identification is to find, recognize and describe risks that might help or prevent the laboratory from achieving its objectives. Relevant, appropriate and up-to-date information is important in identifying risks.

When an NCE has occurred, the risk identification is that the laboratory has failed to meet a requirement. This includes a detailed consideration of uncertainties, risk sources, consequences, likelihood, events, scenarios, controls and their effectiveness. An event can have multiple causes and consequences and can effect multiple objectives. Risk analysis is used to determine the frequency and consequences of the NCE and evaluate the need for action to eliminate the cause(s) to prevent future occurrences.

Risk Analysis

The purpose of risk analysis is to comprehend the nature of risk and its characteristics, including the level of risk.

There are two phases to risk analysis of an NCE:

1. Evaluate the risk to the lab based on what has already occurred (past tense).
2. Evaluate the future risk based on corrective actions(s) proposed or implemented.

Two criteria are evaluated for both phases by asking the following questions:

1. Frequency: How often did/will this happen?
2. Consequence: What was/is the impact of this event happening?

The consequence of the NCE is defined on a scale of low to severe:

- **Low:** No impact on test result, client satisfaction and/or obligations of the laboratory. Addressed without repercussions.
- **Moderate:** Minimal impact on test result, client satisfaction and/or obligations of the laboratory. May affect regulator/accreditation. May affect future ability to test.
- **Severe:** Test result not fit for purpose and/or client use negatively impacted. The laboratory has clearly not met an obligation. May effect the building systems/IT network, other testing units, public relations, regulatory/accreditation and/or previous testing results.

The determined frequency and consequence can then be charted using a risk criteria matrix (**Figure 2**) to determine the overall level of risk associated with the NCE, which can range from very low to very high.

Figure 2. Risk Criteria Matrix*

Consequence	Frequency/Likelihood		
	Uncommon / Unlikely	Occasional / Possible	Frequent / Likely
Severe	Medium	High	Very High
Moderate	Low	Medium	High
Low	Very Low	Low	Medium

Suggested Actions	**Very Low:** Work can continue. Cause and risk have been adequately addressed or the risk is acceptable. **Low:** Work can continue with the existing controls in place. Address how the likelihood and/or consequence can be decreased. **Medium:** Additional controls are advised. Work can proceed at the discretion of the technical supervisor, quality manager(s), and director. **High:** Work must be stopped. Communicate immediately to the quality manager(s), supervisor, and director. Work can only resume if a remedial action is put in place; however, the risk must be reduced through corrective action. **Very High:** Work must be stopped. Communicate immediately to the quality manager(s), supervisor, and director. Likelihood and consequence must be decreased through corrective action.

* Figure 2 is based on the State Hygienic Laboratory at University of Iowa's *How to Manage Nonconforming Events, Version 8.*

Risk Evaluation

The purpose of risk evaluation is to support decisions determining whether additional action is required. Actions may include:

- Do nothing further (not a common response!)
- Continue monitoring the event to see if further action or trends develop
- Consider risk treatment options such as root cause analysis
- Undertake further analysis to better understand the risk
- Maintain existing controls
- Reconsider objectives.

Decisions should take into account the actual and perceived consequences to external and internal stakeholders.

Root Cause Identification

Root cause analysis is a risk treatment technique. Selecting the most appropriate corrective action(s) involves balancing the potential benefits derived in relation to the achievement of the objectives against costs, effort or disadvantages of implementation. Identified actions might not produce the expected outcomes and could produce unintended consequences. Monitoring and review need to be an integral part of the risk treatment implementation to give assurance that the different forms of treatment become and remain effective. The Five "Whys" Analysis Tool and the PT Corrective Action/Root Cause Analysis Investigation Checklist, found in Appendix B, are useful tools for the investigation of root causes. Use the following steps to conduct a root cause analysis:

1. Identify the event and gather preliminary information.
2. Assemble team members with personal knowledge of the processes and systems involved in the event to be investigated. Include facilities, security and IT personnel as appropriate.
3. Describe what happened.
    a. Collect and organize the facts surrounding the event to understand what happened.
    b. Develop a timeline.
    c. Resist the urge to 'find the root cause' or jump to conclusions. Take time to explore all possible sources of the issue.
4. Identify the contributing factors.
    a. The situations, circumstances or conditions that increased the likelihood of the event are identified.
    b. At each step of the timeline, determine what was happening at that point (circumstances increasing the likelihood of an incident.)
    c. Can include environment, equipment, staff, training, etc.
    d. Avoid hindsight bias or knowledge gained after-the-fact.
5. Identify the root causes.
    a. A thorough analysis of contributing factors leads to identification of the underlying process and system issues (root causes) of the event.
    b. Contributing factors are not root causes.
    c. Not the place for judgments about individuals.
6. Design and implement changes.
    a. Team determines how best to change processes and systems to reduce the likelihood of another similar event.
    b. Safeguards, triggers for recurrence, procedural/process changes, early warnings.
    c. Strength of changes:
        I. Strong Actions
            i. Change physical surroundings
            ii. Usability testing of devices before purchasing
            iii. Engineering controls into system (forcing functions which force the user to complete an action)
            iv. Simplify process and remove unnecessary steps
            v. Standardize equipment or process
            vi. Tangible involvement and action by leadership in support of the change
        II. Intermediate Actions
            i. Increase staffing/decrease in workload
            ii. Software enhancements/modifications
            iii. Eliminate/reduce distractions
            iv. Checklist/cognitive aid
            v. Eliminate look alike and sound alike terms
            vi. "Read back" to assure clear communication
            vii. Enhanced documentation/communication
        III. Weaker Actions
            i. Double checks
            ii. Warnings and labels
            iii. New procedure/memorandum/policy
            iv. Training
            v. Additional study/analysis
7. Assess impact of the change. This should be done initially to assess immediate changes and again after a period of time to track long-term outcomes.

Documentation System

The systems used in laboratories are varied in the information collected. The list below is by no means inclusive or exclusive and will be determined by the electronic or paper documentation system used.

General Guidelines for Documenting NCEs

- Provide a complete description of the incident; include as much detail as possible: who (by position only), what where, when and how. Avoid speculations on cause.
- Do not mention involved staff members by name, use titles only. NCE reporting is not to be used for staff discipline, but for quality assurance purposes only. Use procedures established by Human Resources for handling personnel issues separately.
- If instruments are involved: Give the instrument type, serial number, manufacturer and common lab name (ex., 7500 FastDX Real-time PCR System-A)
- If procedure-related: Give the SOP number and procedure name.
- For PT failures: Give the PT even name, provider, and the date received or date results issued.
- For specific locations: Give room number and bench location if relevant to the report.
- Use plain language so that the description is understandable to those without technical knowledge of the subject. Avoid unclarified abbreviations.
- Include LIMS ID number(s) or LIMS batch numbers(s) for any samples related to the NCE.

Types of NCEs

The type of nonconformity may include but is not limited to the following:

- Contamination (sample contamination found during testing, such as microbial, etc.)
- Control failure (failure of QC material during testing)
- Documentation (QA-required records not found, etc. Not for submission form issues.)
- Inspection response (NCE found during an accreditation inspection)
- Instrument/equipment (instrument-related events, failures, missed calibrations, repairs, etc.)
- LIMS/IT (failure of the LIMS, network system, HL7 messaging, etc., not entry errors)
- Monitor follow-up (actions taken after routine monitor exceeds threshold)
- Physical plant (environmental systems failures or out of range conditions, air flow, etc.)
- Proficiency testing (failure to pass a proficiency test with 100% acceptable result)
- Reagents (expired reagents, wrong lot/reagent used, back orders, etc.)
- Remedial action, procedure deviation (SOP not followed, missed/added step or reagent)
- Reporting error (error found on reported results sent to submitter)
- Safety (personnel injury due to improper technique, faulty equipment, etc.)
- Sample/specimen, analytical (loss of sample during testing, other/not contamination)
- Sample/specimen, pre-analytical (rejections by sections, errors on form, collection kit, etc.)
- Security (documentation of a reported security incident or concern)
- Turn-around time/hold time exceeded specified limits

NCE Impact/Risk

The following are ways to categorize the impact or risk of the event; keep in mind that if the NCE involved multiple areas, each one may have a different level of risk.

- High Impact—Building Systems/Network
- High Impact—Multiple Units Affected
- High Impact—Public Relations Sensitive
- High Impact—Regulatory/Accreditation

- High Impact—Requires Review of Previous Test Reports
- Moderate Impact—May Affect Future Ability to Test
- Moderate Impact—Regulator/Accreditation
- Moderate Impact—Requires Response within 30 days
- Low Impact—Addressed without Repercussions
- Low Impact—Requires Review over Long Term

Scope of Impact

Determine the scope of impact for the event:

- Testing unit (i.e., section)
- Scientific area (ex., chemistry, clinical, etc.)
- Multiple areas
- Entire laboratory
- Responsible official
- Sample/specimen analytical
- Security
- Information technology
- Epidemiology
- Department of health
- Submitters

Identify Actions Taken

Actions are single steps taken in response to an incident and may be a mix of corrective, remedial and preventative types.

Include Completion Date

Review Effectiveness of Actions

Include a summary statement describing the effect of the action taken (ex., part was replaced and the instrument passed the operational qualification with positive and negative control values in range).

Document NCE Review

Document Event Closure

CLOSURE

Documentation of the final closure is essential for regulatory compliance. In addition, clear and complete documentation of NSE closures allows NCEs to be reviewed and evaluated on a regular basis to track trends and monitor effectiveness.

If it isn't documented… it didn't happen!

Closure includes not only the report of the event, but the ensuing steps to determine how to correct the event, the determination of the risk analysis, and the review of the report by the laboratory director who is ultimately responsible for the outcome. Below is a general outline for closures.

Final Reporting/Documentation in System

All NCE reports should have official closure following review. The quality director/manager can perform this function.

Quarterly Review

The quality director should maintain a summary of all NCEs and examine them for general trends. Discuss these trends and progress on long-term actions with laboratory management during QA review meetings.

Continued Monitoring

Trends and long-term actions must be monitored and addressed at regular intervals so necessary changes are not lost over time.

Document discussion of trends and interim actions to provide evidence of continued monitoring.

Annual Review/Report

Conduct an annual review of NCEs and compile a report summarizing specific incidents and any trends noted and addressed, including general actions taken to prevent recurrence (preventative actions). The report should be signed by the laboratory director to document involvement in the process.

Complete a review of processes to address any potential failures or shortcomings proactively.

APPENDIX A: EXAMPLE NCE FORM

The following is the NCE-69790.787 Public Health Laboratory Nonconforming Event Form from Washington State Department of Health, Disease Control and Health Statistics.

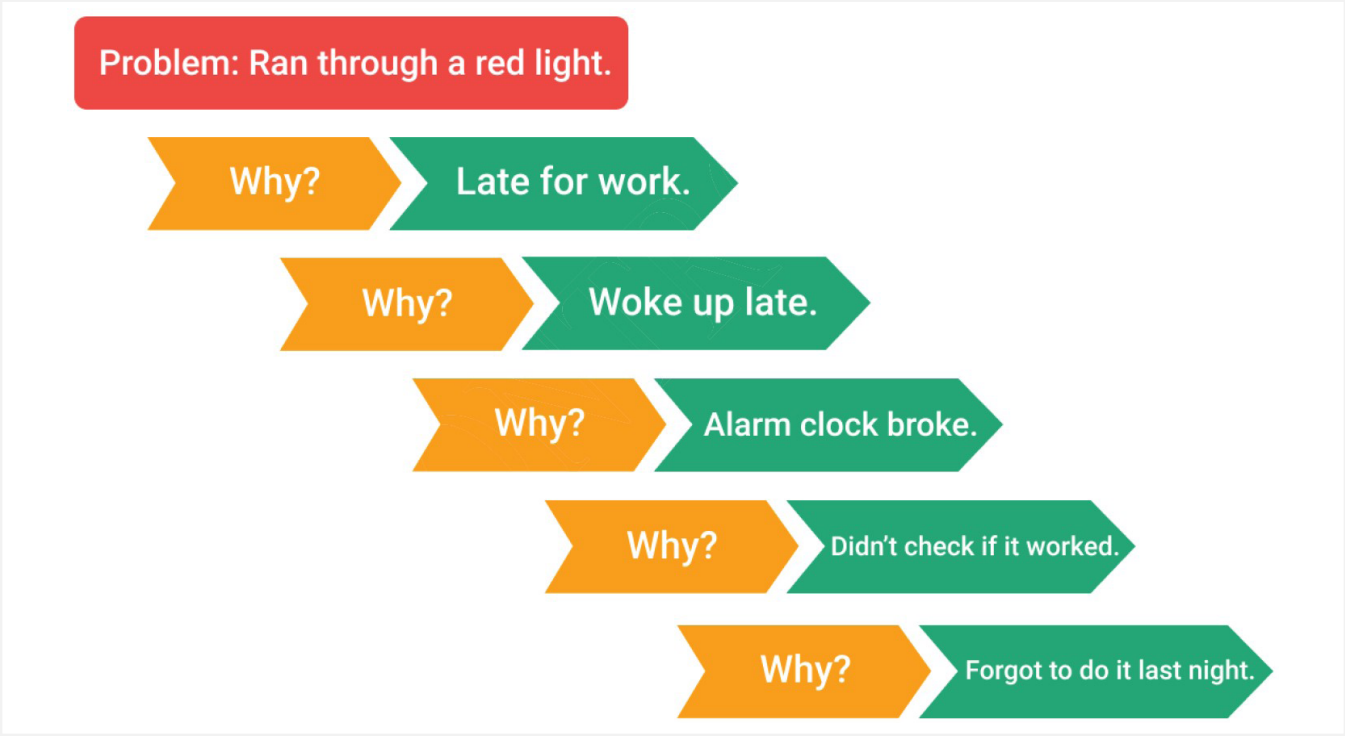
Event	
General Incident Details	
Documents Pertinent to This Event Document control #'s for SOP's, training plans, documents, etc.	
Office	☐ ELS ☐ NBS ☐ OPS ☐ EPI ☐ IT ☐ Admin ☐ Micro ☐ Other: _____
Problem Reported By	
Other Personnel Titles Involved in This Incident	
Sample and Error Identification	
Sample Accession Number(s) Involved No patient identifiers, please.	
Sample Submitted By (Enter the facility name below)	☐ Local Health Laboratory ☐ Reference Laboratory ☐ Hospital ☐ Clinics ☐ DoH Programs ☐ Other: _____
Submitting Facility Name	
Name of Facility Point of Contact	
Phone/Email of Facility Point of Contact	

Pre-analytical Error Type(s)	☐ Sample mislabeled/unlabeled ☐ Sample mix-up/aliquoting or labeling error ☐ Wrong tube type/container ☐ Tests missed at accession/wrong test ordered in LIMS Missing or lost requisition ☐ Sample lost/accidentally destroyed ☐ Delay in sample transport to laboratory ☐ Sample handled/stored improperly ☐ Sample not sent for further testing ☐ Equipment pre-check not performed ☐ Temperature monitoring issue ☐ Other: _____
Analytical Error Type(s)	☐ Result discrepancy ☐ QC failure/not performed ☐ Reagent problem ☐ Instrument failure/problem ☐ Wrong test performed/test performed incorrectly ☐ Testing delayed ☐ Calculation/dilution error ☐ Samples tested in wrong order ☐ Other: _____
Post-analytical Error Type(s)	☐ Bench report incorrect or incomplete ☐ Critical result not reported timely ☐ Other: _____
Other Error Type(s)	☐ Computer issue ☐ Customer service issue ☐ Complaint ☐ Other: _____
Immediate Action(s) Taken	
Description of Incident Who, what, where, when, why, how?	
Did this issue require a notification?	☐ Yes ☐ No
Name of Individual(s) Notified This is primarily for internal notifications.	
Supporting Documentation Examples: labels, reports, error messages, scanned requisitions. Remember: No patient identifiers, please.	

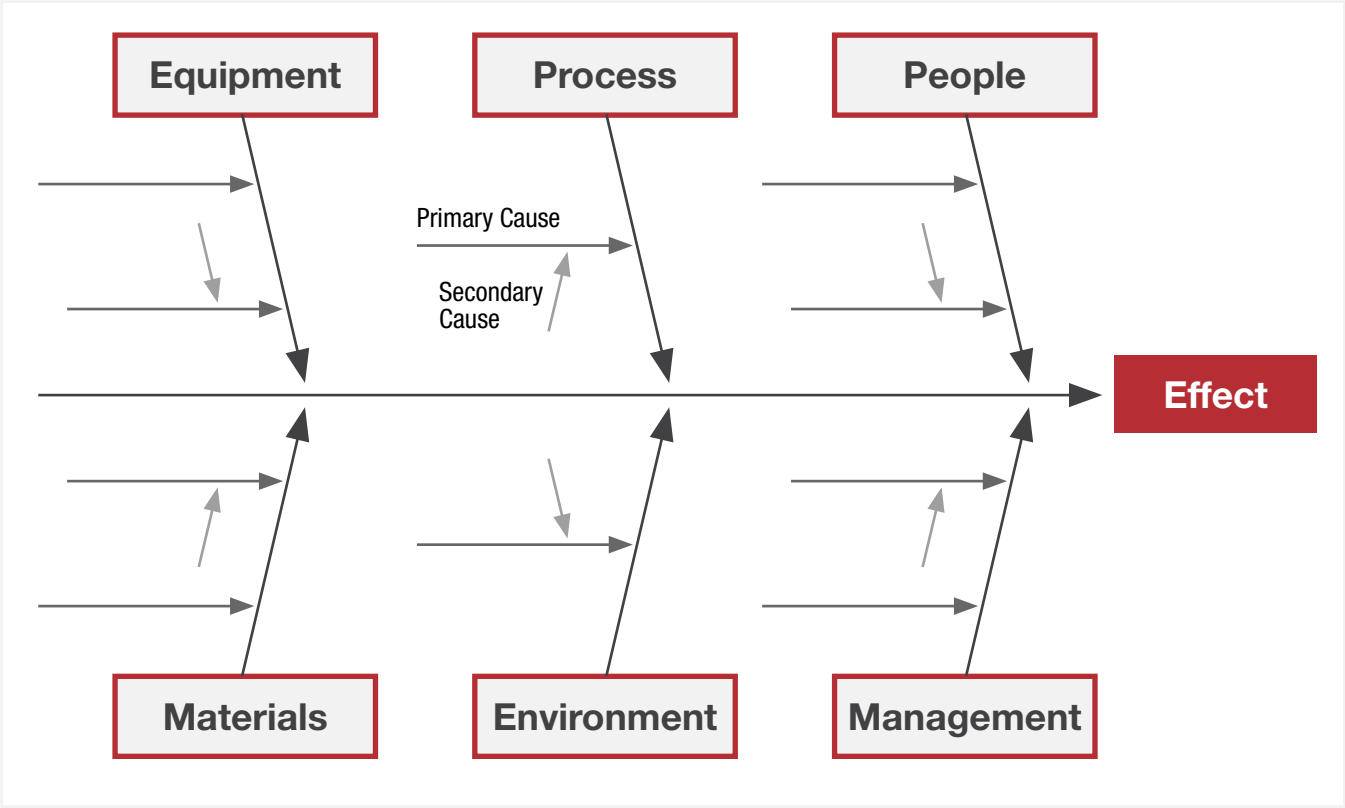
APPENDIX B: EXAMPLE RISK ASSESSMENT FORMS

The following examples are based on materials created by the Arizona State Public Health Laboratory.

The Five "Whys" Analysis Tool



Fishbone Diagram



Corrective Action Report (CAR) Form

CAR ID Number: _____ **Date of** ☐ **Occurrence OR** ☐ **Discovery:** _____
(Select one)

Section I

Part A is due 5 days from the CAR initial occurrence/discovery date.

Fill in the CAR ID Number and Date of Occurrence or Discovery in the header and click gray boxes in the body of the form for writable sections.

Place a check in the box of the most appropriate CAR category:

- ☐ Complaint (internal or external)
- ☐ Errors in Laboratory Reporting (including unsatisfactory PT)
- ☐ Out of QC
- ☐ Other (manufacturer recall, wrong mnemonic, etc.): _____

Provide the following information relevant to the Corrective Action (CLIA-clinical OR Non-clinical) and complete Part A within 5 days of the problem or issue occurrence or discovery date.

Impact to Patient Care, Sample Results or Other Samples

Does the problem have an impact or potential impact to patient care? ☐ Yes ☐ No ☐ Not Applicable

If the problem has an impact to patient care, impacts the final results, or both, answer the following:

- Was the sample submitter notified? ☐ Yes ☐ No ☐ Not Applicable
- Was the communication logged per section procedure? ☐ Yes ☐ No ☐ Not Applicable
- Was an amended report generated? ☐ Yes ☐ No ☐ Not Applicable
- Are any other samples affected? ☐ Yes ☐ No

If yes, contact the area supervisor and evaluate the results in question. Retest the sample(s) if possible.

PART A: Problem Identification

Description of Issue (List any information that is needed for supporting problem information, analysts, equipment, methods, logs, instrument ID, AZ # or serial #; what, when, where, how, etc. List and attach copies of any document errors related to the issue (ex., run log sheets, etc.); any other supporting relevant background information):

Immediate Correction Taken (List immediate measures taken to temporarily mitigate the problem; list and attach copies of revised documents related to the issue, ex., amended StarLIMs reports):

CAR ID Number: _____ **Date of** ☐ **Occurrence OR** ☐ **Discovery:** _____

Section I Approval Signatures

Section I completed by: _____ Date: _____

Supervisor: _____ Date: _____

Technical Supervisor: _____ Date: _____
(Clinical Sections)

Medical Laboratory Director: _____ Date: _____
(Clinical Sections)

Laboratory Director or Designee: _____ Date: _____
(Non-clinical Sections)

Quality Assurance: _____ Date: _____

Section II

Part B/C is due 30 days from the director approval signature of Part A.

Attach any supporting documentation.

PART B: Cause of the Problem (Root Cause Investigation)

Has the problem or a similar problem occurred within the past six months? ☐ Yes ☐ No

If yes, review prior corrective actions for what was not effective, before writing the systemic corrective action(s) for this CAR.

List the possible/confirmed cause(s) of the problem:

PART C: Systemic Correction(s) / Resolution(s) of the Problem

Systemic corrective action(s) taken:

Estimated CAR completion date (if anticipated to be longer than 90 days from CAR initiation): _____

CAR ID Number: _____ **Date of** ☐ **Occurrence OR** ☐ **Discovery:** _____

Section II (PART B&C) Approval Signatures

Section II completed by: _____ Date: _____

Supervisor: _____ Date: _____

Technical Supervisor: _____ Date: _____
(Clinical Sections)

Medical Laboratory Director: _____ Date: _____
(Clinical Sections)

Laboratory Director or Designee: _____ Date: _____
(Non-clinical Sections)

Quality Assurance: _____ Date: _____

Additional comments/questions by reviewers/approvers (if applicable):

Section III

Part D is due 90 days from the director approval signature of Part A.

Attach any supporting documentation.

PART D: Supervisory Follow-Up/Verification of Corrective Action

Additional Follow-Up Notes /Verification of all corrective action(s) taken:

Has this corrective action been fully implemented and proven to be effective? ☐ Yes ☐ No

If NO, provide the following information, and then complete Part E at the end of the monitoring period.

For how long should monitoring be continued? _____

Who will monitor the corrective action? _____

Date discussed at the Section Meeting: _____

CAR ID Number: _____ **Date of** ☐ **Occurrence OR** ☐ **Discovery:** _____

Section III (PART D) Approval Signatures

Section III completed by: _____ Date: _____

Supervisor: _____ Date: _____

Technical Supervisor: _____ Date: _____
(Clinical Sections)

Medical Laboratory Director: _____ Date: _____
(Clinical Sections)

Laboratory Director or Designee: _____ Date: _____
(Non-clinical Sections)

Quality Assurance: _____ Date: _____

Section IV

PART E: Continued Monitoring

Complete if CAR cannot be closed out within 90 days of director approval signature of Part A, or if additional monitoring of the corrective action's effectiveness is necessary. If continued monitoring is needed, complete Part E by the date specified in Part D. Attach any supporting documentation.

Verification notes (Describe what was monitored and the proof of effectiveness or ineffectiveness):

Has this corrective action been fully implemented and proven to be effective? ☐ Yes ☐ No

If no, describe the remedial actions to be taken (ex., Repeating the root cause analysis, initiating a new CAR, etc.):

Section IV (PART E) Approval Signatures

Section IV completed by: _____ Date: _____

Supervisor: _____ Date: _____

Technical Supervisor: _____ Date: _____
(Clinical Sections)

Medical Laboratory Director: _____ Date: _____
(Clinical Sections)

Laboratory Director or Designee: _____ Date: _____
(Non-clinical Sections)

Quality Assurance: _____ Date: _____

PT Corrective Action/Root Cause Analysis Investigation Checklist

PT Event: _____ CAR ID Number: _____

Date Tested: _____ Date results received: _____

Test/Analyte needing investigation/corrective action:

_____

Original sample tested by: _____

Initial and date beside the item to confirm you have completed that part of the investigation. Attach documentation or an evaluation summary, as necessary. If the item is not applicable, record as N/A.

Clerical

1. Was the result correctly transcribed from the instrument report or worksheet? ☐ Yes ☐ No ☐ N/A
   Initial: ____ Date: ____
2. Was the correct instrument/method/reagent reported on the test form? ☐ Yes ☐ No ☐ N/A
   Initial: ____ Date: ____
3. Do the units of measure match between the result form and the instrument report/worksheet? ☐ Yes ☐ No ☐ N/A
   Initial: ____ Date: ____
4. Is the decimal place correct? ☐ Yes ☐ No ☐ N/A
   Initial: ____ Date: ____
5. Do the results reported on the result form match the result found on the proficiency testing evaluation report? ☐ Yes ☐ No ☐ N/A
   Initial: ____ Date: ____
6. Were your results graded within the appropriate peer group based on the method reported on the result form? ☐ Yes ☐ No ☐ N/A
   Initial: ____ Date: ____

A response of "No" to any of these questions could indicate a clerical error. Clerical errors may indicate a need for additional staff training, review of instructions provided with the PT, or investigation of the testing format provided by the proficiency testing provider.

Procedural

1. Were all procedures for testing followed on the day the proficiency testing was performed? Review run worksheets/consult with analyst(s) to confirm. . . . . ☐ Yes ☐ No ☐ N/A

   Initial: ____ Date: ____

2. Were all reagents, controls, and media within their expiration dates at time of use? . . . . . ☐ Yes ☐ No ☐ N/A

   Initial: ____ Date: ____

3. Was the analyst competency/training current at the time PT testing was performed? . . . . . ☐ Yes ☐ No ☐ N/A

   Initial: ____ Date: ____

4. Were all standards/Quality Control results for the testing acceptable? . . . . . ☐ Yes ☐ No ☐ N/A

   Initial: ____ Date: ____

5. Were microscopic examinations interpreted correctly? . . . . . ☐ Yes ☐ No ☐ N/A

   Initial: ____ Date: ____

6. Was staining performed and interpreted correctly? . . . . . ☐ Yes ☐ No ☐ N/A

   Initial: ____ Date: ____

A response of "No" to any of these questions could indicate a procedural error. These errors indicate inappropriate operation of an instrument or performance of a method. A review of the instructions provided with the PT material and/or a review of lab SOPs may be necessary.

Analytical

1. Was the most recent calibration acceptable and within expiration limits at the time PT testing was performed? . . . . . ☐ Yes ☐ No ☐ N/A

   Initial: ____ Date: ____

2. Was all instrument maintenance and service (including PMs) being performed on schedule at the time PT testing was performed? . . . . . ☐ Yes ☐ No ☐ N/A

   Initial: ____ Date: ____

3. Was the intended/correct result within the measurement range for the instrument/method? . ☐ Yes ☐ No ☐ N/A

   Initial: ____ Date: ____

4. Does a review of records indicate that there were no similar test/method problems noted prior to or after performing the PT testing? . . . . . ☐ Yes ☐ No ☐ N/A

   Initial: ____ Date: ____

5. Does a review of previous PT results indicate that test results have been evenly distributed across the range of expected results without bias? . . . . . ☐ Yes ☐ No ☐ N/A

   Initial: ____ Date: ____

A response of "No" to any of these questions could indicate an analytical error. These types of error could indicate a failure to follow recommended instrument maintenance or calibration instructions.

Specimen Handling

1. Were all samples, reagents, controls, and media being stored at their recommended temperatures? ☐ Yes ☐ No ☐ N/A

   Initial: _____ Date: _____

2. Were proficiency testing specimens reconstituted/thawed/prepared as described in the included instructions? ☐ Yes ☐ No ☐ N/A

   Initial: _____ Date: _____

3. Were any special instructions included in the testing package followed? ☐ Yes ☐ No ☐ N/A

   Initial: _____ Date: _____

4. Were the correct tests performed on the correct proficiency testing material? ☐ Yes ☐ No ☐ N/A

   Initial: _____ Date: _____

5. Was the PT material received in the lab within an acceptable amount of time after shipment? ☐ Yes ☐ No ☐ N/A

   Initial: _____ Date: _____

A response of "No" to any of these questions could indicate a specimen handling error. These types of errors could be caused by a failure to read the material provided with the survey.

Additional Investigation

1. **Interview the analyst.** Talk to the person who performed the procedure and ask if they understood the SOP, if they had questions about which controls, media, reagent that should have been used, etc. ☐ Yes ☐ No ☐ N/A

   Initial: _____ Date: _____

2. **Locate and retest PT samples if available.** Attach a review of new findings paired with original results. Include interpretation of new findings (within acceptable limits or the unknown organism identified, etc.). ☐ Yes ☐ No ☐ N/A

   Initial: _____ Date: _____

Investigated by: _____ Date: _____

Reviewed by: _____ Date: _____

Association of Public Health Laboratories

The Association of Public Health Laboratories (APHL) works to strengthen laboratory systems serving the public's health in the US and globally. APHL's member laboratories protect the public's health by monitoring and detecting infectious and foodborne diseases, environmental contaminants, terrorist agents, genetic disorders in newborns and other diverse health threats.

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