The Ins and Outs of the Proficiency Testing (PT) Program, Proper Use of Certified Reference Materials and Reagent Traceability
Quality System Requirements

- Management Review
- Standard Operating Procedures
- Internal Audits
- Corrective and Preventative Action
- Demonstrations of Capability
- Quality Control
- Training Documentation
- Records Management
- Proficiency Testing
- Fields of Certification
- Reagent Tracking and Traceability
• Regulatory Requirements for Proficiency Testing (PT) Providers
• Fields of Accreditation
• Reagent Tracking and Traceability
• Certified Reference Materials
PT Program Requirements for PT Providers
PT Program Background

Stakeholders:

- Accreditation Bodies: National Environmental Laboratory Accreditation Program (NELAP) and non-NELAP
- PT Providers
- Laboratories
- PT Provider Accreditors
- NELAP PT Program Executive Committee
- The NELAC Institute (TNI) PT Expert Committee
- Others
Applicable Regulations

- **TNI 2009 Volume 3** - “General Requirements for Environmental Proficiency Test Providers”

- **TNI 2009 Volume 4** - “General Requirements for an Accreditor of Environmental Proficiency Test Providers”

- **ISO 17043** - “Conformity Assessment. General Requirements for Proficiency Testing”

- **ISO Guide 34** - “General Requirements for the Competence of Reference Material Producers”

- **ISO 17011** - “General Requirements for Accreditation Bodies Accreditting Conformity Assessment Bodies”
PT providers must be accredited by a TNI-approved Proficiency Testing Provider Accrreditor (PTPA) for every field of proficiency testing which they offer in their PT Program.

Fields of Proficiency Testing (FoPT) tables outline the matrix, technology/method, analytes included in the PT Program.

- Managed by the PT Program Executive Committee.
PT Provider Accreditors

A2LA
• Advanced Analytical Solutions
• Environmental Resource Associates (ERA)
• New York Department of Health
• Phenova

ACCLASS
• Absolute Standards
• NSI Solutions
• Sigma- Aldrich RTC
Approval of PTPAs

• Ensure all regulatory requirements are met
• Approve policies and procedures used to approve PT Providers
• Conduct biennial assessments
  – PTPA Offices
  – PT Provider On-site observation
PT Program Oversight

- Semi-annual PTPA reports covering PT Performance information
  - Failure rates
  - Complaints and resolution

- Arbitrator of
  - Complaints concerning PTPAs received from AB or PT Providers
  - Disputes between PTPAs
Technical and Administrative

- 17011 Accredited
- Technical expertise conforming with Guide 34
- Expertise in statistical applications
- Capability to conduct on-site audits of PT Providers

Assessment of PT Providers

- Assessments must be designed to ensure PT Providers meet all requirements of Volume 3
- Additional requirements must be approved by the PTPEC
SOPs, Forms and Procedures

- PT Provider Application
- On-site assessment checklist
- Accreditation Process Procedures
- Revocation of a PT Providers accreditation
- Appeals process for accreditation determinations

Database

- Summary information of participant results and all sample verification, homogeneity and stability determinations
- Instructions for PT Provider data submittal
List of Accredited PT Providers

• Scope of Accreditation for all PT Providers readily available to stakeholders (A2LA and ACLASS Websites)

• Ensure PT Providers follow protocols regarding advertising and marketing of their accreditation status
Ethics and Confidentiality

- Shall serve as an impartial body to objectively evaluate information about PT Providers
- Shall be able to demonstrate freedom from financial conflict of interest
- Shall be unbiased in evaluating information
- Shall maintain confidentiality of proprietary information and treat all data as confidential information
Initial Application Review

• PT Provider qualifications
• Sample designs
• Analyte and sample scoring procedures
• Procedures used to validate new PT sample formulations are fit for use
• Adequacy of data processing and analysis techniques
• Confirmation of absence of conflict of interest
• Providing PT Provider with checklist to be used during assessment
On-Site Assessment

- Quality Management System
- Staff Qualifications
- Sample manufacturing and analytical verification procedures
- Procedures for Standards of Conduct and confidentiality of assigned values and participant results
- Data reporting systems including time periods
- Exit meeting including discussion of findings
- Final Report
- Report response including corrective action and objective evidence prepared by the PT Provider
Sample Verification and Study Data

• Concentrations
• Minimum number of analytes included where applicable (organics)
• Documentation of changes in initial assigned values
• Confirmation of calculations of assigned values and acceptance limits
• Verification of assigned values
• Homogeneity and Stability testing
Correct and complete analyte lists per scope of accreditation
• All NELAC Compliant samples that are produced

Process for handling complaints
• Documented with records available for review

Compliance with TNI Analyte codes
• TNI Manages a database with analyte codes

Appropriate study lengths, including announced start and end dates
• Requirements in Standards and verified through data submissions

Timeliness of customer reports to customers, ABs and PTPAs.
PT Provider Ongoing Monitoring cont.

Review critical operational parameters
• Changes in ownership or senior management
• Evidence of internal audits
• Evidence of management review

Unscheduled on-site assessments
• Persistent complaints
• Failure to respond to inquiries
• Evidence of non-conforming activities
PTPAs must evaluate all complaints and notify the affected PT Provider if the complaint warrants investigation. The PT Provider must resolve the complaint to the satisfaction of the PTPA.

Provide a summary of all PT Provider complaints to the PTPEC annually.

Review all complaints received by PT providers:
- Written summary
- All complaints unresolved after 90 days
PTPA may determine accreditation suspension or revocation for nonconformance with the TNI 2009 Standard

- Review of study data
- On-site assessments
- Corrective Actions associated with complaints

Formal written notification provided to the PT Provider including reasons for revocation/suspension

Appeals Process
Meet AB Requirements for PT Analysis
• Are there additional PT requirements beyond the NELAP FoPTs?
• Frequency and Schedule

PT Provider Accreditation
• Review PT Provider Scopes of accreditation before ordering PT studies

Correct Reporting
• Significant figures
• Units
• Appropriate LOQs are used
Laboratory Responsibility

Be Proactive

• Communicate anything unusual to the PT Provider (sample appearance, precipitates, packaging problems)

• Analyze PT samples as close to the protocols used to analyze routine as possible
  – Same QC
  – Routine Analyst
Laboratory Responsibility

Thoroughly Troubleshoot Failures

• Obtain study data from PT Providers
• Use root cause analysis
• Don’t fault the sample until all other possible causes have been eliminated
Facilitate Program Improvement

- Defined process for submitting complaints
- Work with AB to address if PTs are fit for use
- Join TNI and volunteer for the PT Expert Committee or the PTP Executive Program
Questions
Commercial- NELAC 2003-

- 5.5.6.4- Documentation and labeling of Standards, reagents, and Reference Materials

Non-Commercial-1 VAC30-45-

- No regulatory Reference
- Recommended QA Protocol:
  - Troubleshooting
  - Defensibility
It is better to record too much information than not enough.

If it isn’t recorded there is no objective evidence it happened.

Enough detail must be recorded to reconstruct everything that happened as long as data records are maintained.
The ability to verify the history, location, or application of an item by means of documented recorded identification.

The capability (and implementation) of keeping track of a given set or type of information to a given degree, or the ability to chronologically interrelate uniquely identifiable entities in a way that is verifiable.
Reagent Tracking and Traceability

Traceable from the time of receipt, through use in analysis through expiration and/or disposal

Helpful for Troubleshooting

Validates correct protocols employed

Documents appropriate reagent grade used to meet method requirements
Reagent Log
- Lot Numbers
- Number of Containers and When Received
- Shelf Life
- When Put into Use
- When Taken out of Use

Reagent Preparation Log
- Volume Prepared
- Lot Numbers of all Reagents Used
- Analyst Preparing
- Holding Time (Prep and expiration dates)
Sample Preparation Logs

- Sample Date and Time (if holding time is less than 48 hrs.)
- Volume Sample Used
- Reagents and Quantities Added
- Digestion/Distillation Start and End
- Temperature
- Unusual observations
- Identification of Analyst(s)
Storage and Preparation Temperature recordings

– Refrigerators, incubators, Ovens, etc.
– Ensure Thermometers Have had Annual Verification
– Ensure Thermometer is Sensitive Enough and in Proper Range (tenths place graduations)
– Celsius or Farenheit
Pipet/Dispenser Maintenance

- Serial Number
- Received
- Put into Service
- All Maintenance and Verifications
  - Parts replaced and serial numbers if applicable
- Removed from Service and Disposal
Reagent Tracking and Traceability

Logbook or Spreadsheet

- Parameter for which reagent is used
- Manufacturer
- Product
- Lot Number
- Number of Containers
- Date of Receipt
- Expiration Date
- Date Put into Use
- Date Taken out of use
- Storage Conditions
Reagent preparation documentation

• Name of chemical or solution
• Preparation date
• Expiration date
• Analyst identification
Traceability from reagent to analysis

- Preparation dates
- Standard lot numbers
- Reference to SOPs for preparation directions
Questions
Certified Reference Materials

Virginia Good Laboratory Practices
Shawn Kassner
Sr Product Manager
Phenova, A Phenomenex Company
What are we talking about?

- ISO 17025 requirements for labs?
- How does this impact laboratories?
- What is the reality/status of the 2nd source requirements today?
- What are the other uses for CRMs and Quality Control (QC) Samples?
ISO 17025 Requirements
ISO 17025 Second Source Requirement

• 5.9 Assuring the quality of test and calibration results

• 5.9.1 The laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results. This monitoring shall be planned and reviewed and may include, but not be limited to, the following:

  a) regular use of certified reference materials and/or internal quality control using secondary reference materials;
Historical 2\textsuperscript{nd} Source Interpretation

- Independent raw material
- Independent reference material vendors
- Independent manufacturing lots
- Independent all of the above!

- For all ISO 17025 accreditations – Laboratories, PT Providers, etc!
ISO 17025 requirements for labs and CRM/PT providers, are they the same?

YES!
What are the best practices of CRM Providers?
What is a CRM?

- ISO Guide 30

- **2.2 certified reference material CRM** - reference material characterized by a metrologically valid procedure for one or more specified properties, accompanied by a certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability

**NOTE 1** The concept of value includes qualitative attributes such as identity or sequence. Uncertainties for such attributes may be expressed as probabilities.

**NOTE 2** Metrologically valid procedures for the production and certification of reference materials are given in, among others, ISO Guides 34 and 35.

**NOTE 3** ISO Guide 31 gives guidance on the contents of certificates.
Best Practices – What do we do?

- Manufacturing and analytical requirements are found in ISO Guides 34 and 35.
- ISO Guide 31 tells us what has to be CRM Certificates of Analysis.

- But what do we really do....
Manufacturing Best Practices

• All raw materials are tested for purity and identity.

• Impurities are identified and purity values are accounted for in manufacturing.

• All balances are NIST calibrated on a schedule – usually annually.

• All glassware is Class A grade and calibrated.
WHY?

• Calibrated balances and glassware allow us to:
  – Calculate manufacturing uncertainties
  – Ensure the accuracy of our measurements
  – Ensure the consistency of our measurements
  – Ensure the quality of our measurements
Verification Best Practices

• For ISO 17025 and Guide 34 accredited providers
  – Validated analytical methods
    • Calculated method repeatability
  – Calibrate with independent CRMs,
    • Typically with 2\textsuperscript{nd} and 3\textsuperscript{rd} sources.
  – Verify accuracy of Certified Values.
  – Verify the homogeneity of each lot.
WHY?

• Validated methods and method repeatability allow us to calculate analytical uncertainties.

• Using independent CRM, 2\textsuperscript{nd} and 3\textsuperscript{rd} sources allows us to:
  – Ensure that certified values are independently verified
  – Benchmark across the industry
TOTALLY WHY?

- Each step in the process of the CRM provider involves calibrated equipment and calculated uncertainty.
- All of these uncertainties are used to calculate the expanded uncertainty on the Certificate of Analysis.
How does this impact laboratories?
Laboratory Requirement

• Must also meet the ISO 17025 and TNI second source requirements.
• a) regular use of certified reference materials and/or internal quality control using secondary reference materials;
• The requirements have been inconsistently interpreted and applied.
Laboratory Impact

• Laboratories are purchasing CRM’s that have uncertainty values calculated at each step of manufacturing and verification.

• Each CRM has been evaluated to multiple sources.
Laboratory Impact

• These steps ensure that laboratories using CRMs can rely on the fact that a single manufacturing event or CRM lot has its own manufacturing and analytical pedigree.
What is the reality/status of the 2nd source today?
Historical 2\textsuperscript{nd} Source Interpretation

- Independent raw material
- Independent reference material vendors
- Independent manufacturing events
- Independent all of the above!

- For all ISO 17025 accreditations – Laboratories, CRM Providers, etc!
Raw Materials Reality

• Many raw materials are only available from a single primary source.
  – PCBs, PCB congeners, PAHs
• More raw materials are moving in this direction.
• Neat chemical providers are consolidating their inventories and re-focusing their core business.
Reality - Reference Material Vendors

• Economics
  – Many laboratories and laboratory networks have business agreements with a single vendor.
  – Consolidating vendors has become a common business practice.

• Custom standards have become common for many laboratories

• Analyte offerings vary from vendor to vendor

• Not all vendors offer the same suite of CRMs
Independent Manufacturing Lots

- YES!
- Each vendor does have the ability to offer multiple lots of a CRM.
- **Lot** – a definite amount of a material produced during a single manufacturing cycle and intended to have uniform character and quality. (per ISO/IEC 9001:2000)
Independent Manufacturing Lots

• Each lot having its own historical manufacturing and analytical pedigree
• Each lot has its own uncertainties; manufacturing, analytical, and expanded.
• Availability of a second lot allows laboratories to meet the ISO 17025 requirements.
New Definitions

- Individual lots can be seen as separate sources.
- Starting to be adopted throughout the industry.
- TNI - the definition is being added to Quality Systems for the 2015 TNI standards.
CRM and QC Other Uses
Demonstration of Capability

• Don’t have time for a PT?
  – Blind QC’s and CRM’s may be used to provide evidence of DOC.
  – Great for use when you need to add an analyst *FAST*
Method Development

• Known quality control standards with:
  – Extended analyte lists
  – Analytically Verified Certified Values
  – Known Uncertainties
• **Corrective Action and Preventative Action**
  
  – Check that your corrective action is what corrected the problem
  
  – Monitor periodically to ensure that your new procedures are effective
On-Going QC Monitoring

• Great labs think a like!
  – Many labs have a regularly scheduled QC program.
  – Keeps your analysts familiar with the instructions and format of PTs.
  – Allows you to monitor the quality of your lab using 3rd party standards with acceptance limits.
Questions?
Thanks!

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Proficiency Testing Resources

Virginia Good Laboratory Practices

Shawn Kassner
Sr Product Manager
Phenova, A Phenomenex Company
PT Resources Available

- TNI Fields of Proficiency Testing (FoPT) tables.
- Provider Resources
  - Instructions
  - Data Reporting Sheets
  - Websites
- After study help!
TNI FoPT tables

• What are they?
• What’s in them?
• Where do they come from?
• How do we use them?
• Where are they?
What are they?

- FoPT tables are all of the criteria for PT samples for **ALL** TNI accredited providers.
- FoPT tables are used for:
  - Manufacturing of PTs
  - Calculation of Acceptance Limits
  - Reporting Information for Laboratories
# NELAC PT for Accreditation

## Fields of Proficiency Testing with PTRLs

### Non-Potable Water (NPW)

*Effective January 4, 2010*

<table>
<thead>
<tr>
<th>Matrix</th>
<th>EPA Analyte Code</th>
<th>NELAC Analyte Code</th>
<th>Analyte_{1,2}</th>
<th>Conc Range</th>
<th>Acceptance Criteria_{3,4,5,6}</th>
<th>NELAC PTRL_{7}</th>
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<tbody>
<tr>
<td>NPW</td>
<td>0038</td>
<td>1530</td>
<td>Demands_{12}</td>
<td>mg/L</td>
<td>a        b        c        d</td>
<td>mg/L</td>
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<tr>
<td>NPW</td>
<td>0102</td>
<td>1555</td>
<td>Carbonaceous BOD_{12}</td>
<td>15 to 250</td>
<td>0.6312</td>
<td>0.1919</td>
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<tr>
<td>NPW</td>
<td>0036</td>
<td>1565</td>
<td>COD_{12}</td>
<td>30 to 250</td>
<td>0.9517</td>
<td>0.4748</td>
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<tr>
<td>NPW</td>
<td>0037</td>
<td>2040</td>
<td>TOC_{12}</td>
<td>6.0 to 100</td>
<td>0.9904</td>
<td>0.1647</td>
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<table>
<thead>
<tr>
<th>Minerals</th>
<th>mg/L</th>
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<th>mg/L</th>
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<tbody>
<tr>
<td>NPW</td>
<td>0027</td>
<td>1505</td>
<td>Alkalinity, total (CaCO₃)</td>
<td>10 to 120</td>
</tr>
<tr>
<td>NPW</td>
<td>0023</td>
<td>1035</td>
<td>Calcium</td>
<td>3.5 to 110</td>
</tr>
<tr>
<td>NPW</td>
<td>0028</td>
<td>1575</td>
<td>Chloride</td>
<td>35 to 275</td>
</tr>
<tr>
<td>NPW</td>
<td>0029</td>
<td>1730</td>
<td>Fluoride</td>
<td>0.3 to 4</td>
</tr>
<tr>
<td>NPW</td>
<td>0022</td>
<td>1755</td>
<td>Hardness, total (CaCO₃)</td>
<td>17 to 440</td>
</tr>
<tr>
<td>NPW</td>
<td>0024</td>
<td>1085</td>
<td>Magnesium</td>
<td>2.0 to 40</td>
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<tr>
<td>NPW</td>
<td>0026</td>
<td>1125</td>
<td>Potassium</td>
<td>4.0 to 40</td>
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<tr>
<td>NPW</td>
<td>0025</td>
<td>1155</td>
<td>Sodium</td>
<td>6.0 to 100</td>
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<tr>
<td>NPW</td>
<td>0020</td>
<td>1610</td>
<td>Spec. Cond. (25°C)</td>
<td>200 to 930 μmhos/cm</td>
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<tr>
<td>NPW</td>
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<td>2000</td>
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<tr>
<td>NPW</td>
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<tr>
<td>NPW</td>
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<td>Total Dissolved Solids at 180°C</td>
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<td>1950</td>
<td>Total Solids</td>
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<td>1515</td>
<td>Ammonia as N</td>
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<tr>
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<td>0032</td>
<td>1810</td>
<td>Nitrate as N</td>
<td>0.25 to 40</td>
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<td>NPW</td>
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<td>Nitrate-nitrite as N</td>
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<tr>
<td>NPW</td>
<td>1840</td>
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<td>Nitrate as N</td>
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<td>0034</td>
<td>1795</td>
<td>Total Kjeldahl-Nitrogen_{12}</td>
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<td>NPW</td>
<td>0035</td>
<td>1910</td>
<td>Total Phosphorus</td>
<td>0.5 to 10</td>
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</table>
### Analyte List

<table>
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<tr>
<th>Matrix</th>
<th>EPA Code</th>
<th>NELAC Code</th>
<th>Analyte</th>
<th>Concentration Range</th>
<th>Acceptance Criteria</th>
<th>NELAC PTOL</th>
</tr>
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<tbody>
<tr>
<td>NPW</td>
<td>0038</td>
<td>1530</td>
<td>Demands</td>
<td>mg/L</td>
<td>a</td>
<td>0.6312</td>
</tr>
<tr>
<td>NPW</td>
<td>0102</td>
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<td>5-day BOD</td>
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<td>b</td>
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<td>NPW</td>
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<tr>
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<td>2040</td>
<td>COD</td>
<td>mg/L</td>
<td>d</td>
<td>0.9904</td>
</tr>
</tbody>
</table>

### Estimated % Std Deviation

- Estimated mean
Where do they come from?

- PT Program Executive Subcommittee
  - Gathers data from PT provider’s from each study.
  - Statistically reviews the data collected per a TNI SOP.
  - Develops concentration ranges and acceptance criteria.
How do we use them?

• Concentration Ranges
  – Know what range your PTs are going to be within.

• PTRL – PT Reporting Limit
  – Know how low you have to go!

• Acceptance Criteria
  – Know how you are being graded.
Where are they?

- All TNI FoPT tables can be found on the TNI website
- [http://www.nelac-institute.org/content/NEPTP/fopt.php](http://www.nelac-institute.org/content/NEPTP/fopt.php)
- Click of “NELAP”
PT Provider Instructions

• Instructions
  – How to prepare the PT sample
  – Lists the following
    • Analytes in the PT sample
    • Concentration Range of each analyte
    • May list the PTRL
  – May include some guidance for analysis
PT Provider Website

• Data Entry
  – Allows you to select reporting options for your PT
  – Allows you to select your ABs
  – Each Standard has listed:
    • Analytes in the PT sample
    • Concentration Range of each analyte
    • May list the PTRL
Call your Provider. Please.

• Inspect your PT the day they arrive.
  – Call your provider immediately for replacements for broken samples

• Instructions questions? Call!

• Samples broken in the lab? Call!

• Web site questions? Call!
How can your PT Provider Help After the Study?
Technical Help

• Speak with the Experienced Technical Staff
  – Chemists
  – Microbiologists
• They manufactured the standard
  – Have insight into the analyses
  – Have historical data to tell what your results should be
  – How the standards were made
What can your PT Provider do for YOU!

- **Study statistics**
  - **Study Mean**
    - How did you compare to your peer groups?
    - How did the mean compare to the Assigned Value?
  - **Study Reported Data**
    - How did you compare to labs running the same method?
    - How did other methods perform?
    - How did your technology perform?
    - Where did you fall within the data? High? Low?
Is the PT standard any good?

- **Verification/Homogeneity Analysis**
  - Verification Mean must be within 1/3 of lab limits
  - Verification standard deviation/homogeneity must be within ¼ of the lab limits
  - All standards must pass to be used in a PT study.

- **Stability Data**
  - PTs analyzed after the study closes.

- **Ask for the data!!**
Call your Provider. Please.

• We want to see you succeed.
• Make us a part of your corrective action investigation.
• Do not be afraid to call.
If it’s not the PT??????
Corrective Action

Another Way To Look for Improvement
Corrective Action

“Not Acceptable” Or Quality Non-Conformance
Threatened Accreditation • Jeopardized Customer Data

Room For Improvement
Better Methods • Improve Training • Update Procedures

Strategy and Planning
Corrective Action • Preventive Action
Issue/Failure

01 Root Cause Analysis
Identify the underlying cause of the failure or issue

02 Corrective Action Strategy
Implementing solutions to remedy the failure or issue

03 Preventive Action Strategy
A change in policy or procedure that helps mitigate a repeat occurrence of the failure or issue

04 Continuous Improvement
On-going monitoring of laboratory practices to ensure the efficacy of corrective and preventive actions and/or to identify any other vulnerabilities to your quality program.
## Root Cause Analysis

<table>
<thead>
<tr>
<th>Problem Sources</th>
<th>RCA Tools</th>
<th>Data Sources</th>
<th>Evaluation Sources</th>
</tr>
</thead>
</table>
| - Which PT Failed?  
- What Was The Quality Failure?  
- Which Data Was Out of Control? | - The 5 Whys (p. 8)  
- The 4 Ms (p. 9)  
- Root Cause Investigation Checklist (pp. 10-11) | - PT Manage® (p. 21)  
- Lab Notebooks  
- Digital Records  
- Technician Testimonial  
- FoPT Tables  
- PT Provider Paperwork  
- Laboratory Benchsheets  
- PM Records  
- Calibration Records  
- Instrument Inspection  
- Training Records | - Review with Subject Matter Experts  
- Consult with Phenova’s Technical Team  
- Evaluate with QC Standards (p. 22) |

### Problem Sources
- Which PT Failed?  
- What Was The Quality Failure?  
- Which Data Was Out of Control?

### RCA Tools
- The 5 Whys (p. 8)  
- The 4 Ms (p. 9)  
- Root Cause Investigation Checklist (pp. 10-11)

### Data Sources
- PT Manage® (p. 21)  
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- Instrument Inspection  
- Training Records

### Evaluation Sources
- Review with Subject Matter Experts  
- Consult with Phenova’s Technical Team  
- Evaluate with QC Standards (p. 22)
5 Whys Example

Example: pH PT Failure.

1) Why did the pH PT result fail?
   The pH calibration standards and reagents expired

2) Why were they used?
   No new standards available for use

3) Why were there no new standards available?
   The order was placed the day the standards expired

4) Why was there a delay?
   No one noticed until the day the standards expired

5) Why did no one notice?
   No one had specific responsibilities for the standards or there was lack of training
4 M Diagram

How to Use the 4Ms

Write down the categories and brainstorm all the possible reasons why it happened as a question in relation to the 4M categories and try to determine the answer for each.

- Were working solutions made correctly?
- Were any materials expired?
- Were materials accurately labeled?
- Were materials contaminated?
- Were the correct materials used?

- Do my instruments work correctly?
- Were they calibrated?
- Was the performance maintenance done?
- Were the data entry protocols followed?

- Were the protocols clear and understandable?
- Were procedures clearly defined?
- Were the laboratory working conditions optimal for analysts
- Were laboratory technicians working according to Protocol?
- Were Analyst aware of problems?
- Was training conducted correctly and regularly?
- Is the level of expertise appropriate?
## Root Cause Investigation Checklist

The following checklist defines the items that may be reviewed when evaluating a “Not Acceptable” PT evaluation in order to prepare an efficient corrective action and preventive action procedure. This checklist may be filed with other associated PT records as determined by your laboratory’s Quality Management System. Note: Multiple causes may contribute to an out-of-control PT result.

### Completed by:

<table>
<thead>
<tr>
<th>PT Study ID:</th>
</tr>
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<table>
<thead>
<tr>
<th>Date:</th>
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<table>
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<tr>
<th>Sample ID:</th>
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<table>
<thead>
<tr>
<th>Analyte/Method:</th>
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</table>

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>Comments</th>
</tr>
</thead>
</table>

### Sample Prep

- **Was the sample properly prepared by following Phenova’s work instructions (i.e., dilution volumes, properly preserved)?** Please refer to your documented quality records.

| ☐ | ☐ |

- **Was the sample prepared (i.e., digested or extracted) and analyzed within the recommended hold time?** (Holding time for amputated samples begins once the vial is opened).

| ☐ | ☐ |

### Reporting

- **Please review reporting documents to determine any transcription errors. Were there any erroneous reporting of the results?**

| ☐ | ☐ |

- **Were dilution schemes performed correctly and applied correctly in the calculation of the final result?**

| ☐ | ☐ |

- **For any dilution schemes performed (i.e., original result exceeded the calibration range), did they provide detection within the calibration range?**

| ☐ | ☐ |

### Identification

- **Was the reported value confirmed using a second analytical column, if applicable?**

| ☐ | ☐ |

- **If both a primary and confirmation column were used, was there a significant difference between the two results?**

| ☐ | ☐ |

- **For any dilution schemes performed (i.e., original result exceeded the calibration range), did they provide detection above the mid-range of the calibration?**

| ☐ | ☐ |
Corrective Action Strategy

Addressing an “out of control data point” or “not acceptable” PT result by finding a solution to eliminate the root cause(s).

**PLAN**
Establish the objective and process necessary to identify the solution(s) that may resolve the non-conformance.

**DO**
Implement the solution(s), execute the process and collect any data if applicable.

**ACT**
If the Check step demonstrates that the plan and solution(s) is effective, make it part of your process, otherwise re-strategize. If not go back to step 1 (Plan).

**CHECK**
Study the results of the plan and check against the expected ideal outcome. Did the solution fix the problem? Use QC Standards to corroborate your findings.
Preventive Action Strategy

An implemented process change to address the vulnerability found in your quality program to significantly reduce or eliminate the probability that the underlying source of your root cause will happen again.
Preventive Action Examples

**Schedule Instrument Maintenance**

Create a log book that notes when parts, reagents, or systems were created, replaced and/or supported for future reference.

**Accreditation Management**

Implement internal policy/procedures to keep track of your accreditation. Review application renewal dates, QA results, or accreditation fees.

**Quality Assurance Program Review**

Managerial review of working groups within the program to ensure performance integrity. Examples include, training records, demonstration of capability, SOP evaluation, analysts evaluation, method performance evaluation.
Continuous Improvement

Historical Performance

Accreditation Tracking

Analyst Performance

Trending Data

Method Comparison

PT Statistics

PT Manage
Analytics & Reporting Software
How QC Standard Fit In Your Quality Program

**Routine Internal Quality Evaluation**
Verify your laboratory or instrumentation are in control and meet your data quality objectives.

**Train Your Analytical Staff**
A powerful tool in your training regimen. Staff can analyze QC standards as if they are real-world samples and results can be compared with known data.

**Root Cause Investigation**
Determine root causes for a “Not Acceptable” and identify your corrective action.

**Corrective Measure Investigation**
Does your corrective action practice make sense; is it working?
4 Steps to a Stronger Quality Program

- Root Cause Analysis
- Corrective Action Strategy
- Preventive Action Strategy
- Continuous Improvement

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Questions?
Thank you!

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