NJ Water Environmental Association

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How Can Your PT Provider Help?

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.

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

Not Acceptable PT Evaluation

Out of Control Data

01

Root Cause Analysis

Identify the underlining 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.

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Root Cause Analysis

01 Identify the Problem

Problem Sources

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

02 Map Out Potential Causes

RCA Tools

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

03 Data Collection

Data Sources

- 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

04 Root Cause Identification

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.

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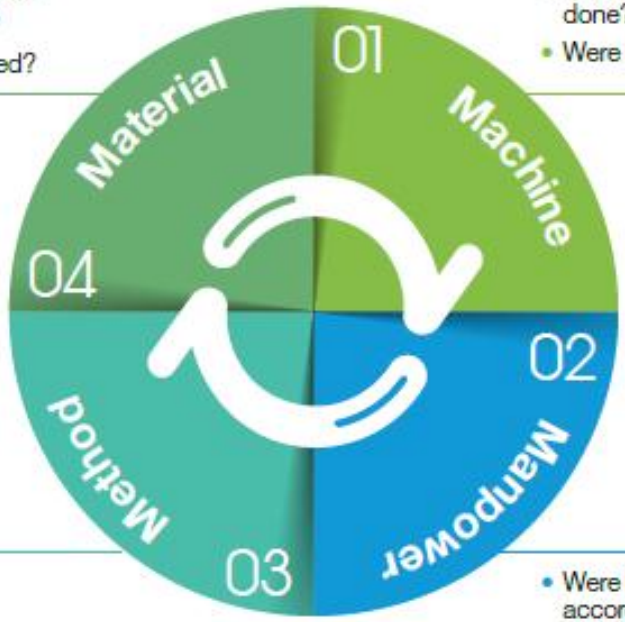
4 M Diagram

How to Use the 4Ms

Write down the categories and brainstorm all the possible reason 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

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: **PT Study ID:**

Date: **Sample ID:**

Analyte/Method:

	Yes	No	Comments
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 ampulated samples begins once the vial is opened).	☐	☐	
Reporting			
Please review reporting documents to determine any transcription errors. Were there any erronous 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

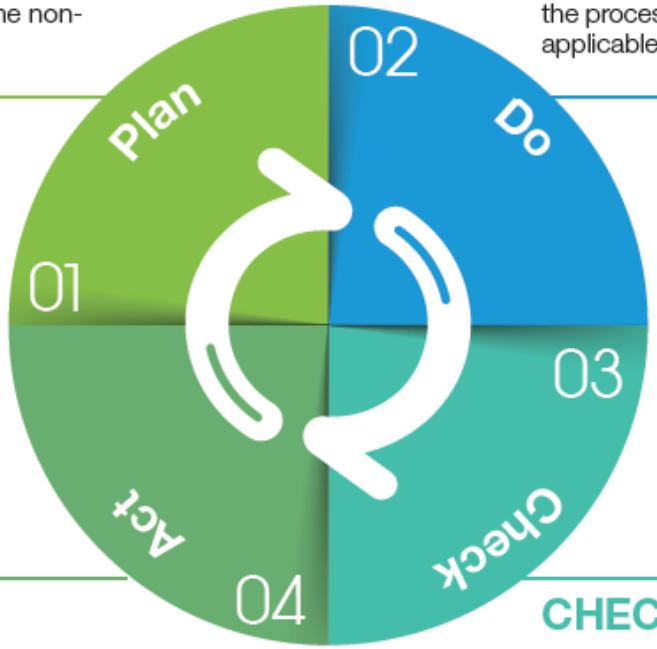
Addressing an “out of control data point” or “not acceptable” PT result by finding a solution to eliminate the root cause(s).

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

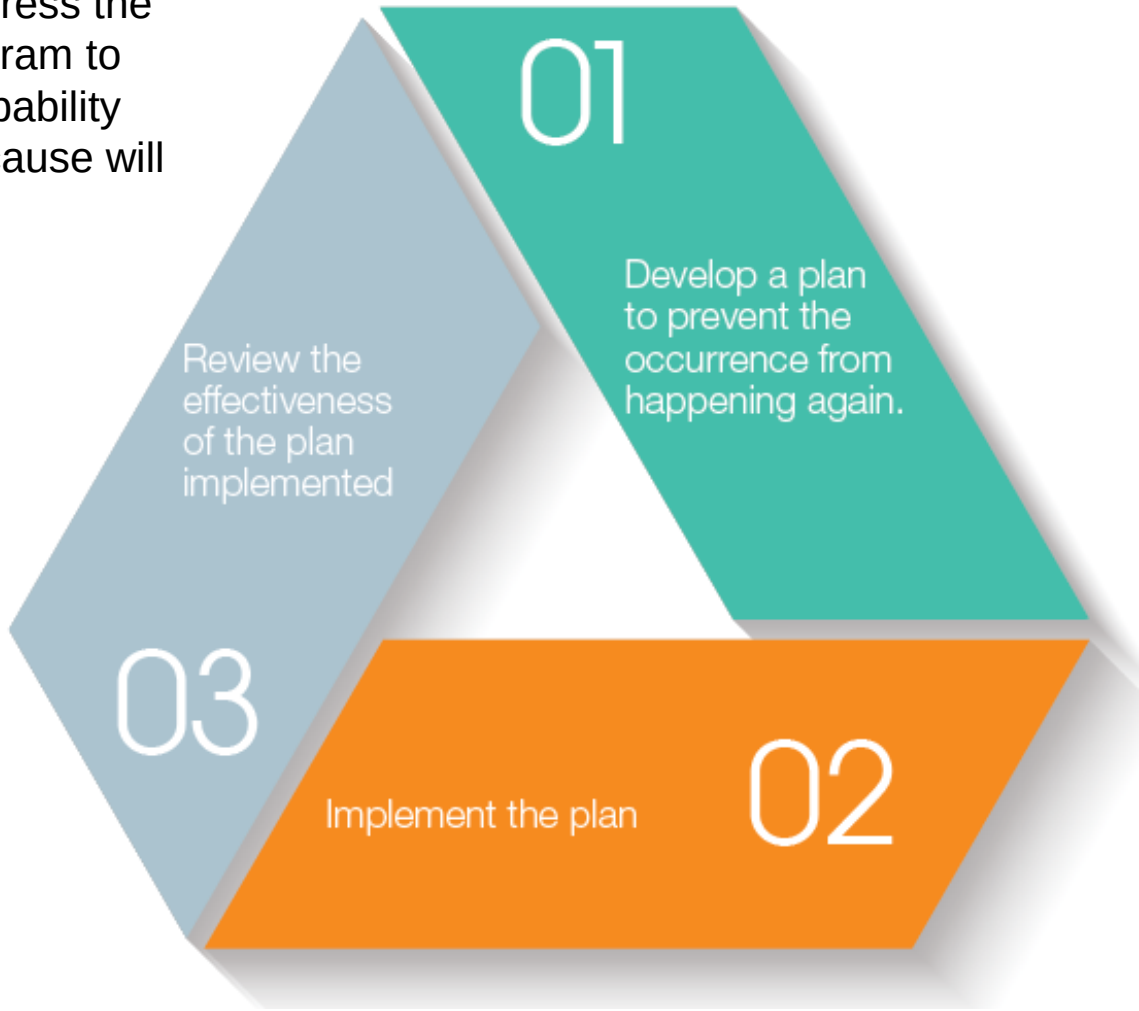
If the Check step demonstrates that the plan and solution(s) is effective, make it part of your process, otherwise re-strategize. If not go back to step 1 (Plan).

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 a 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 prorgam to to ensure peformance integrity. Examples include, training records, demonstration of capability, SOP evaluation, analysts evalution, method performance evaluation.

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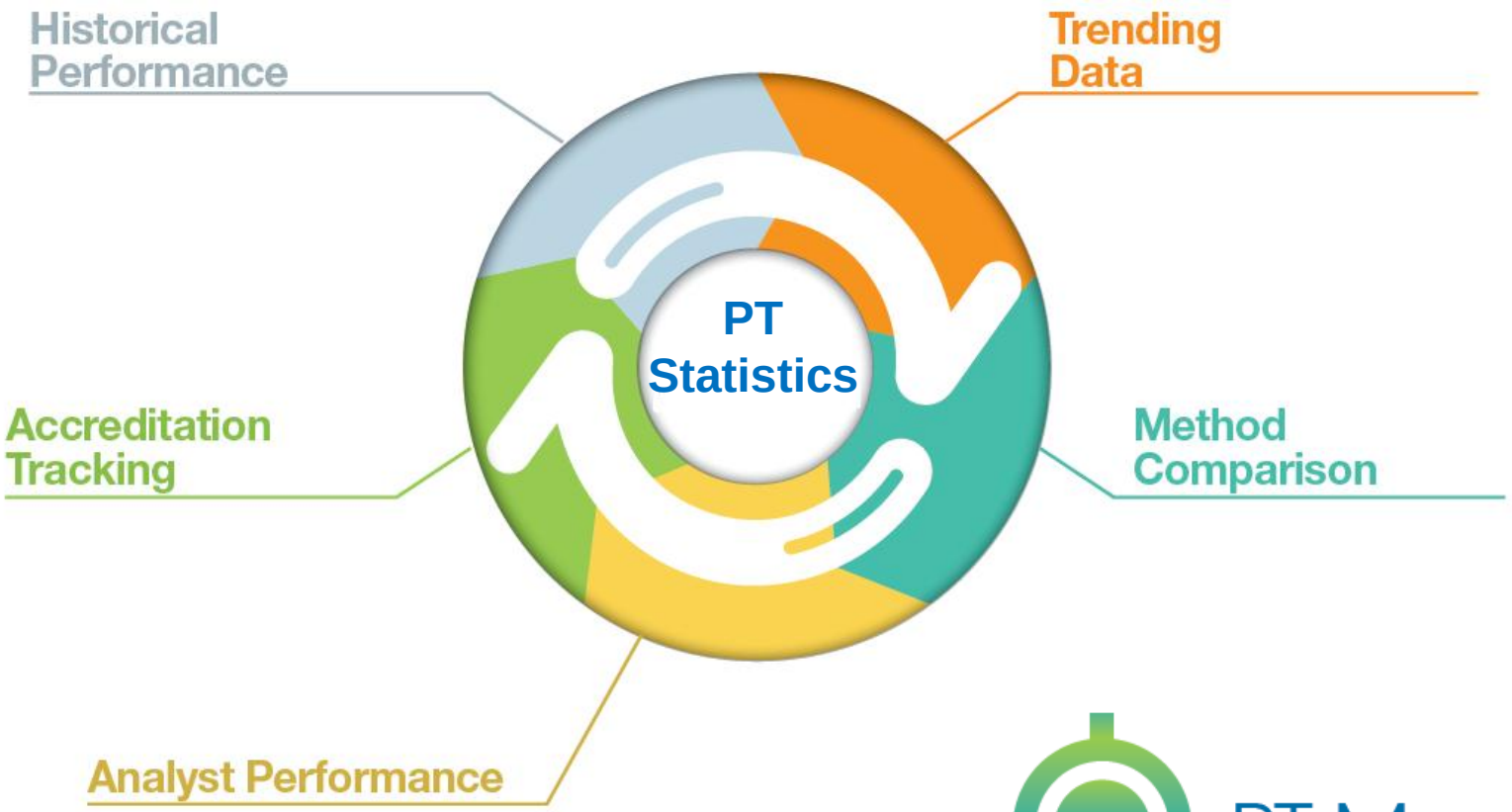
Continuous Improvement



PT Manage™
Analytics & Reporting Software

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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

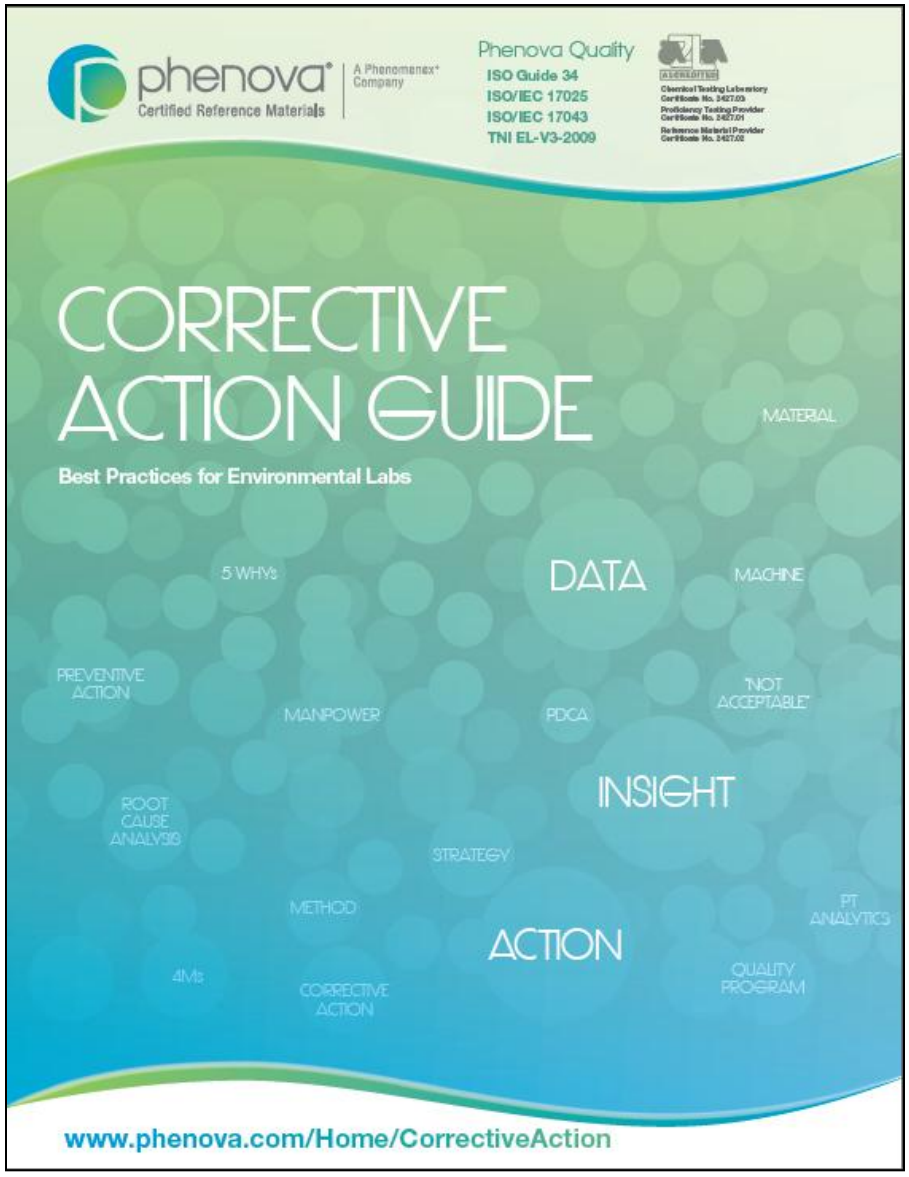
A powerful tool in your training regimen. Staff can analyze QC standards as if they are real-world samples and results can be compared with known data.

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

Get Your Free Copy

www.phenova.com/correctiveaction

Questions?
Thank you!

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