



the standard in safety

Did You Get the Correct Results?

Proficiency Testing (PT) from the Point of View of the Accreditation Authority

Eugene J. Klesta

Underwriters Laboratories

September 17, 2007

Did You Get the Correct Results?

- Accrediting Authorities:
 - know the value of Proficiency Testing (PT) samples
 - determine the capability of the laboratories
 - want acceptable, consistent results
 - use samples with known target concentrations

Did You Get the Correct Results?

- US Department of Agriculture
 - Pesticide Data Program (PDP)
 - All PDP laboratories analyzing water will participate in PT sets designed by MPO and administered by a selected commercial vendor.
 - Technical Director shall be responsible for overall monitoring of the proficiency of PDP laboratories.

Did You Get the Correct Results?

- US Department of Agriculture
 - Microbiological Data Program (MDP)
 - Proficiency Testing (PT) samples will be analyzed according to the current MDP Semi-Annual Program Plan and the particular test protocol supplied by the USDA Monitoring Program Office (MPO)
 - PT samples prepared by the laboratory Quality Assurance Unit (QAU) and transferred to the Technical Program Manager (TPM) or designee for analysis

Did You Get the Correct Results?

- US Environmental Protection Agency
 - Proficiency Testing (PT) studies provide an objective demonstration that participating laboratories are capable of producing valid data for monitored pollutants.
 - PT vendors manufacture and distribute samples to the participating laboratories who then submit their analytical results to these vendors for evaluation.

Did You Get the Correct Results?

- US Environmental Protection Agency
 - PT vendors then send evaluations of the submitted data to the laboratory and any other designated certifying/accrediting authority.

Did You Get the Correct Results?

- USEPA: 40 CFR 141.23 (k)(3)
 - Analyze Performance Evaluation (PE) samples provided by EPA, the State or by a third party (with the approval of the State or EPA) at least once a year.
 - For each contaminant that has been included in the PE sample and for each method for which the laboratory desires certification achieve quantitative results on the analyses that are within the following acceptance limits:

Did You Get the Correct Results?

<i>Contaminant</i>	<i>Acceptance Limit</i>
Antimony	± 30 at ≥ 0.006 mg/L
Arsenic	± 30 at ≥ 0.003 mg/L
Asbestos	2 standard deviations based on study statistics
Barium	± 15 at ≥ 0.15 mg/L
Beryllium	± 15 at ≥ 0.001 mg/L
Cadmium	± 20 at ≥ 0.002 mg/L
Chromium	± 15 at ≥ 0.01 mg/L
Cyanide	± 25 at ≥ 0.1 mg/L
Fluoride	± 10 at ≥ 1 to 10 mg/L
Mercury	± 30 at ≥ 0.0005 mg/L
Nickel	± 15 at ≥ 0.01 mg/L
Nitrate	± 10 at ≥ 0.4 mg/L
Nitrite	± 15 at ≥ 0.4 mg/L
Selenium	± 20 at ≥ 0.01 mg/L
Thallium	± 30 at ≥ 0.002 mg/L



Did You Get the Correct Results?

- Laboratories need some type of certification or accreditation to operate effectively in their particular “business arena.”
- Customers of laboratories, which may be internal and/or external, want some way to know that the quality of analytical data is the best available from the laboratory they are using.

Did You Get the Correct Results?

- How do these customers achieve their goal?
 - They can audit the laboratory and provide their own PT samples.
 - They can select a laboratory that is certified by the state.
 - They select a laboratory accredited by NELAP, USDA or FDA.

Did You Get the Correct Results?

- Accreditation Authorities:
 - typically audit the laboratories
 - require acceptable performance on PT samples
 - administrative process that requires the laboratories
 - to describe their scope of accreditation
 - submit fees for the accreditation
 - pay for the performance of an on-site assessment

Did You Get the Correct Results?

- Scope of Accreditation
 - very important in determining the expertise of the laboratory
 - may need to contact multiple Accrediting Authorities to be accredited in all areas
 - focus on drinking water analysis
 - Regulated pesticides
 - Regulated volatiles
 - Metals
 - Radiochemistry, etc.

Did You Get the Correct Results?

- Safe Drinking Water Act (SDWA)
 - lists hundreds of methods
 - which include multiple analytes
 - even when a laboratory only provides analysis of regulated compounds, there are hundreds of compounds for which proficiency must be demonstrated

Did You Get the Correct Results?

- During the assessment, Accrediting Authorities:
 - will review performance on PT samples
 - look at the following related to the analysis of the PT samples:
 - Traceability
 - Calibration
 - Record keeping
 - Training

Did You Get the Correct Results?

- Accreditation Authorities review Proficiency Testing performance:
 - Initially with their application
 - On a regular basis between scheduled assessments
 - results sent directly to them from the PT providers
 - compliance with the required frequency
 - results have not been altered in any way

Did You Get the Correct Results?

- United States Drinking Water Laboratory accreditation system:
 - requires a frequency of two PT studies per year
 - all analytes must have acceptable results in two of the last three PT studies
 - PT studies are used to develop regression constants for acceptability of results

Did You Get the Correct Results?

- PT provider
 - inserts the target quantity
 - upper and lower limits of acceptance are calculated
 - using the published regression constants
 - reports results to the laboratory
 - Reports results to the Accrediting Authority

Did You Get the Correct Results?

- New methods and new analytes
 - categorized as experimental tests
 - use at least one year's experimental data to establish acceptance criteria constants
 - method includes multiple analytes
 - produce acceptable results for 80%
 - a sample that contains 10 to 14 analytes the laboratory must not produce failing results for more than two analytes

Did You Get the Correct Results?

- Corrective action process is required when performance does not meet the criterion
 - analyze supplemental PT samples
 - investigates the cause of the failing result
 - minimum amount of time between failed PT results and the make-up PT.
 - avoid loss of accreditation for an analyte or a method

Did You Get the Correct Results?

- Performance criteria are prescribed in federal statutes
 - overlay on top of the criteria determined by the accreditation authority
 - EPA method for volatile organics (524.2) includes criteria for acceptability of quality control sample recoveries at $\pm 30\%$ recovery
 - internal standard, surrogate standard and laboratory-fortified blank are all judged based on this 30% window

Did You Get the Correct Results?

- Performance criteria (cont'd)
 - 40 CFR 141.24 (f) (17) requires that volatile organic PT samples must fall within +/- 20% of the target
 - when the target concentrations are ≥ 0.010 mg/L
 - $\pm 40\%$ when the targets are ≤ 0.010 mg/L
 - can be “in control” according to the method but fail the PT sample when the recovery is 121%

Did You Get the Correct Results?

- Accrediting Authorities
 - expect laboratories to get the correct results for PT studies
 - expect the laboratory to take corrective action when failures occur
 - understand that PT sample results are only one part of the overall accreditation process

Did You Get the Correct Results?

- Availability of PT Samples
 - not all matrices
 - not all analytes
 - certificate does not indicate whether or not PT samples were analyzed
 - laboratory user is unsure of which methods used PT samples and which ones did not
 - without PT samples the assessment may need to be more detailed

Did You Get the Correct Results?

- Pt Results are not the only “ruler” to use for accreditation
 - Quality systems
 - Training
 - Equipment
 - Record-keeping
 - Documentation
 - Onsite assessments
 - are all used by Accrediting Authorities to make the final decision

Did You Get the Correct Results?

Any Questions?