

## ENVIRONMENTAL LABORATORY APPROVAL PROGRAM CERTIFICATION MANUAL

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Several scoring protocols are used based on the regulatory scoring requirements found in NYCRR 55-2.8. For chemistry and bacteriology studies, the linear regression coefficients, fixed percentage limits, concentration ranges and reporting levels are found in the Field of Proficiency Testing (FOPT) tables on the NELAC Institute (TNI) website (<http://www.nelac-institute.org>).

### Data Scored by Robust Statistics

#### Introduction

Past experience with reported proficiency test results has shown that one inevitably finds some of them to be incredible. Such results can arise from transcription errors, data entry errors, computation errors, or instrumentation errors. The robust analytical techniques underlying all of our scoring protocols preclude the overt effect of such incredible results, or outliers, on the analysis of the proficiency test results as a whole. Robust analytical technique can be divided into three parts - data treatment, parameter estimation, and error modeling.

#### Data Treatment

A data set is a set of results reported for a particular proficiency test sample. Because of the likely presence of outliers, the values of the results probably form a wide range with a few values near either extreme of the range. For some data sets, it may be necessary to convert the values within these data sets to a different scale. The types of conversion used include the logarithmic transformation and the power transformation. In the log transformation, the natural log of the value in a data set is used instead of the value. In a power transformation, the value raised to the power  $p$  is used instead of the value, where  $p$  can take on any value between -1 and 1 except 0. A weight assignment scheme is used so that values that are near the extremes are assigned very low weights.

#### Parameter Estimation

For each treated data set, the parameters that are of interest are the mean and the standard deviation. The mean is defined to be the sum of the weighted values in a treated data set divided by the number of values in such a set. The standard deviation is defined to be the square root of the sum of the square of the difference of a value from the mean divided by the number of values. An estimate of each parameter is obtained.

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### **Error Modeling**

In this step, the distribution of the values in a treated data set is tested to see if it follows a normal distribution. The "goodness of fit" is measured by three statistics; they are the Cramer-VonMises statistic, the Komogonov-Smirnov statistic and the Anderson-Darling statistic. These statistics allow one to judge the "goodness of fit" objectively.

### **Acceptance limits**

The acceptable range is typically:

Robust mean +/- 3 robust standard deviations

### **Data Scored by Fixed Percentages**

#### **Acceptance Limits**

For water chemistry, EPA Program regulations specify the acceptance criteria. For many analytes, fixed percentages of the target value are used to establish the acceptance limits. A list of water analytes and fixed percentages can be found on the TNI website as mentioned above.

### **Data Scored by Regression Equation**

An EPA, TNI, or NYSDOH regression equation is used to determine the mean and standard deviation based on the gravimetric prepared value. The acceptance limits in these cases are set at +/-2 standard deviations for drinking water and +/-3 standard deviations for non-potable water.

### **Asbestos in Friable Materials**

The proficiency test consists of a set of samples containing various bulk materials. Each laboratory is required to quantitate all fibrous materials in each sample by an ELAP approved method. Specific instructions and reporting sheets accompany the samples.

Scoring is based on the correct identification of the type of asbestos and the accuracy of the quantitation of asbestos fiber in the sample. The accuracy of fiber percentage quantitation is based on the mean of results from laboratories.

The score for each bulk sample is:

- Unsatisfactory for incorrect identification of asbestos type.

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- Unsatisfactory for quantitation outside 2 standard deviations of regulatory laboratory or formulation values.
- Satisfactory for correct identification of dominant asbestos type **plus** asbestos quantitation results within 2 standard deviations of regulated laboratory or formulation values.
- A satisfactory overall evaluation for the analyte requires satisfactory scores for at least three of the four samples (75%).

The RSD of the method is typically 50% (+/- 15%) depending on the sample composition. When the sample data set RSD is more than 34% and the lower acceptance limit for the data set is less than 1.0% asbestos, the lower acceptance limit for the data set is adjusted to the 95% confidence limit based on an RSD of 34% or 1.1% asbestos, whichever is lower.

### **Asbestos In Drinking Water By TEM**

The EPA has mandated that the acceptance limits shall be the 95% confidence limits centered on the robust study mean. Results outside of these limits will be scored unsatisfactory.

### **Asbestos in Non-Friable Material**

Each laboratory is required to perform a gravimetric analysis on the proficiency samples. For each sample the percent residue and the percent asbestos in residue must be reported. Acceptable results are within  $\pm$  three standard deviations of the laboratory mean.

### **Asbestos in Air (TEM)**

The proficiency test consists of two samples in air cassettes. Scoring is based on the correct identification of asbestos and the accuracy of the quantitation of asbestos fiber in the sample. The accuracy of fiber quantitation is based on the mean results from laboratories. Acceptable results are within three standard deviations of the mean. Identification of asbestos is based on pass/fail. Correct identification is satisfactory, incorrect identification is unsatisfactory.

### **Fibers in Air (PCM)**

The proficiency test consists of a set of four samples containing various fiber materials on filters. The laboratories are required to quantitate all fibrous material on the filters using NIOSH 7400 A Rules.

Scoring is based on the quantitation of the fiber concentration on each filter. Acceptable results are within three standard deviations of the robust study mean.

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### Potable Water Bacteriology

Participating laboratory results shall be considered Acceptable or Unacceptable when compared to known presence or absence of total coliform or fecal coliform (or E. coli) bacteria. Passing shall be considered as nine out of ten samples having acceptable results, and no false negatives reported.

### Appeals and Complaint Resolutions

Laboratories, who wish to appeal a score and have it used toward their PT accreditation history, may do so in writing to the ELAP office ([Biggs Laboratory, Wadsworth Center, NYS Department of Health, Empire State Plaza, Albany, NY 12237 ,P.O. Box 509, Albany, NY 12201-0509](#) or [elap@health.ny.gov](mailto:elap@health.ny.gov)). When appealing please provide, in writing, the following:

- [your laboratory ELAP ID number](#)
- the study number,
- sample number, and
- analyte in the description of your appeal.

Where appropriate, provide a copy of the PT report and all laboratory records and documentation regarding the data for which an evaluation is being appealed. ELAP may require more information or data from the laboratory or PT provider in order to properly evaluate the appeal. ELAP will provide a formal response to the appeal after a decision is made.

A laboratory can submit questions about PT samples or performance evaluations. The laboratory may do so by contacting either the NYSDOH Wadsworth Center PT program at (518) 473-1398 or [dehspt@health.ny.gov](mailto:dehspt@health.ny.gov) or ELAP at the contact information noted above. Also, ELAP will submit any questions about PT samples or performance evaluations made by the PT provider to the PT provider. If the PT provider is not able or is unwilling to resolve the question to the satisfaction of the laboratory or other entity, ELAP can refer those questions to the PT Provider Accreditor, an organization that is approved by TNI to accredit and monitor the performance of PT providers.