NATIONAL ENVIRONMENTAL LABORATORY ACCREDITATION CONFERENCE

DRAFT
ON-SITE ASSESSMENT

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PROFICIENCY TESTING

2.0 PROFICIENCY TESTING PROGRAM

Proficiency testing (PT) is an independent means of evaluating a laboratory's performance in comparison to a group of laboratories testing identical unknown samples at the same time under controlled conditions. The required PT programs in which a laboratory must participate in order to become accredited are defined in this section.

Laboratory participation in PT programs fulfills only one part of the quality assessment requirements of NELAC. Therefore, an effective on-site audit of all laboratory operations at appropriate intervals is an essential complement to regular proficiency testing.

2.1 ACCREDITATION AND APPROVAL OF PROFICIENCY TESTING (PT) PROGRAMS

This section provides the criteria which all PT program providers shall meet in order to be approved by NELAC or its designee. While rigorous and demanding, it is anticipated that several governmental and private sector organizations will meet NELAC acceptance criteria and become approved. NELAC program criteria and on-going oversight by the PT Provider oversight body will assure that the performance of all laboratories will be evaluated in an effective, fair and consistent manner.

NELAC or its designee will approve PT program providers on an analyte/method suite basis for each type of sample matrix in each regulatory program. Each applicant offering PT programs must provide written documentation of the study samples it seeks approval for. The following sample descriptors are referred to collectively as field of testing:

a) Regulatory or environmental program (e.g., Safe Drinking Water Act);

b) Analyte/method suites (e.g., regulated volatiles); and

c) Samples matrix types (e.g., soil, waste oil, water).

In order for a provider to have a PT program approved by NELAC for a field of testing, it must annually offer a minimum of four studies with a maximum of 90 days between PT studies. This schedule will allow a laboratory with a failed result to quickly re-establish its acceptable performance.

The matrix of all PT samples must reasonably resemble the matrix for which the laboratory seeks accreditation. The target concentration of each analyte in each lot of PT samples must be unique and each lot of samples may be used only once for

proficiency testing purposes. The target value for each analyte in each sample lot must be randomly varied throughout the year over a concentration range to cover the analytical range of the appropriate promulgated method(s). The required analytes in each sample covering each field of testing is determined by NELAC or its designee and is updated annually as required.

The samples must be designed, manufactured and tested by the PT program provider for homogeneity, stability and verification of target values. This testing must verify that the quality of all samples is appropriate for use in each field of testing PT study. Each PT program provider must demonstrate that it has the procedures and resources to notify participants of the start date of each study and to distribute the PT samples and quickly resolve any problems resulting from the shipping process.

The PT program provider must have enough participants to result in 20 valid data points for each analyte in each study. However, NELAC or its designee may wave this requirement for analytes which are analyzed infrequently by the laboratory community. This number of data points will allow valid statistics to be applied to each study's data set. NELAC or its designee shall provide (and update on an annual basis) the data acceptance criteria which all PT program providers shall use for all PT studies data. In this way, all laboratories' performance will be judged fairly and consistently. Each PT program provider must demonstrate that it can receive and evaluate the data and issue a report within 21 calendar days of the close of each study.

Each PT program provider must certify that it is free of any organizational conflict-of-interest. A PT sample producer shall never split a sample lot and offer these same samples for sale as unknowns before the unknown samples are used in a PT study. In addition, each provider must demonstrate that its security procedures are adequate to maintain confidentiality of all target values through the closing date of each study. All records must be retained for a period of five years.

Final NELAC approval is contingent on the PT program provider demonstrating that it has adequate policies and procedures to: 1) assure freedom from organizational conflict-of-interest; and 2) maintain absolute confidentiality and security of all target values through the close of each study. In addition, the PT program provider must demonstrate that the design and operation of each PT program for which it seeks approval meets NELAC requirements.

A list of all NELAC approved PT providers will be maintained by NELAC or its designee. This list shall be continually updated and published on intervals not to exceed six months. On this same interval, NELAC or its designee shall also publish the list of

analyte/method suites necessary to satisfy the PT requirements in a given field of testing for each regulatory program.

While accreditation and NELAC approval are granted on an annual basis, a PT program provider shall be de-accredited or de-approved if serious, documented deficiencies identified by primary accrediting agencies, NELAC or PT study participants are not resolved within 30 calendar days of being notified in writing of the problem.

2.1.1 SPECIFIC PROCEDURES FOR ACCREDITATION AND NELAC APPROVAL OF PT PROGRAM PROVIDERS

Providers must meet NELAC specified standards for an internal quality management program. The provider's overall program must be accredited by NELAC or its designee. NELAC or its designee will conduct periodic reviews of providers.
These reviews will include the program, operations, QA/QC processes, systems, records, data management, security and all other applicable operations.

The specific procedures for approval by NELAC or its designee of a PT program provider are detailed in the attached Appendix 1, *(to be added later)*.

2.2 ENROLLMENT IN PROFICIENCY TESTING PROGRAM(S)

In order to be accredited initially, and to maintain accreditation, each laboratory must enroll in a NELAC-approved PT program(s) for all fields of testing for which the laboratory desires accreditation. Each laboratory shall participate in four PT studies per year. Each study shall require the analysis of one test sample for each field of testing. This section provides the time that a laboratory has to analyze the PT samples and report the results. In addition, this section provides the NELAC-required data evaluation and acceptance criteria to be used in PT studies.

At the time it applies for accreditation, as well as prior to changing or adding PT suppliers at any time, each laboratory shall notify its primary accrediting authority or designee which program(s) it chooses to participate in to meet PT requirements. For those tests for which PT samples are not available, the laboratory must assure the reliability of its testing procedures by maintaining a total quality management system that meets the applicable NELAC requirements.

Laboratories seeking accreditation may select any provider from the list of NELAC-approved PT program providers and shall bear the cost of any PT program subscription. Each laboratory must authorize the PT program provider to report its results and acceptance status

directly to the appropriate primary accrediting authority or designee and NELAC or its designee, as well as to the lab itself.

All participants' results shall be evaluated according to accepted protocols using the acceptance criteria established and required by NELAC. These acceptance criteria may be revised annually. PT program providers must report an evaluation of test results within 21 calendar days of the close of each study. The laboratory's individual results and their acceptance shall be provided to the laboratory, its primary accrediting authority or designee and NELAC or its designee.

2.3 REQUIREMENTS FOR TESTING PT SAMPLES

A laboratory must participate in four NELAC-approved single-sample PT programs per year for each field of testing for which it seeks or wants to maintain accreditation. The samples must be analyzed and the results returned to the PT program provider no later than 30 calendar days from the date of sample receipt. The laboratory's management and all analysts must attest to the fact that all PT samples were tested using the same staff, procedures, equipment, facilities and frequency used to analyze routine environmental samples.

Laboratories must comply with the following restrictions on the transfer of PT samples and communication of PT sample results:

a) A laboratory may not send any PT sample or a portion of a PT sample to another laboratory for any analysis for which it seeks accreditation;

b) A laboratory may not knowingly receive any PT sample or portion of a PT sample from another laboratory for any analysis which the sending laboratory seeks accreditation;

c) Laboratory management and staff may not communicate with any individual at another laboratory (even intra-company) concerning the PT sample results until after the closing date of the relevant study; and

d) Laboratory management and staff may not attempt to obtain the target value of any PT sample from the program provider until after the closing date of the relevant study.

Any laboratory that the primary accrediting authority or NELAC determines intentionally referred any PT sample to another laboratory for analysis before the closing date of the study and submits the other laboratory's results as its own will have its accreditation revoked for a minimum period of one year. Any laboratory that knowingly receives any PT sample from another laboratory for testing before the closing date of the study must

immediately notify its primary accrediting agency of the receipt of those samples. Laboratories not doing so may also have their accreditation revoked for a minimum period of one year. This policy is not intended to prevent interlaboratory testing designed as part of a methods development or evaluation study, and only applies to PT samples used for NELAC accreditation purposes.

The laboratory shall receive and handle all PT samples under the chain-of-custody initiated by the PT provider. The laboratory shall maintain for five years a copy of all written or printed records (including but not limited to bench sheets, instrument strip charts or print-outs, data calculation and report forms) resulting from the analysis of any PT sample. These records shall include a copy of the PT program report forms used by the laboratory to record PT results, and an attestation statement signed by the laboratory management and analysts stating that the PT samples were tested in the same manner as routine samples. All of these laboratory records shall be made available to the primary accrediting staff during on-site audits of the laboratory.

2.4 EVALUATION OF PROFICIENCY TESTING RESULTS

For the first calendar year after the NELAC program becomes established, the data acceptance criteria used historically by EPA for the WS, WP and DMRQA studies will be used to assess all PT study results. This approach will assure continuity and consistency in the evaluation of PT results by all program providers. Subsequently, the data acceptance criteria will be reviewed annually at the NELAC Annual Conference by the Performance Testing Committee or its designee. The Committee or its designee will also consider alternative data acceptance criteria at the Conference. These new criteria would be test-run using the PT results in the NELAC data-base and appropriate adjustments made before the new criteria are brought on-line.

2.4.1 SCORING OF PROFICIENCY TESTING STUDY RESULTS

PT program providers shall evaluate results from all PT studies using accepted statistical protocols and NELAC-mandated acceptance criteria as described in Appendix 2 *(to follow at a later date)*. Each result shall be scored on a pass-fail basis. The PT program provider shall provide the participant laboratories, the primary accrediting authority and NELAC or its designee a report showing the target value, study mean, acceptance range and the pass-fail status for each analyte for each laboratory participant. Each participant laboratory shall only receive an evaluation of its own results.

2.4.2 ACCREDITATION CRITERIA AND STATUS

There shall be two accreditation categories: 1) accredited; and 2)

not accredited. The primary accrediting authority shall use the results of the NELAC-required PT samples in conjunction with the results of the on-site audit and any other published criteria in determining a laboratory's accreditation status.

A laboratory can be accredited for a specific field of testing upon passing any two out of three consecutive PT samples, provided that all other accreditation criteria are met. If an NELAC accredited laboratory submits failing results on two out of three consecutive PT samples for a specific field of testing, the laboratory's accreditation status for that field of testing is changed to "not accredited". The laboratory shall immediately submit a written corrective action plan to its primary accrediting authority or designee and analyze another PT sample within 30 calendar days. Upon meeting the criteria described above for accreditation, i.e., passing two out of three consecutive PT samples, the laboratory regains its "accredited" status for that field of testing. Note that this procedure allows the laboratory to request and analyze remedial (make-up) samples. These remedial samples count within the "two-out-of-three" criteria even if the lab fails to analyze them successfully.

Laboratories shall agree to test additional PT samples at the option of the primary accrediting agency for the following situations:

1) A major change in the ownership, management or supervision of the laboratory;

2) Significant substantiated complaints by the laboratory's clients, past or present employees;

3) Seriously unsatisfactory results on any PT sample; and

4) A request by the laboratory to be reinstated in a field of testing.