

pennsylvania

DEPARTMENT OF ENVIRONMENTAL PROTECTION
BUREAU OF LABORATORIES

June 28, 2011

Re: Primary NELAP Accreditation - Implementation of TNI Standard

Dear Technical Director:

This letter is to notify all Primary NELAP accredited and applied laboratories of the Pennsylvania Department of Environmental Protection - Laboratory Accreditation Program's ("LAP") implementation plan for the 2009 TNI Standard. Originally, the LAP planned to implement the 2009 TNI Standard on July 1, 2011. Unfortunately, the tools necessary for the implementation of this standard, including but not limited to assessment checklists have not been provided to the NELAP Accreditation Council. Until these tools are provided by TNI, evaluated, and determined appropriate for use, the LAP will delay the official implementation of the 2009 Standard until at least September 1, 2011. During this interim period, the LAP will continue the use of the 2003 NELAC Quality Systems and Technical Checklists. The effect of this delayed implementation will be in the format of the on-site assessment and assessment report.

On-Site Assessment Implementation Plan:

The implementation delay will most likely be short and virtually undetectable for most accredited laboratories because the assessment scheduled for most laboratories will occur after the LAP officially adopts the 2009 TNI Standard. However, for those laboratories that must participate in an on-site assessment during this interim period, the LAP will continue to assess laboratories to the 2003 NELAC Standard. All laboratories will be notified via letter and phone call regarding the version of the Standard will be used during the assessment. Laboratories will be notified if the LAP determines that a later implementation date is necessary. Should laboratories choose to move toward implementation of the new 2009 TNI Standard prior to September 1, 2011, these laboratories will not be penalized during an on-site assessment or other assessment of data, sample receiving, or reporting procedures.

PT Implementation Plan:

Effective July 1, 2011, the LAP will accept PT studies that are handled and scored in accordance with the 2009 TNI Standard. The LAP will allow laboratories to use the 2009 TNI Standard for calculation of the 15-day separation from analysis date of one study to analysis date of the second study as well as reporting PT studies to the LOQ. However, be warned that if a laboratory chooses to report results with "less than" (" $<$ ") symbols, the LAP will request the analytical data and calibration records to ensure that these results were reported correctly and appropriately. The Department will also require proof that the laboratory does not report client samples below these LOQ values reported in the PT studies. If during this data review, the LAP determines that PTs were not reported appropriately, these results will be invalidated and will not be used as part of the laboratory's PT history. Laboratories may choose to continue to report PTs to the established and published PTRLs without fear of penalty. The LAP would like to remind all laboratories that all drinking water PTs MUST be reported to the PTRL in order to be considered valid.

Additional Warning for Laboratories with Secondary Accreditation from NY-DOH:

For those laboratories seeking secondary NELAP accreditation from the New York - Department of Health (NY-DOH), the LAP strongly recommends that these laboratories continue to report PT results to the PTRLs to ensure continued secondary accreditation and ability to analyze and report NY-DOH samples.

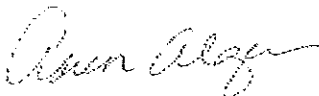
Additional PA-DEP Specific Requirements All NELAP Accredited Laboratories Must Know:

The LAP would also like to remind all NELAP laboratories that many sections of 25 Pa Code Chapter 252 also apply to NELAP accredited laboratories and must be followed. In addition to meeting all requirements of NELAP, the following Chapter 252 requirements also apply (note that not all regulatory requirements are listed here):

- § 252.5(b)—“An environmental laboratory seeking NELAP accreditation shall:
 - (1) Submit a complete application as provided by Subchapter B (relating to application, fees and supporting documents).
 - (2) Comply with Subchapter E (relating to PT study requirements).
 - (3) Comply with Subchapter F (relating to onsite assessment requirements).
 - (4) Comply with Subchapter G (relating to miscellaneous provisions).”
- § 252.501(n)—“An environmental laboratory seeking to obtain or maintain accreditation in the drinking water matrix shall participate in PT studies that meet the requirements of 40 CFR Part 141 (relating to national primary drinking water regulations).”
- § 252.601(h)—“Unless otherwise approved by the Department, deficiencies shall be corrected within 120 calendar days of receipt of the on-site assessment report.”
- § 252.705(b)—“Environmental laboratories using the Department’s name, making reference to its accreditation status or using the Department’s logo in catalogs, advertising, business solicitations, proposals, quotations, laboratory analytical reports or other materials, shall:
 - (1) Distinguish between testing for which the laboratory is accredited and testing for which the laboratory is not accredited.
 - (2) Include the environmental laboratory’s accreditation number.”
- § 252.705(d)—“NELAP accredited laboratories shall accompany the Department’s name or the NELAC/NELAP logo with the phrase “NELAP accredited” and the laboratory’s accreditation number.”
- § 252.707(a)—“An environmental laboratory MAY NOT subcontract testing or analysis covered under this chapter to an environmental laboratory that is not accredited and in compliance with this chapter.”
- § 252.707(b)—“The accreditation number of the subcontracted environmental laboratory shall be indicated on the final report.”
- § 252.708(a)—“An environmental laboratory conducting testing or analysis of drinking water under Chapter 109 (relating to safe drinking water) shall:
 - (1) Meet the reporting and notification requirements of that chapter;
 - (2) Review all sample analysis data within 24 hours of acquisition of the initial sample results for microbiological, inorganic nonmetals, and trace metals analyses. The 24-hour deadline may be extended to a maximum of 72 hours to accommodate a holiday or weekend when the laboratory is closed for business;
 - (3) Review all sample analysis data within 7 days of acquisition of the initial sample results for organics.”
- § 252.708(b)—“An environmental laboratory shall notify the Department, in writing, within 20 calendar days of a permanent change in laboratory supervisor.”
- § 252.708(c)—“An environmental laboratory shall notify the Department, in writing, within 30 calendar days of a change in the legal name of the laboratory.”
- § 252.708(d)—“An environmental laboratory shall notify the Department, in writing, within 30 calendar days of a change in any item contained on the application for accreditation.”
- § 252.708(e)—“An environmental laboratory shall notify the Department, in writing, if a change in the laboratory’s capability to produce valid analytical results persists for more than 90 calendar days for any FOA listed on the laboratory’s Scope of Accreditation.”

Should you have any additional questions or concerns regarding laboratory accreditation, please contact your laboratory’s accreditation officer, Ron Houck, at 717-346-8210.

Sincerely,



Aaren S. Alger, Chief
Laboratory Accreditation Program