



Welcome to the first issue of the Laboratory Accreditation Newsletter! This newsletter was developed to keep you informed about the news, happenings, regulations and changes to the Laboratory Accreditation Program and the Department of Environmental Protection.

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Introduction to the Laboratory Accreditation Program

The Laboratory Accreditation Program (LAP) was established to protect public health, safety, welfare and the environment by ensuring the accuracy, precision and reliability of data generated by environmental laboratories.

Pennsylvania offers a dual accreditation program: State Accreditation and NELAP Accreditation. State accreditation is based upon the laboratory accreditation regulations at 25 Pa Code Chapter 252 and NELAP accreditation is based upon the requirements in the 2003 NELAC Standard, which is based upon ISO 17025.

The LAP is a section in the DEP Bureau of Laboratories directed by Dr. Martina Q. McGarvey, DM. The LAP is structured to consist of a Section Chief and twelve Accreditation Officers. The team of Accreditation Officers is composed of one microbiologist and eleven chemists.

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Each accredited laboratory is assigned to an accreditation officer. The accreditation officer is the primary contact person for the laboratory and is knowledgeable about the accreditations held by each of his or her assigned accredited laboratories. Each accreditation officer is responsible for processing the applications, leading on-site assessments, processing proficiency test results, and tracking the accreditation status for each of his or her assigned laboratories. The "PA Accredited Environmental Laboratories" list on the LAP's website (www.depweb.state.pa.us/lab) identifies the accreditation officer assigned to each laboratory.

The Chief of the LAP is responsible for making accreditation decisions based upon the reports and recommendations from the accreditation officers. The LAP Chief is also responsible for the regulations at 25 Pa Code Chapter 252 and the Pennsylvania NELAP Accreditation Body.

Proposed Chapter 252 Regulation

The LAP has been working over the past year to revise the Chapter 252 regulation. On June 20, 2009, the Chapter 252 Proposed Rulemaking was published in the *PA Bulletin*. The proposed regulation will amend 25 Pa Code Chapter 252, the Environmental Laboratory Accreditation Regulation that was developed in accordance with the Environmental Laboratory Accreditation Act of June 2002. The proposed rulemaking was open for public comment for 30 days, and ended on July 20, 2009. The Department anticipates that the final rule publication will occur in early to mid-2010.



Introduction to the LAAC

Have you ever heard of the LAAC? The LAAC is the Laboratory Accreditation Advisory Committee. This committee was established by the Act of June 29, 2002 (P.L. 596, No. 90) (dealing with environmental laboratory accreditation) (27 Pa C.S. §§ 4101 – 4113). The committee was established by the Act to provide technical assistance to the Laboratory Accreditation Program. The LAAC has been instrumental with the development of the Chapter 252 regulations and the new proposed Chapter 252 regulations. The committee consists of eleven members, representing various types of environmental laboratories, various environmental industries and the general public.

The next meeting of the LAAC is on September 10, 2009 at the DEP-Bureau of Laboratories Building, Room 206 at 2575 Interstate Dr., Harrisburg, PA 17110. The LAAC will be discussing the comments to the proposed Chapter 252 regulations. The general public is welcome to attend any advisory committee meeting. If you have any interest in the proposed regulation or the comments, please feel free to attend.

DMR-QA Changes

On July 14, 2008, the U.S. EPA approved the Department's request to withdraw from the NPDES DMR-QA Program. EPA granted approval of the withdrawal because the Department's state-wide laboratory accreditation program is an adequate surrogate for the DMR-QA Program. The withdrawal became effective beginning in 2009.

If your laboratory currently holds an accreditation certificate and participated in the DMR-QA study last year, then you will need to perform a WP Study from an approved proficiency testing provider within 12 months of the closing date of the previous DMR-QA study, or by September 2009, for those fields of accreditation that are listed on your laboratory's Scope of Accreditation and for which PT samples are required.

If your laboratory is registered with the Department and only performs the accreditation-by-rule testing allowed in 25 Pa Code Chapter 252, § 252.6, then your laboratory does not have to perform proficiency test samples or participate in any further DMR-QA studies.

For further information regarding the withdrawal from the DMR-QA program, please visit our website or contact the Laboratory Accreditation Program.

New Proficiency Testing Tables

The Department publishes proficiency testing (PT) tables or "Fields of Proficiency Testing". These PT tables are lists of PT analytes required to maintain your accreditation. There are many analytes for which PT samples are not available. These tables indicate only those analytes for which PTs are required. The tables are separated into the three matrices: drinking water, non-potable water, and solid and chemical materials. A laboratory must perform PTs for any analyte on the PT tables for which they hold accreditation in a specific matrix.

The Department has recently published new and updated PT tables. These tables add new or additional requirements to the current proficiency test tables. These new tables added additional PTs for microbiology and whole effluent toxicity testing (WETT). The tables have been added to our website. A brief description of the new tables or PT changes is listed below.

- On March 21, 2009, new PT requirements for microbiology were published in the PA Bulletin. State laboratories are required to perform PTs for these new analytes before January 1, 2010 in order to maintain their accreditation. NELAP accredited laboratories are required to perform PTs for these new analytes by July 1, 2009 and every 6-7 months thereafter. These new PTs are:
 - Drinking Water — Enumeration PTs for E.coli, Fecal, and Total Coliforms were added.
 - Non-potable Water — Enumeration PTs for E.coli were added.
- On May 23, 2009, new PT requirements for WETT and microbiology were published in the PA Bulletin. State laboratories are required to perform PTs for these new analytes before April 1, 2010 in order to maintain their



accreditation. NELAP accredited laboratories are required to perform PTs for these new analytes by November 1, 2009 and every 6-7 months thereafter (except for WETT). These new PTs are:

- Drinking Water — Presence/Absence PTs were changed for E.coli and Fecal Coliforms. The PTs are now separated.
- Non-potable Water — WETT PTs were added.

Ethics Training Announcement

The Laboratory Accreditation Program is now offering ethics training workshops. Watch for further information about this course. The course is entitled, "Train the Trainer: Laboratory Ethics and Data Integrity". If you have been looking for guidance about ethics training and ethics programs, we encourage you to enroll in this training. Please visit the Laboratory Accreditation Program's website for a complete course description (www.depweb.state.pa.us/labs).

Don't forget your training documentation

There are several types of training that must be performed and documented regularly. Have you ensured all your appropriate training documentation? Below is a list of training that must be performed and documented annually or any time there is a change in the laboratory's procedures:

- Initial demonstrations of capability,
- Demonstrations of continued proficiency,
- Quality manual signoffs,
- Standard operating procedure (SOP) signoffs,
- Ethics training, and
- Participation in training courses or workshops on specific equipment, analytical techniques or laboratory procedures that relate to each employee's job responsibilities.

This training documentation will be reviewed during your on-site assessment. Don't forget your training and training documentation.

Compliance Assistance and Guidance Documents

The Laboratory Accreditation Program offers many forms of compliance assistance to the regulated laboratory community. We want to help you establish programs and procedures that are compliant with the Chapter 252 regulations and the NELAC Standard. We encourage you to take advantage of the resources and guidance available from the Department. The LAP has developed and updated several guidance documents to assist laboratories with the implementation of the Chapter 252 requirements at their facilities. If you haven't seen any of our guidance documents recently, check them out. Each of the guidance documents is available on our website. If you don't have access to the web, you may request copies from the Department. Below is a list of some of the guidance documents available on the LAP website:

- Writing a Quality Manual for PA State (Chapter 252) Accreditation
- Required Documentation for PA State (Chapter 252) Accreditation
- Writing an Analytical SOP for PA State (Chapter 252) Accreditation
- Proficiency Test (PT) Study Guidance for Laboratories
- Coliform Density Calculation FAQ
- NPW Microbiology Holding Time FAQ
- Instructions for Applying for a Distillation Variance

Lastly, the LAP is available to answer any laboratory related questions during normal business hours. Please call or e-mail your accreditation officer or send an e-mail to our general e-mail account, eplabaccredit@state.pa.us.

Timeline Reminders

There are several timelines that are important to laboratories in order to maintain your accreditation. Laboratories need to ensure that they meet the timelines for application renewal and the timelines for responses to on-site assessments. Failure to meet these timelines may result in the loss of your laboratory's accreditation.



Renewal Applications

Renewal applications must be received by the Department 60 days prior to the expiration of your certificate in order to ensure that your laboratory will not experience a lapse in your accreditation. The application must be complete. A complete application includes all required forms and documentation and the appropriate fees. Please review the application instructions prior to submitting your application to the Department. The application instructions and application forms and materials are available on our website. If you do not have internet access or if you have further questions about the application, please call or e-mail your Laboratory Accreditation Officer to request copies of the application materials and/or clarification of the application requirements.

Renewal applications received less than 60 days prior to the expiration of your certificate may result in a lapse of your accreditation. If the application is received prior to the expiration date of your certificate, your laboratory will not have to pay an initial application fee, and may still pay the renewal application fee. The Department will make all reasonable efforts to process your application before the expiration date of your certificate, however your application will not receive priority over those applications received by the appropriate deadline.

Renewal applications received after the expiration date of your laboratory's certificate will result in a lapse in your laboratory's accreditation. In addition, if your laboratory's accreditation lapses, your laboratory will need to submit an initial application and pay the initial application fee, rather than the discounted renewal application fee. Once your laboratory's accreditation certificate expires, your laboratory must discontinue all testing. Your accreditation status will not extend past the expiration date of your certificate. Initial applications become effective after they have been processed.

On-site Assessment Responses

Laboratories have timelines to respond to an on-site assessment report. These timelines vary depending on whether your laboratory holds State or NELAP accreditation. All laboratories must respond to the on-site assessment report with a written corrective action report. Your laboratory must document the corrective actions taken to correct each deficiency. Unless otherwise approved by the Department, deficiencies must be corrected within 120 calendar days of the receipt of the on-site assessment report.

State Accredited laboratories must respond to an on-site assessment report within 60 calendar days of the receipt of the report and NELAP Accredited laboratories must respond to an on-site assessment report within 30 calendar days of the receipt of the report. The Department will review and respond to the written corrective action report. If any portion of the corrective action report is not acceptable, your laboratory must submit a revised corrective action report within 30 calendar days of receipt of the Department's response to your corrective action report. Failure to respond to the assessment findings or failure to submit an acceptable corrective action report within timeframes indicated may result in revocation of your accreditation as a State or NELAP accredited laboratory.

Call for Suggestions and Improvements

The Laboratory Accreditation Program is always looking for suggestions for improvement. If you have ever thought of any ideas to make the Laboratory Accreditation Program better or more accessible, we'd like to hear from you. We're looking for suggestions for training and guidance documents, ideas to make our website better, and ideas for improved laboratory resources. Please send any ideas or suggestions to our general e-mail account: eplabaccredit@state.pa.us.

Commonwealth News

The Commonwealth of Pennsylvania has not yet passed a state budget for the 2009-2010 fiscal year. Currently, state employees are working without a state budget. The LAP is currently working and will continue to perform essential accreditation functions during this period. We will still be processing applications, reviewing PTs, and corresponding with laboratories. We are still performing assessments.