# Laboratory Accreditation Advisory Committee
# Minutes for December 2, 2015 – Harrisburg, PA

## MEMBERS PRESENT

Anita Martin, Chester Water Authority (Municipal Authority)
Danielle Cappellini, A.E. Kirby Memorial Health Center (Commercial Environmental Laboratory)
David Barrett, Mahaffey Laboratory LTD (Small Environmental Laboratory)
Stephen Morse, P.E., Skelly and Loy (Environmental Engineer)
Twila Dixon, M.J. Reider Associates, Inc (Technical Expertise in the Testing and Analysis of Environmental Samples)
Bryan Swistock, Penn State University (General Public Member)
Marykay Steinman, Analytical Quality Assistance (General Public Member)

## DEPARTMENT OF ENVIRONMENTAL PROTECTION STAFF PRESENT

Aaren Alger, Laboratory Accreditation Program Chief
Laura Edinger, Regulatory Coordinator, Policy Office
Virginia Hunsberger, Laboratory Accreditation Program
Yumi Creason, Laboratory Accreditation Program

## CALL TO ORDER AND ATTENDANCE

The meeting was called to order by Ms. Steinman. Committee members gave introductions.

## REVIEW AND APPROVAL OF 9/30/15 MEETING MINUTES

Mr. Barrett moved to approve the minutes. Mr. Morse seconded the motion. All present were in favor and the meeting minutes were approved.

## DISCUSSION OF FEE REPORT FORM

Ms. Alger explained that the fees are required to be evaluated every three years, and the last fee amendment occurred in 2010. The 2010 fees were re-evaluated again in 2013 and 2015. The 2013 re-evaluation determined that a fee change was not needed. Due to the withdrawal of a significant number of secondary NELAP accredited laboratories and the consolidation of laboratories since the 2013 review, the Program has observed a shortfall in revenue as compared to costs to operate the program. Due to mostly the withdrawal of secondary NELAP accredited laboratories and consolidations, the work load of the laboratory accreditation program has not decreased – only the revenue has decreased. The program costs for fiscal year 2014-2015 was lower than projected with expenses moving forward due to assessor vacancies, turnover in the IT department, and the loss of an administrative officer. The Program expects to have a full complement early next year, which means that the projected revenue is unlikely to cover the costs of the Program.

Ms. Alger explained that changes in the Chapter 252 draft include additional changes to the fees since they were originally proposed in late 2014, including an approximate 25% increase in fees. Ms. Capellini asked when the new fees would be effective. Ms. Alger responded that the fees would be effective upon promulgation of the final rulemaking. The final rulemaking is not expected to be promulgated until 2017. Ms. Alger clarified that the fees would be in place for three years from the final approval date and not three years from now in the draft phase. Ms. Alger also explained that the Program is exploring options to reduce costs, including automated PT tracking, scoring, and evaluation and electronic submission of applications by laboratories.

Ms. Alger asked for additional feedback on how it will impact business. Mr. Morse asked Mr. Barrett what the impact is for a 25% increase in cost. Mr. Barrett explained that it would increase costs for his laboratory by approximately $3,000-$4,000. Ms. Alger noted that large laboratories would have about a $5,000 increase while treatment plants would see about a $300 increase. She explained that it is not a one to one increase due to some categories being more expensive than others and due to amount of time taken to assess. Ms. Dixon added that this rise in fees may see a number of laboratories, especially outside of the state, withdraw.

Ms. Steinman added that wastewater treatment plants may decide to withdraw as it may be cheaper to subcontract the work. Ms. Alger explained that the costs of operating the Program need to be equally distributed to all applicant laboratories and must be reflective of the costs associated with the lab's accreditations. The cost to accredit a wastewater treatment plant must go up as the costs of operating the Program go up. The Department cannot require commercial laboratories to pay more to keep costs down for treatment plants. Mr. Barrett explained that he understands the reasons for the increases but the cost of testing is competitive and this increase could be difficult for commercial laboratories. He stated a similar concern to others on the Committee that a rise in fees could have the unintended consequences of plants dropping out and also the withdrawal of small to medium laboratories.

Ms. Cappellini asked how many laboratories are accredited by the state program versus NELAP. Ms. Alger responded that there are approximately 450 laboratories that are mostly state, the majority of which are small treatment plants. The program certifies around 80 secondary NELAP accredited laboratories and 30 primary NELAP laboratories. Ms. Dixon asked what the difference in effort is in assessing NELAP versus State accreditation. Ms. Alger responded that State accredited laboratories require half the PT review, no quality systems review, the assessment schedule is less frequent, and the training and oversight to become a state assessor is much less stringent than the NELAP requirements.

The public asked if there were other states interested in joining the NELAP program. Ms. Alger responded that California withdrew about two years ago and may reapply to the program. Oklahoma will be applying to become a NELAP Accreditation Body very soon. Ms. Alger also explained that many states use NELAP accreditation but are not part of the program, such as Ohio, Georgia, and Washington. This lack of participation creates additional work for currently recognized NELAP ABs, such as PA-DEP, because the laboratories are often seeking Primary NELAP accreditation from the Department without performing any DEP compliance work.

Ms. Cappellini asked who decides if the Program offers NELAP accreditation. Ms. Alger responded that the Environmental Laboratory Accreditation Act of 2002 requires that the PA-DEP seek recognition as a NELAP AB and offer NELAP accreditation. Ms. Alger explained that the plan is to present the fee report to the Environmental Quality Board (EQB) on March 15, 2016 and Ms. Edinger added that, once the proposed rulemaking is prepared and materials distributed to the EQB, a regulatory analysis form will be made available on the EQB webpage.

In sum, the LAAC members understand the reasoning behind the amended fees but voiced concern as to the impact increased fees may have on business. The Department noted that the Committee feedback is valuable and both LAAC members and members of the public are encouraged to offer comment during the public comment period once the proposed rulemaking has been approved for publication.

## DISCUSSION OF CHAPTER 252 DRAFT AMENDMENTS

Ms. Alger explained that the Chapter 252 draft is a pre-draft standard and is not a proposed standard. The Department is still accepting comments, and this revision is not the final product. Ms. Alger went through the revised draft to explain the reason behind the Department's changes.

### Proposed changes to 252.4(b), general requirements

Ms. Alger explained she added "reporting results" to this section because some businesses, such as sample drop-off locations, are reporting results on test reports. The Department must ensure that all test results reported for compliance meet the minimum requirements of Chapter 252.

### Proposed changes to 252.5(b)(6) and (7), NELAP equivalency

Ms. Alger added two sections of Chapter 252 to the requirements that all NELAP laboratories would need to follow. These additions were to address the clarifications added to sample receiving and sample handling. The word "on-site" was removed throughout the document so that the Department could be pro-active in its approach to assessing laboratories. There were no comments or questions from the committee or public.

### Proposed changes to 252.203(d), accreditation renewal

Ms. Alger changed the wording in this section to address feedback given at the previous meeting. There were no comments or questions from the committee or public.

### Proposed changes to 252.204, fees

As discussed previously, Ms. Alger reaffirmed that the fees were changed and that the Department welcomes feedback concerning the impact the fee increases will have on the laboratories.

**Proposed changes to 252.206, out-of-state onsite reimbursement**

Ms. Alger changed the travel time for each assessor to $75/hour from $50. The $50 had been the rate of travel since 2006. This change does not affect in-state laboratories. There were no comments or questions from the committee or public.

**Proposed changes to 252.301(h), laboratory supervisor**

Mr. Barrett commented that many small laboratories might not have a second, qualified supervisor to meet this requirement and asked if absence could be defined or if it would be allowable for a supervisor to be available by other means. Ms. Alger explained that laboratory supervisors are responsible for reviewing the day to day operations of the laboratory and ensuring that all Chapter 252 requirements are met. The supervision responsibilities are not limited to data review and approval and a laboratory supervisor cannot perform this function off-site. Mr. Barrett remarked that if a small laboratory has three people and the supervisor was on a three-week vacation, it may be acceptable if he/she checks in on a routine basis. Mr. Barrett asked to extend the period to 21 days. Ms. Alger agreed to the change and incorporated the requested change into the draft regulation

**Proposed changes to 252.302(c), laboratory supervisor**

Mr. Barrett asked if the requirement for four credits of microbiology is relevant now that there are new methods like Colilert. Ms. Alger responded the microbiology credits verify that the supervisor is qualified and understands what is involved in the testing. The Department does not believe that requirement for four credits is unreasonable for a laboratory supervisor.

**Proposed changes to 252.306(f)(2)(iv), thermometers**

Ms. Cappellini explained that during a recent audit from New York her laboratory was cautioned against using the two-degree difference for working thermometers because the EPA requires only one-degree difference. Ms. Alger responded that the one-degree difference was removed in the last revision of Chapter 252 and was reviewed by EPA Region 3. She explained that it is possible other EPA regions differ on the requirements, but the two degrees is acceptable for PA work.

**Proposed changes to 252.306(g)(6), expired standards**

Ms. Alger changed the wording of this section to address feedback provided at the previous LAAC meeting to include the allowance of segregating expired standards rather than requiring that laboratories remove expired reagents from the laboratory. There were no comments or questions from the committee or public.

**Proposed changes to 252.307(h), sample collection instructions**

Ms. Alger changed the wording of this section, to address feedback provided at the previous LAAC meeting, to clarify that laboratories maintain instructions rather than be required to

develop and maintain standard operating procedures for sample collection. This section also does not specify 'how' these instructions shall be made available to clients, just that they be made available. The public asked if this was required for all samples. Ms. Alger responded that any accredited laboratory must maintain instructions for the collection of compliance samples.

**Proposed changes to 252.401(f), sample condition verification**

Ms. Martin asked how this section would affect in-house tests where samples would be collected from a tap and analyzed immediately. Ms. Alger responded that the laboratory must have instructions on how they collect samples and verify that the sample was properly preserved. Ms. Dixon asked if an in-house laboratory would be able to measure the pH at the tap if pH and residual chlorine can be measured onsite. Ms. Martin noted that the regulation states it must be per sample container. Ms. Alger explained that verification of unpreserved samples is just as important as verifying preserved samples, especially in the case where improper preservation will invalidate a test result, such as chlorination and testing for nitrite.

Ms. Cappellini asked how the pH should be taken. Ms. Alger answered that the requirements would be per the tolerance of the method. If the sample requires a preservation to tenths of a pH unit, then a pH probe is probably necessary, but if the pH must be <2 then paper would be acceptable. The sample pH check is simply to ensure that the sample was not accidentally, or intentionally, preserved.

The public commented that some people do not have a way of measuring pH for microbiology without contamination using the IDEXX bottles. Another member of the public responded that they collect samples in whirl pack bags instead of the IDEXX bottles so they have extra sample. The laboratory could also check the pH on the same aliquot of sample used for residual chlorine checks. One member of the public asked if taking the pH of microbiology samples is required. The committee, general public, and the Department representatives agreed that all samples need a pH verification. Ms. Dixon responded that there is not a pH tolerance for microbiology. Ms. Alger commented that samples that are acid preserved are not acceptable for microbiology testing.

The public commented that the previous language was clearer. Ms. Cappellini responded that the section was changed due to the change in requirements for taking residual chlorine. The public asked if they were supposed to document the actual temperature or a check to verify it was within temperature. Ms. Alger responded that the laboratory must document the actual observation. She stated that the Department is planning to develop a technical guidance document for specific exclusions to these requirements. The public asked if they had to document for each container if the size and type was acceptable. Ms. Alger explained that laboratories are required to verify the condition of each sample received. The public noted that the header of the section states "each sample" and suggested changing 'each' to 'the'. Ms. Alger agreed.

After additional discussion, the committee recommended a return to the original language with a few clarifications, such as the requirement to check residual chlorine when its presence would negatively impact the test. Ms. Alger agreed.

**Proposed changes to 252.601, assessment**

Ms. Alger removed the word "onsite" which was missed in the last revision. There were no comments or questions from the committee or public.

**Proposed changes to 252.601(e), corrective action**

Ms. Alger changed the wording for clarification of the current requirements and added the requirement for the laboratory to provide a timeframe for completion of the corrective action. There were no comments or questions from the committee or public.

**Proposed changes to 252.601(h), corrective action**

Ms. Alger added clarification that corrective actions must be implemented and maintained in the timeframes given by the laboratory or required by the Department. The Department will sometimes mandate stricter timelines for correction for major deficiencies. There were no comments or questions from the committee or public.

**Proposed changes to 252.701(b)(17), 252.702(b)(18), and 252.703(c)(7) denial, revocation, and suspension**

Ms. Alger clarified that failure to maintain instruments or other supplies required for accredited analytical testing could result in denial, revocation, and suspension of accreditation. There were no comments or questions from the committee or public.

**Proposed changes to 252.702(b)(11) and 252.703(c)(8) revocation and suspension for PT performance**

Ms. Alger clarified that failure to analyze PT studies per the requirements of the regulation could result in revocation or suspension. There were no comments or questions from the committee or public.

**Proposed changes to 252.705, use of accreditation**

Ms. Alger changed this section to add the terms NELAC and NELAP. There were no comments or questions from the committee or public.

**Proposed changes to 252.707(c), subcontracting**

Ms. Alger suggested that subsection (c) was added in an attempt to avoid problems related to transcription errors when one laboratory reports the results of another accredited laboratory instead of providing the actual subcontracted laboratory report directly to the customer. Ms. Cappellini commented that since the laboratory is already referencing the other laboratory on its test reports, it should not be required to provide the subcontracted laboratory's test report. The public commented that you can import subcontracted work into LIMS to avoid transcription

errors. Ms. Dixon responded that not all laboratories have a reporting system like LIMS. Ms. Alger commented that the Department requires the most accurate results and there are increasing problems such as incorrect lab name, incorrect results, and failure to properly include all appropriate data qualifiers. This section would ensure that the customer and ultimately the Department receive the correct information.

Mr. Barrett suggested the Department send out group emails when it sees ongoing pervasive issues such as transcription errors. The public asked if the laboratory was required to ensure a subcontracted laboratory was accredited down to the specific method and matrix. Ms. Alger answered in the affirmative and clarified that if the subcontracted laboratory loses accreditation after accepting the samples then the subcontract laboratory is responsible for ensuring that all compliance testing is performed by an accredited laboratory and must notify all customers of the change in accreditation status. The public asked if this was only for compliance purposes. Ms. Alger responded that the Department has no authority over non-compliance samples, but if the laboratory publicizes that it has accreditation, it must report the results accurately and with appropriate qualifiers.

**Proposed changes to 252.708(a)(6), reporting**

Ms. Alger clarified that reporting in this section only applies to samples reported to DWELR. The laboratory can provide qualified data results on its own reports, but cannot report them to the Department without specific approval. Ms. Cappellini asked if the Department received a lot of requests to qualify drinking water data. Ms. Alger responded that the Department has received about 300 requests this year and that they are becoming more consistently acceptable requests.

Mr. Morse stated that most people do not notice qualifiers unless they are next to results and urged the laboratories to make sure the qualifiers are more apparent. Mr. Morse asked if there was a guidance document on how qualifiers should be worded. Mr. Morse stated that he has seen people interpret language differently, such as qualifiers "not in holding time" versus "not valid, sample analyzed out of holding time." Ms. Alger responded that this type of guidance is scheduled to be developed once the Chapter 252 draft rule is finalized.

## OTHER BUSINESS AND CONCLUSION

Ms. Alger asked if there were any other questions on Chapter 252. Ms. Dixon asked if the Department could require training on reporting drinking water results to DWELR in the regulation due to recent issues with out of state laboratories. Ms. Alger responded that the Department could look into a webinar but it intends to ask all secondary NELAP laboratories for their drinking water reporting procedures as part of the annual renewal requirements.

## APPROVAL RECOMMENDATION OF DRAFT CHAPTER 252 EDITS

Ms. Steinman asked if the Committee is comfortable moving the Chapter 252 regulation forward to the EQB with the changes of removing the subcontracted laboratory test report requirement, 14 days of absence to 21 days, and the revised sample receiving sections.

**Ms. Cappellini motioned to move the regulation forward as amended. Mr. Morse seconded the motion. All members of the committee agreed to move the regulation forward for EQB consideration.**

Ms. Martin asked if this would appear in the March EQB meeting. Ms. Edinger responded that the fee report would be in the March meeting, but the regulation would not get there until the May EQB meeting. Ms. Alger suggested the committee work on drinking water reporting, notification and technical guidance for sample receiving during the committee's 2016 meetings. Ms. Alger will also send a distribution list of laboratories to PaAAEL to work on the target quantitation limits. The public asked if there would be one section describing the major technical changes. Ms. Alger responded that the preamble lists all the changes and will be in a track changes format. Ms. Edinger stated she could provide a document on how to read the regulations. Ms. Martin reminded the public that anyone can submit comments on the Chapter 252 changes.

## ADJOURN

Ms. Cappellini motioned to adjourn the meeting. Ms. Dixon seconded the motion.