Laboratory Accreditation Advisory Committee
Minutes for October 12, 2017 – Harrisburg, PA

MEMBERS PRESENT

Anita Martin, Chester Water Authority (Municipal Authority)
Danielle Cappellini, A.E. Kirby Memorial Health Center (Commercial Environmental Laboratory) via phone
Cristin Geletei, US Steel Clairton Works Laboratory (Industrial Environmental Laboratory)
John Stolz, Duquesne University (Academic Laboratory) via phone
David Barrett, Mahaffey Laboratory LTD (Small Environmental Laboratory)
Stephen Morse, P.E., Skelly and Loy (Environmental Engineer)
Joel Jordan, PA Rural Water Association (Association of Community Water Supply Systems) via phone
Gene Greco, Franklin Township Municipal Sanitary Authority (Association of Wastewater Systems) via phone
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) via phone
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
Abbey Cadden, Executive Policy Specialist, Policy Office
Virginia Hunsberger, Laboratory Accreditation Program
Yumi Creason, Laboratory Accreditation Program
Amber Ross, Laboratory Accreditation Program
Martina McGarvey, Bureau Director of the DEP Bureau of Laboratories

CALL TO ORDER AND ATTENDANCE

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

REVIEW AND APPROVAL OF 12/07/16 MEETING MINUTES

Ms. Cappellini moved to approve the minutes. Ms. Geletei seconded the motion. All present were in favor and the meeting minutes were approved.

UPDATED DEP POLICIES

Ms. Edinger spoke about changes to the regulatory review policy. The new policy should be available for comment on eLibrary on October 13, 2017 for a 60-day comment period. The policy was originally created in 1996 and updated in 1999. Changes were made now to increase transparency and clarity with all stakeholders. Additionally, some aspects were internal DEP requirements that complicated the workflow of the policy and were removed and made into an internal SOP for the DEP. The policy is meant to provide an overview to the public on how the regulatory review process is implemented under the Regulatory Review Act and ensure relevance to the current practices based on Act 76 of 2012 related to small businesses.

Ms. Cadden summarized the new technical guidance policy for the committee. The policy is for the creation of documents that provide practical information on statues and regulations to the regulated community. The policy includes how the public and regulated community can be involved in the public participation process when revisions to technical guidance is open for comment. The DEP established an online eComment tool to increase transparency and enhance public participation. The importance of guidance documents is for the conformance with statutes and regulations, as a tool for transparency and to be helpful to the regulated community.

Ms. Edinger reviewed the new advisory committee policy. The last publication of the policy was in 1998 and has been updated to reflect current roles, functions and expectations of advisory committees and members. DEP has over 25 advisory committees. The goal of the policy is to allow for enhanced and meaningful collaboration with the public and stakeholders concerning new regulations and technical guidance. The Pa Bulletin publishes the meeting dates for all advisory committees and DEP has a public participation webpage that includes meeting minutes, agendas and a list of advisory committees. DEP functions as an informational liaison to each advisory committee as well as provides administration support. Advisory committees are required to include time for public feedback during their meetings.

Ms. Edinger and Ms. Cadden reminded the committee that the new policies will be open for comment starting October 13, 2017 on the public participation and eComment website through December 16th. Feedback is welcome and encouraged.

DISCUSSION OF CONCEPT PAPERS

The committee first reviewed the sample collection concept paper. Ms. Alger gave an overview of the reason behind the creation of a technical guidance document. Ms. Alger explained that the updated Chapter 252 has been published in the Pa. Code and the DEP has included a link on the laboratory accreditation website. Ms. Alger further explained that with all of the various options and different laboratory types, it would not be possible to include specific details or requirements in the Chapter 252 regulation for sample collection. However, public comments for Chapter 252 did include several requests for guidance on how to comply with the regulation. Ms. Alger explained that instead of creating a guidance document first, the Department is releasing a concept paper to get feedback and comments now to assist with the eventual development of the guidance document.

Ms. Alger reminded members of the public in attendance as well as LAAC members that, while the new regulations require sample collection instructions to be provided to all individuals that collect samples (both employees of the laboratory and customers), the new regulations do not require laboratories to be responsible for training non-employees. Ms. Alger also added that the guidance document is only to clarify or add suggestions for compliance. The guidance document cannot add, change or amend the regulations in any way. Ms. Steinman opened the floor for questions.

Mr. Barrett asked for clarification concerning the verification of pH. As he understood it, the requirements are for all WETT and drinking water samples but not for non-potable water samples. Ms. Alger responded that he was correct. However any sample that requires a pH adjustment or when a method would require a pH check, then the laboratory must perform and document these checks, too.

Ms. Cappellini asked why subcontracted samples were specifically mentioned in the concept paper as those samples are handled in the same way as any other received sample. Ms. Alger responded that the Department wanted feedback on any specific sample handling differences and that this section could be removed if not applicable.

Ms. Cappellini asked if section 4, bullet iii on page 5 of the concept paper requires that the name of the collector be present and not just initials. Ms. Alger responded that if the laboratory can recognize the initials and has a list that matches to the collector's name, that would also be acceptable. Ms. Dixon asked about the requirement to maintain that information as the subcontract laboratory. Ms. Alger responded that this is similar to the reasoning for separating out subcontracting samples. As long as one of the accredited laboratories had the collector information, it is not necessary that the subcontracted laboratory maintain/have that information. The laboratory can proceed with testing without the collector's name in this circumstance.

A member of the public asked how this affects samples moved between satellite laboratories. Ms. Alger responded that to the DEP, satellite laboratories are considered two different laboratories and samples must be processed as if it were subcontracted from a different laboratory. Receiving samples from a sister laboratory does not negate the requirement to check the accreditation status of the subcontracted laboratory or check the temperatures of samples at receipt.

Another public comment concerned qualifications on temperatures at receipt and specific temperature requirements versus on ice requirements. Ms. Alger responded that the Department can add this discussion to the concept paper.

Ms. Cappellini asked if the concept paper is open to treatment plants as well. Ms. Alger responded that the concept papers were added to the public participation website and are available to the public and stakeholders. Mr. Greco asked if it was okay to circulate the paper amongst laboratories to get comments since the concept paper could be confusing to single person treatment plants. Ms. Alger affirmed that would be okay. Ms. Edinger added that when distributing the paper, it should be made clear that this paper is for guidance. Mr. Greco asked Ms. Alger to write up a note for the paper that would include this warning. Ms. Alger agreed.

Mr. Greco commented that page 6 for acceptance and rejection of samples should include that samples have to be rejected prior to analysis. Ms. Alger agreed that this was an important statement and that the drinking water supply section has been clear that any result you obtain after analysis for a sample that should have been rejected at sample receiving is the result you are stuck with.

A member of the public asked about a reasonable time frame for not taking the temperature at receipt. He often receives samples within minutes of collection at the plant. Ms. Alger responded that temperature is required if receipt is greater than 15 minutes from sample collection. She added that for samples collected the same working day and on ice will almost always have a negligible temperature as evidence of cooling will have begun. She warned that laboratories should still be aware of what is written on a chain of custody for anomalies. An example being a sample collected from a stream in winter should not arrive at 85F at the laboratory on the same day of collection. Ms. Alger added that similarly we are not requiring a specific range for unpreserved sample pH checks. That will be up to the laboratory to decide what to put in its sample acceptance policy.

A member of the public had an issue with the drinking water sampling plans for copper and lead not being available on the DEP website, resulting in invalid sample results. Ms. Alger responded that those questions should be addressed to DEP's Bureau of Safe Drinking Water about making that information public. LAAC is not able to assist with drinking water sampling plans.

Ms. Steinman asked for any other questions or comments on the sample collection concept paper. There were no further questions or comments from the committee or the public on the paper. Ms. Steinman and Ms. Alger requested that any other comments can be sent to Ms. Alger, the accreditation program's general email account (eplabaccredit@pa.gov) or to the committee members.

Ms. Steinman asked for comments on the microbiology incubator concept paper. Ms. Alger opened be noting a correction – on page 2, bullet number 1 is above section (j) and (i)-(iii) should be (1)-(3) under (j). Ms. Alger explained that the Department received comments that circulating baths should be exempt, so they were removed in the final rulemaking. The Department wanted to provide technical guidance on the temperature distribution study and incubators in general because incubators have presented significant issues during recent assessments. The concept paper also includes references from standard methods to demonstrate existing requirements concerning temperature distribution studies.

Ms. Martin asked if the concept paper should include the edition of standard methods referenced. Ms. Alger explained that the concept paper was to show the committee the language existed.

Ms. Dixon asked if the committee should add a section stating that if all samples are taken out in the morning on a weekend, and the incubator is not in use in the afternoon, no afternoon temperature is required to be taken. Ms. Alger agreed and that the guidance document should add that clarification.

A member of the public asked if an average temperature passed criteria, could the incubator be used. Ms. Alger responded that the regulation is clear that any area that fails the temperature requirements cannot be used. Averaging the temperatures is not allowed. Additionally, the Department recommends not opening the door during the study and instead using thermocouples for better accuracy. If the laboratory knew the reason for an outlier temperature, an exclusion may be allowed.

Members of the public wanted clarification on number of shelves versus height of the incubator and height of each shelf. Ms. Martin commented that if every shelf position was used, it is required to be included in the study. Ms. Alger added that the study has different requirements than sample analysis. Only top and bottom shelves are checked during analysis, but all shelves are required to be checked during the distribution study. The Department did not put a specific study procedure in place due to the different types of incubators the can be used, thus it is up to the laboratory to establish a proper procedure.

Ms. Dixon asked if every shelf had to be done all at the same time since laboratories might not have enough thermometers to perform that study all at once. Ms. Alger responded that DEP would not require all shelves to be studied simultaneously.

Ms. Steinman asked if the laboratory was required to perform this study or if they could hire a third party. Ms. Alger answered that the laboratory is not required to perform the study and can hire someone else.

Ms. Martin was concerned about page 6 and evaluating the impact and handling past data, especially when data spans three years. Ms. Alger recommended the laboratory perform an ongoing study, regularly moving thermometer locations to complete the study. Ms. Martin asked what a laboratory should do if they do not use all the shelves in the incubator. Ms. Alger responded that only the shelves used during testing are required to be tested. Mr. Barrett added that labs would need to document which shelves they are using for samples.

A member of the public wanted to know what to do with incubators currently in use. Ms. Alger answered that since the regulation went into effect July 2017, the temperature distribution study must be performed before July 2020 (taking into account the 3-year rule of the regulation). If an incubator is repaired or a new one purchased, then the laboratory is required to perform the study before using that incubator. Ms. Alger added that the new MDL procedure will be required during the next cycle of MDLs, whenever that occurs for each laboratory.

Ms. Steinman asked if there were any other questions or comments. There were no additional comments or questions from the committee members or the public. Ms. Steinman requested any suggested wording or comments be sent to Ms. Alger or a committee member.

OTHER BUSINESS AND CONCLUSION

Ms. Steinman suggested scheduling next year's meetings. Ms. Edinger stated that all meeting dates are published at the end of December, but that those dates may be cancelled or some dates added. The committee agreed to have two scheduled meetings in 2018. The meetings would be held on April 12, 2018 and October 16, 2018 if the conference room is available. Ms. Steinman asked the public and committee members for any other business. There was no other business to discuss.

ADJOURN

Mr. Greco motioned to adjourn the meeting. Mr. Barrett seconded the motion. The meeting was adjourned at 10:50 AM.