Laboratory Accreditation Advisory Committee
Minutes for September 30, 2015 – Harrisburg, PA

MEMBERS PRESENT

Cristin Geletei, US Steel Clairton Works Lab (Industrial Environmental Laboratory)
David Barrett, Mahaffey Laboratory LTD (Small Environmental Laboratory)
Gene Greco, Franklin Township Municipal Sanitary Authority (Association of Wastewater Systems)
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)
Stephen Morse, P.E., Skelly and Loy (Environmental Engineer)

DEPARTMENT OF ENVIRONMENTAL PROTECTION STAFF PRESENT

Aaren Alger, Laboratory Accreditation Program Chief
Martina McGarvey, Building Director for the DEP Bureau of Laboratories
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 6/24/15 MEETING MINUTES

Ms. Dixon moved to approve the minutes. Mr. Greco seconded the motion. All present were in favor and the meeting minutes were approved.

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 feedback, and this revision is not the final product. Ms. Alger reminded the public that all feedback needs to be submitted to her or other members of the committee at least six weeks before the next LAAC meeting to be considered for the draft to be discussed on December 2. The committee hopes to be completed with the Chapter 252 amendments during the December meeting. Ms. Alger went through the revised draft and explained the reason for the Department's changes.

Proposed changes to 252.201, applications

The Department is developing a new database and left the option open for future applications to be submitted electronically. This section was updated to allow for an electronic version.

Ms. Dixon asked if section 252.203(d) could read "in a manner approved by the Department" instead of "in writing." Ms. Alger agreed.

Proposed changes to 252.204, fees

The Department added in the option to pay by credit card, but the Department cannot pay the service charge related to such payments, so an additional fee requirement was added. Laboratories may still pay by check without incurring the extra service charge.

The public asked if the Department was able to obtain a list of reasons for the increase in fees. Ms. Alger responded that the Department is preparing a program fee report, but it was not completed and ready for this meeting. The fee report will be presented at the December meeting.

The public also asked if the Department was considering third party assessors. Ms. Alger responded that the law and regulations allow for the use of third party assessors, but the Department does not anticipate a need to use third party assessors. Ms. Alger asked for input from the laboratories present concerning third party assessors. One member of the public stated that third party assessors would benefit them as the laboratory is already assessed to DOD and ISO by a third party. Ms. Steinman responded that she is aware of issues concerning the lack of consistency across the board between third party assessors. Another attendee expressed that she does not want the Department to use third party assessors because it will be much more expensive and that she appreciates the consistency that comes from the LAP staff. The Accreditation Program is not a for-profit organization, so the costs would likely be lower with state employed assessors instead of third party assessors.

Proposed changes to 252.302(j), supervisor qualifications

The Department removed the whole effluent toxicity requirements from the microbiology supervisor section and created a new whole effluent toxicity section. The requirement for microbiology credit hours was therefore removed. There were no committee or public comments/questions.

Proposed changes to 252.304(b)(3)(vi)(D), initial demonstrations of capability

The Department clarified what it would expect to see for IDOCs. The Department added language specifying that IDOCs must be analyzed consecutively. The Department also clarified that each laboratory control sample must be evaluated individually for percent recovery – not just an evaluation of the mean percent recovery. There were no committee or public comments/questions.

Proposed changes to 252.306(c), equipment

The Department added language for clarification after the last meeting to note that if there are no specifications for a supply or reference material, there is no requirement to assure its consistent operation. There were no committee or public comments/questions.

Proposed changes to 252.306(f)(9)(i), volumetric dispensing devices

The Department clarified what types of dispensing devices are required to be checked annually and which are required to be checked quarterly. Ms. Dixon asked if the term “lot” was correct for glassware. Ms. Alger responded that disposable pipettes can be verified per lot.

Proposed changes to 252.306(g), supplies

The Department clarified that a laboratory is only required to maintain a record of supplies that are directly essential to obtaining the analytical results. There were no committee or public comments/questions.

Proposed changes to 252.306(h)(6), standards and reagents

The Department added language that expired standards and reagents must be removed by the laboratory due to a recent influx in deviations concerning the use of expired standards. The public asked if language could be put in to reflect that some laboratories segregate and label expired standards as for research purposes only. Ms. Alger agreed that such language could also be added into this section.

Proposed changes to 252.307(h), sampling SOP

The Department added language to require the laboratory maintain an SOP for sampling instructions and requirements and have that SOP available to all customers and employed samplers. This requirement is based on Chapter 109 which requires a sampling SOP be maintained. This addition is meant to ensure better collection of samples.

Ms. Steinman asked if a separate SOP was required or would part of an already existing SOP be sufficient. Ms. Alger responded that the intent was that a laboratory would have the written directions in some fashion, not necessarily a separate SOP. Ms. Steinman responded that the language reads as if the regulation requires a separate SOP. Mr. Morse stated that it may not be reasonable to hand a 15-page SOP to a sampler as the procedure likely would not be read. Ms. Steinman suggested just supplying one page of the SOP. Mr. Morse asked if laboratories were required to hand the procedure to the sampler. Ms. Alger explained that the procedures would need to be made available to the customers. The public asked if it could be a guidance document or SOP. Ms. Steinman suggested maintaining instructions. Ms. Alger responded that instructions could work. She also stated that there could be different training for employees than for customers.

Proposed changes to 252.401(f), sample acceptance verification

The Department explained that since the last meeting, a requirement was added that the pH must be taken for each container and the SDWA compliance language was removed. The Department added language stating that residual chlorine only must be taken when the presence of residual chlorine compromises the test results.

The public asked if the pH check can be done prior to analysis rather than in sample receiving. Ms. Alger responded that as long as the pH check is documented, it can be taken at any time before the reporting of the results. The Department will be working on a technical guidance document on sample receiving after the changes to Chapter 252 have been approved for public comment.

Proposed changes to 252.401(j), test reports

The Department removed the language that required a report to say “test report” after comments from the last meeting and is only requiring that reports be labeled as “amended” or “revised.”

Ms. Dixon asked what the difference was between 252.401(j)(5) and 252.401(j)(16). Ms. Alger responded that some laboratories serialize test reports instead of sample identification number.

Proposed changes to 252.402(c)(4), calibration documentation

The Department corrected a typo in this section by changing “individual” to “identification.” There were no committee or public comments/questions.

Proposed changes to 252.404(c)(1)(i), autoclave

The Department clarified that pressure cookers cannot be used under any circumstances, not just concerning sterilization of media. There were no committee or public comments/questions.

Proposed changes to 252.404(g)

The Department clarified that any individual involved with microbiology testing must have his/her initials documented. There were no committee or public comments/questions.

Proposed changes to 252.404(h)

The Department corrected some typos.

The public asked if the Department has procedures for section (h)(4). The Department responded that the laboratory has to develop one and that this section is not different than the chemistry requirement for expired standards. The public asked if 252.404(k) means checks can be performed only before first use or concurrently with first use. Ms. Alger responded that to run checks concurrently runs the risk of having to invalidate results. Ms. Alger stated the intent was to make sure all quality control checks are not performed two months after results have been reported for compliance purposes.

Proposed changes to 252.601(a), assessment

The Department removed the requirement for all assessments to be performed "on-site" due to new technology. The Department did not want to hinder any future decisions to start performing some assessments off-site and through, for example, a webcam.

There was much discussion from the committee and the public regarding the individual assessors' authority to remove accreditation at the time of the on-site assessment. Ms. Alger and Dr. McGarvey both assured the attendees that the accreditation officers do not have the authority to change a laboratory's accreditation status.

Proposed changes to 252.601(i), extensions

The Department added language that it can accept extensions to corrective actions. Without the language, the Department would not be able to accept any extension requests. There were no committee or public comments/questions.

Proposed changes to 252.701(b), denial of application

The Department removed the term "on-site" in this section. Ms. Steinman asked if the "on-site" terms still left in were intended. Ms. Alger responded in the affirmative but would review the section again to make sure.

Proposed changes to 252.706(b), recordkeeping

The Department removed the terms sonication and extractions for clarification. The Department also removed the incubator recovery section. The Department also removed the requirement to document the in and out temperature of the incubator as this was not the intention of the Department. There were no committee or public comments/questions.

Proposed changes to 252.707(b), subcontracting

After the discussion during the last meeting, the Department removed the requirement that test reports shall include the name of the subcontracted laboratory. There were no committee or public comments/questions.

Proposed changes to 252.708, notification requirements

The Department added clarification on the notification requirements. Mr. Barrett asked if the 15-minute requirements changed the incubation period to, for example, 24 hrs +/- 15 minutes for IDEXX. Ms. Alger explained that it is 15 minutes after taking the samples out of the incubator.

The public asked that if section 252.708(a)(6) included microbiology samples where the results are positive but the temperature was outside of the method limits. Ms. Alger responded that this section is only concerning the

reporting to PADWIS/DWELR and not reporting to the PWS within one hour. The committee agreed that this section needs clarification.

OTHER BUSINESS AND CONCLUSION

Ms. Steinman asked if anyone else had suggested amendments. The public asked if the 15 minutes could be extended to 30 minutes due to large sample batches. Ms. Alger responded that she would have to check this with the drinking water program and the LAP's microbiologist. Mr. Barrett asked if the intent of the standard was to read 15 minutes after each sample. Ms. Alger responded that the 15 minutes starts after the incubation period.

Ms. Alger responded to an email comment about digital thermometers. The Department intentionally kept the quarterly calibration requirement rather than the TNI standard requirement of annually. Ms. Alger noted that the TNI standard will likely move that to quarterly in the next revision. Ms. Alger stated that feedback can be sent to her or anyone else on the committee.

The public asked what guidance was posted to the website. Ms. Alger responded that it was an FAQ on preparing a corrective action. The Drinking Water accredited laboratory spreadsheet, search function instructions and list of all accredited laboratories was also updated on the website.

Ms. Dixon talked about a recent discussion at another meeting with Dawn Hissner. The Department is requiring laboratories to report positive TTHM results to the client and Department for 21 VOC samples. Other laboratories are not doing this and clients are getting upset with her laboratory. Ms. Dixon asked if there is no requirement, what is she supposed to do to meet her client requests and the Department's needs. Ms. Alger said that she would invite Dawn Hissner to the next meeting.

Ms. Edinger added that the revised Total Coliform Rule was published Saturday and will be available for comment starting October 3rd. The rule will be open 60 days for comment.

Ms. Dixon asked if there was a target date for having a list of acceptable qualifiers for Drinking Water reporting. Ms. Alger responded that she doesn't have a date and is reluctant to have a blanket statement when some laboratories are submitting the correct forms while others are not. Ms. Dixon replied that her customers are concerned about the lag time reporting results. Ms. Alger responded that she is aware of that and has recently changed the LAP's procedure to send requests down weekly after review.

The public asked if there were any updates concerning the target quantitation limits for permit renewals. Ms. Alger responded that she did not hear anything new and asked if someone else or another group would be able to gather and compile the information necessary to bring to Sean Furjanic. The public responded that they have had discussions with permit writers and have not had recent issues. Mr. Barrett relayed that it was not universal and he still had clients with issues.

Ms. Edinger provided an overview of DEP's Technical Guidance Policy. The policy aims to provide new tools to engage with DEP and see feedback received, provide early notice as to policies and guidance DEP is working on to maximize the opportunity for public participation, and ensure DEP is engaging the experts on advisory committees. The major revisions to the policy include the development of a non-regulatory agenda and enhanced advisory committee consultation. Additionally, Ms. Edinger discussed the development of a new tool, eComment, for public engagement and feedback. eComment can be accessed at http://www.ahs.dep.pa.gov/eComment/. DEP encourages prospective commenters to use eComment to submit comments on its regulations, policies, guidance documents and other documents open for comment. DEP will continue to accept comments via email and US postal mail. eComment can be used to provide comments on the Revised Total Coliform Rule. In addition, two public hearings will be held for this rule on November 3rd in New Stanton and November 5th in Norristown.

The public asked if Pennsylvania's revised total coliform rule would be finalized by April 1, 2016. Ms. Edinger responded that it would not, but it was her understanding that laboratories had to meet the federal requirements

which would be in place by then. She did not know if laboratories still had to submit the required documentation to the Department by April 1. Mr. Barrett added that there is a PaAAEL seminar on the revised total coliform rule on October 26th in Lancaster.

The next meeting will be held on December 2, 2015.

The meeting schedule for next year is:

- March 22, 2016
- June 14, 2016
- September 22, 2016
- December 7, 2016

ADJOURN

Mr. Morse motioned to adjourn the meeting. Mr. Greco seconded the motion.