MINUTES
LABORATORY ACCREDITATION ADVISORY COMMITTEE
March 11, 2015 – Harrisburg

MEMBERS PRESENT

Anita Martin, Chester Water Authority (Municipal Authority)
Danielle Cappellini, A.E. Kirby Memorial Health Center (Commercial)
Cristin Geletei, US Steel Clairton Works Lab (Industrial)
David Barrett, Mahaffey Laboratory LTD (Small commercial)
Stephen Morse, Skelly and Loy (Engineer)
Joel Jordan, PA Rural Water Association (Water Systems)
Gene Greco, Franklin Township Municipal Sanitary Authority (Wastewater Systems)
Twila Dixon, M.J. Reider Associates, Inc. (Technical Expertise testing and analysis)
Marykay Steinman, Analytical Quality Assistance (General Public)

DEPARTMENT OF ENVIRONMENTAL PROTECTION STAFF PRESENT

Aaren Alger, Laboratory Accreditation Program Chief
Laura Edinger, Regulatory Coordinator, Policy Office
Sean Furjanic, Bureau of Point and Non-Point Source Management Program Manager
Thomas Starosta, Bureau of Point and Non-Point Source Management
Virginia Hunsberger, Laboratory Accreditation Program

CALL TO ORDER AND ATTENDANCE

The meeting was called to order and roll call was taken by Ms. Steinman at 9:08 am.

REVIEW AND APPROVAL OF 12/11/14 MEETING MINUTES

Mr. Barrett proposed that the 12/11/14 meeting minutes be revised to show that he was nominated to serve as vice-chair by Ms. Steinman.

Ms. Dixon moved to accept the minutes with the proposed revision. Ms. Cappellini seconded the motion. All present were in favor and the meeting minutes were accepted.

DISCUSSION OF CHAPTER 252 DRAFT AMENDMENTS

Aaren Alger, section chief of the Department of Environmental Protection's (DEP) Laboratory Accreditation Program (LAP) gave an overview of proposed changes to Chapter 252, as summarized in the document, "DRAFT Changes to 25 Pa. Code Chapter 252, For Discussion Purposes Only, January 21, 2015," made available to meeting participants prior to the meeting on the LAP website.

Ms. Alger explained that the changes were originally only going to consist of fee changes, as discussed at the 12/11 14 meeting. During that meeting, a suggestion was made to consider revision to the supervisor qualification section, so the Department decided to review all of the Chapter 252 regulation for possible improvements. The draft changes presented today are a starting point for discussion and do not reflect the only changes being considered by the Department.

Proposed Changes to Section 252.204, Fees

Ms. Alger explained that the proposed fee structure is just a starting point, and other revisions could be made to the fees based on more recent information. Ms. Steinman asked if there was any time constraint on the fee changes. Ms. Alger answered that it is projected that the increased fees would not go into effect until sometime in 2017, so that the committee can take its time to consider other changes to the standard. At least the next meeting would be needed to work through the process. Mr. Greco asked whether the increased fees would make LAP self-sufficient, and Ms. Alger answered in the affirmative.

Ms. Alger reviewed how some streamlined procedures are planned within the LAP that, once implemented, will decrease the amount of time spent on various office duties (PT review, review of secondary NELAP applications). This will hopefully help keep LAP costs from increasing.

Proposed Changes to Section 252.302, Qualifications of the laboratory supervisor

Ms. Alger reviewed the proposed changes to this section, which included the addition of some qualifying language, a requirement that at least four college semester credit hours be in microbiology for proposed microbiology supervisors, and a reduction in the required experience from two years to one year for inorganic non-metals area and limited microbiology.

Ms. Alger reviewed that past ideas to change the approval process included development of a test to qualify supervisors, but this was not workable due to insufficient staff to develop such a test and that multiple tests would be necessary for all of the varying types of methodology, techniques and other specializations that the individuals would be required to demonstrate understanding. Also proposed in the past was an interview process for supervisor approval, which was not workable due to its subjective nature.

Ms. Geletei suggested that any supervisor approval process based on interviews would only work if some independent agency made the decisions, to avoid any potential for bias.

Ms. Steinman gave the illustration of a laboratory where someone with 15 years of experience is unable to qualify as a supervisor due to insufficient college credits. She asked if there is any way that experience can count towards education. Ms. Alger explained that any process to count experience towards the education requirements would need to be structured so that it is not subjective, and stated that experience would need to be verified.

Ms. Geletei added that there are people who are very good at running analyses, but who would be wholly unsuited to the job of laboratory supervisor. Experience in and of itself does not make someone qualified to be a laboratory supervisor.

Ms. Dixon added that multiple individuals can supervise in multiple areas so that there is overlap within the laboratory.

Ms. Cappellini added that the microbiology college credits are still an issue for laboratories, and asked whether another supervisor qualification section could be established for the simpler tests (e.g., Colilert, SimPlate) that do not require the same skills as other microbiological techniques (e.g., no colony counting, no media preparation).

Mr. Barrett pointed out the language in Chapter 252 regarding a 16-day absence of the supervisor [Section 252.301(h) – An environmental laboratory shall designate another staff member meeting the qualifications of a laboratory supervisor to temporarily perform this function when a laboratory supervisor is absent for a period of time exceeding 16-consecutive calendar days.] He inquired if, with current technology, a supervisor who was away from the laboratory could still review data. Ms. Alger responded that data review could be done remotely, but that data review is only one aspect of laboratory supervision.

Ms. Alger requested that all suggested changes, including proposed language, for the supervisor qualification section, be submitted for possible inclusion in the next draft version. These submissions may be made to either Ms. Alger or to Ms. Steinman. Ms. Edinger reminded meeting participants that formal public comment to any proposed changes will be solicited once changes to Chapter 252 are published in the PA Bulletin, probably sometime next year.

Questions/comments from public regarding qualifications of the laboratory supervisor

- Wording of Section 252.302(c)(2) implies 16 college semester credit hours are required in microbiology, and an additional 16 college semester credit hours are required in biology. Ms. Alger agreed that the wording of the section could be improved for clarity.

- Is there any interim approval process for supervisors that would give a laboratory time for a proposed supervisor to acquire needed college credits? Ms. Alger answered that interim approval was not currently available.

- Must a supervisor who is already approved under the current provisions of Chapter 252 go back and be re-approved under any future, more stringent requirements? Ms. Alger answered that any supervisor approvals already in place under the current regulation would stand, and no re-evaluations would be performed retroactively.

- Would approval as a supervisor at one laboratory under the current requirements transfer to a different laboratory for the same supervisory area? Ms. Alger answered that supervisor approvals at one laboratory do not transfer to a new laboratory. In this case, the proposed supervisor at the new laboratory would need to meet the qualification requirements current at the time of nomination as supervisor.

- How is a laboratory director approved for a large laboratory where it is unlikely one person would qualify to supervise all areas of the laboratory? Ms. Alger explained that laboratories may name a laboratory director who does not meet the qualifications for laboratory supervisor in any area of the laboratory. However, all official correspondence from LAP will be addressed only to an approved supervisor who does meet the

qualifications for a laboratory supervisor in at least one area of the laboratory. Each laboratory is encouraged to name multiple laboratory supervisors to cover all areas of the laboratory, preferably with sufficient overlap to allow for coverage should a supervisor leave employment at the laboratory.

- How are proposed supervisors evaluated with respect to experience – by broad area or by individual technology? Ms. Alger answered that, per Chapter 252, each proposed supervisor must have experience in the "representative fields of accreditation for which the environmental laboratory seeks to obtain or maintain accreditation." Field of accreditation is defined by matrix, method/technology, and analyte. The LAP evaluates experience based on technology, but not on matrix or analyte.

- It is often difficult to find a qualified supervisor with enough education to meet Chapter 252 requirements, especially when a current supervisor leaves employment at the laboratory, and a new supervisor must be hired because no one currently employed at the laboratory meets the requirements. Ms. Alger reminded meeting participants that Chapter 252 requires that, once 16 calendar days pass following the loss of a current supervisor, the laboratory would have the following options for the affected areas of the laboratory: withdraw accreditation for the affected areas of the laboratory; outsource all analyses in the affected of the laboratory to an accredited laboratory; name a replacement supervisor meeting the qualification requirements for the affected areas of the laboratory. All laboratories are encouraged to have supervisor alternates in place to make the adjustment process seamless.

- Can successful performance of PT samples be used to verify a proposed supervisor's abilities to allow the individual to qualify as a supervisor? Ms. Alger answered that successful performance of PT samples merely shows that the person is able to perform the test, but does not demonstrate whether that person is able to perform all the duties required of a laboratory supervisor.

- The requirement for a minimum number of credits is acceptable as it currently stands and should not be changed.

- Even with back-up supervisors in place, a laboratory's situation can change quickly. Laboratories need a way to handle sudden situations regarding supervisors. Could two ways of approval be established? One way, for the majority of supervisors, would be the current procedure. An alternate way would be via an interview process, with a fee levied on all supervisors who elect this method of approval.

- It was proposed that the organization ABC (Association of Boards of Certification) be used as a way that individuals with insufficient college credits could be qualified as supervisors. This organization offers testing at four levels, with the 4th level covering laboratory supervisory duties. Both experience and education are analyzed before an individual is permitted to sit for one of the tests.

- Can the list of analytes in Section 252.302(d) for limited microbiology be amended to include E. coli? Ms. Alger agreed that this was an omission, and E. coli should be added.

- Where does the "16 consecutive calendar days" in Section 252.301(h) regarding an absence of the supervisor come from? Ms. Alger replied that this time period was intended to cover a two week vacation, with weekends.

Proposed Changes to Section 252.401, Basic requirements

Ms. Alger explained that the proposed changes are intended as improvements to the section relating to checking condition of samples on receipt at the laboratory, including guidance on measuring the temperature of received samples. Changes were considered due to observations at numerous laboratories where samples are not being checked properly on receipt. For example, if a sample for a particular analysis is required to be collected at neutral pH, laboratories often do not check the pH of the sample. It is possible that the sample could have been improperly preserved with acid, leading to a sample that is inappropriate for the test. A chemically unpreserved sample can be just as important as a properly preserved sample, depending on the analyte to be measured, and this must be verified. She further explained that, for laboratories that employ their own trained collectors, proper chemical preservation of samples may be documented by the collector at the time of collection. In this case, checking of samples for correct chemical preservation upon receipt at the laboratory may not be necessary.

After much discussion with the committee and the public, the Department agreed that a technical guidance document should be developed to address the multitude of options and situations that occur with sample acceptance and receipt.

Proposed Changes to Section 252.706, Recordkeeping

Ms. Alger explained that the changes to this section were for clarification, and were not actual new requirements. For example, in the case where one analyst makes an observation in the laboratory and a second analyst records that observation, the identity of both individuals must be documented.

Questions/comments from the committee regarding recordkeeping

- Ms. Steinman asked why the word "data" was changed to "records." Ms. Alger explained that all records require documentation, not just data.

- Ms. Geletei asked for an example of electronic data where changes must be documented. Ms. Alger provided the example of manual integration with chromatography data, where the original data must be maintained, as well as the manually integrated data with identification of the individual performing the manual integration.

- Ms. Alger explained that the language in Chapter 252 related to recordkeeping is intended to cover 500+ laboratories with widely varying methods of recordkeeping.

Questions/comments from public regarding recordkeeping

- How should a laboratory document changes made to information in an Excel spreadsheet? One laboratory uses an error-code correction on its electronic records, even for the correction of simple typos. Ms. Alger explained that the laboratory could use an audit-trail system, where all changes are "saved-as" to maintain the original record.

Proposed Changes to Section 252.708, Reporting and notification requirements

Ms. Alger explained that microbiology was removed from Section 252.708(a)(2) because positive microbiological results for drinking water samples are considered to be valid as soon as they are read, and no provision for a 24 or 72 hour data review period is appropriate. She further explained that the apparent change in Section 252.708(b) was a typographical error only – the 20 calendar day requirement for notification of a permanent change in supervisor is already in the current standard.

Wrap-up to discussion on Chapter 252 draft amendments

Ms. Steinman requested that all suggested changes for any section of Chapter 252 be submitted for possible inclusion in the next draft version. These submissions may be made to either Ms. Alger or to Ms. Steinman.

NPDES TARGET QUANTITATION LIMIT (QL) LIST DISCUSSION

Mr. Furjanic provided a handout summarizing key points on the topic of Target QLs and NPDES permitting, and Ms. Alger distributed the handout to meeting participants. An "Attachment B," from DEP permit application instructions, consisting of a list of the current target QLs was made available to meeting participants prior to the meeting on the LAP website.

Mr. Furjanic and Mr. Starosta invited consensus from the committee to recommend modifications to the Target QLs. They noted that there is pressure from EPA for lower limits for some analytes (mercury, as one example). Mr. Furjanic explained that the laboratories are not required to analyze every single compliance sample to the limits listed in the "Target QL" table. These limits are to be used when a permittee is preparing to send their permit renewal or an initial permit application. If a permittee's discharge regularly results in higher concentrations than listed here, then the laboratory may continue to test the samples using a less sensitive method. The Target QL list is to provide guidance to the permittees and laboratories to what limits the Department will evaluate permit renewal data.

Mr. Morse requested clarification of the difference between quantitation limit and detection limit. Ms. Alger provided an answer, and then reminded meeting participants that EPA's proposed Methods Update Rule includes significant changes to the procedure for determination of the MDL. The public comment period on the proposed rule ends on April 20, 2015.

Ms. Steinman asked meeting participants whether the current Target QLs were of concern, and which ones. BOD and Ammonia were offered as two examples with unrealistic Target QLs. Ms. Steinman requests all meeting participants to send their lists of analyte QLs and MDLs to Ms. Alger or to Ms. Steinman for review and compilation. Limits should be clearly identified as quantitation limits or as detection limits.

Mr. Furjanic will provide the Target QL listing in spreadsheet format to Ms. Alger for distribution.

Ms. Cappellini questioned why Fecal Coliform does not have a Target QL, and questioned whether full volume (100 mL) samples must be filtered. Ms. Alger explained that laboratories are required to use historical information on individual sources to do their best to try to meet the required number of colonies and avoid less-

than or greater-than results. Occasional less-than or greater-than results are unavoidable, but repeated, long term less-than or greater-than results are not acceptable (with the allowance that less-than results for full 100 mL samples are acceptable).

A request from the public was made that Ms. Alger make the request for laboratory QLs and MDLs more widely known, so that data can be gathered from other laboratories not represented at this meeting.

A comment from the public was made that no laboratories (other than the DEP laboratory) are able to meet some of the low levels. This is a set-up for laboratories to either drop accreditation, or commit fraud.

OTHER BUSINESS AND CONCLUSION

Ms. Dixon requested clarification from Mr. Furjanic regarding the reporting of total nitrate-nitrite results when one of the results is a non-detect (i.e., a less-than result). For example, if the nitrate result is 14 mg/L, and the nitrite result is < 0.1 mg/L, should the total nitrate-nitrite result be reported as < 14.1 mg/L? Mr. Furjanic explained that this is correct, and guidance on this subject may be found in the Discharge Monitoring Reports Overview and Summary guidance document. Mr. Furjanic will send a link to this guidance document to Ms. Alger for distribution.

Ms. Steinman encouraged all meeting participants to submit their lists of analyte MDLs and quantitation limits, as well as all suggested changes to Chapter 252. These submissions may be made to either Ms. Alger or to Ms. Steinman.

The next meeting will be on June 24, 2015 in Harrisburg.

ADJOURN

Mr. Greco motioned to adjourn the meeting, Ms. Martin seconded the motion. The meeting was adjourned at 11:50 am.