

MINUTES
LABORATORY ACCREDITATION ADVISORY COMMITTEE
December 7, 2016 – Harrisburg

MEMBERS PRESENT

Anita Martin, Chester Water Authority (Municipal Authority)
Cristin Geletei, US Steel Clairton Works Lab (Industrial)
Stephen Morse, Skelly and Loy (Environmental Engineer)
Twila Dixon, M.J. Reider Associates, Inc. (Technical Expertise)
Marykay Steinman, Analytical Quality Assistance (General Public)
Danielle Cappellini, A.E. Kirby Memorial Health Center (Commercial)
John Stolz, Duquesne University (Academic)
Joel Jordan, PA Rural Water Association (Water Systems)

DEPARTMENT OF ENVIRONMENTAL PROTECTION STAFF PRESENT

Aaren Alger, Laboratory Accreditation Program Chief
Laura Edinger, Regulatory Coordinator, Policy Office
Amy Hackman, Laboratory Accreditation Program
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 9:00 am.

REVIEW AND APPROVAL OF MARCH 2016 MEETING MINUTES

The committee reviewed the meeting minutes from the March 22, 2016 LAAC meeting.

Ms. Dixon moved to accept the minutes. Ms. Geletei seconded the motion. All present were in favor and the meeting minutes were accepted.

DISCUSSION OF DRAFT CHAPTER 252 PROPOSED CHANGES

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 Final Annex A – Environmental Laboratory Accreditation Rule, December 2016,” made available to meeting participants prior to the meeting on the LAP website.

Ms. Alger explained that all the comments to the proposed rule, as published in August 2016, are available for review.

Ms. Alger went through the document to explain the reasoning behind all the changes shown in red text. Some changes were based on recommendations from IRRC (Independent Regulatory Review Commission) and other changes were based on public comments. Some changes were merely corrections to previous errors.

Discussion on changes in specific sections of the document

252.201(a) and 252.203(a)

Ms. Steinman asked about the use of the wording “on forms provided” by the Department, since the LAP does not actually provide the forms directly to laboratories, but makes the forms available on its website. She suggests wording of “on forms developed” by the Department. Ms. Alger stated this could be considered.

252.203(d)

Ms. Alger reported that this added language regarding notification to customers following loss of accreditation was the result of a recommendation from IRRC. The same language will be added in the sections covering revocation, suspension and voluntary relinquishment: 252.702(d); 252.703(e) and 252.704(c). Ms. Cappellini asked how these notifications are monitored. Ms. Alger replied that the Department requires laboratories to submit a customer list and a copy of the notification, but the Department does not normally contact these customers to ensure that they actually received the notification.

352.301 and 252.302

Ms. Alger reported that the comments received regarding supervisor qualifications ranged from comments stating that the revised requirements were not stringent enough, to comments stating that the revised requirements were too stringent.

Ms. Martin asked if the operator certification program would continue to require two years of experience even after the Chapter 252 rule is changed to require only one year of experience. Ms. Alger clarified that the experience for the operator certification program may be experience with any analytical method, while the experience to qualify as a laboratory supervisor for accreditation purposes must be in the specific methods/technologies employed by the accredited laboratory.

Mr. Stolz asked whether the requirement for microbiology college credits should be revised to specifically require laboratory coursework. He stated that many colleges and universities are offering courses in microbiology that do not include any laboratory component. Ms. Dixon commented that, in the past, most four-credit microbiology courses would have included a laboratory, but this may not be the case anymore. Ms. Cappellini commented that the requirement for microbiology coursework is for supervisors only, not for analysts. Ms. Alger added that it is supervisors who are required to have the appropriate education and experience so that they may provide effective supervision for their employees.

In conducting a quick poll, committee members discussed whether each was in favor of amending the requirement for microbiology college credits to specifically require laboratory coursework. Of those present, only one committee member voted in favor of making this change. All others present voted against it.

252.304(a)(4)

Ms. Alger reported that this added language concerning personnel requirements was the result of a recommendation from IRRC.

252.304(b)(3)(vi)(D)(I)

Ms. Dixon asked whether the requirement that the initial demonstration of capability be conducted with the analyte concentration “in the lower half of the calibration range” would be satisfied if a laboratory used an analyte concentration at the midpoint of the calibration range. Ms. Alger replied that a concentration at the midpoint is not in the lower half of the range, so it would not technically meet this requirement.

252.306(h)(6)

Ms. Alger reported that language permitting expired standards, reagents and media to be used was removed based on comments. The Department agreed with the comments.

252.306(j)

Ms. Alger reported that an exception to a new requirement for incubator temperature distribution studies in the case of circulating water baths was added based on comments. The Department agreed with the comments.

Ms. Dixon asked whether this incubator temperature distribution study requirement had not been previously removed from the rule. Ms. Alger clarified that a requirement for incubator temperature recovery studies had been considered and was then removed, but the incubator temperature distribution study requirement was never removed.

Ms. Dixon asked if there is any prescribed location on a shelf or time requirements for the incubator temperature distribution study, and whether a guidance document was forthcoming. Ms. Alger replied that a technical guidance document could be created.

A member of the public asked whether the incubator temperature distribution study requirement would apply to very small incubators. Ms. Alger replied that all incubators used for microbiology would require a temperature distribution study but how the study is performed would be specific to the size and type of incubator and number of shelves.

252.307(j)

Ms. Alger reported that several comments were received regarding the requirement to develop a standard operating procedure (SOP) for sample collection and preservation as opposed to maintaining a document or using materials from another source. The Department agreed with the comments and removed the requirement to develop the SOP.

252.401(f)(1)(ii)

Significant discussion focused on clarification that was added to define sample handling and preservation checks. Specifically, discussion centered on a requirement to check sample pH for all samples to be analyzed for chemistry, whole effluent toxicity and radiochemistry fields of accreditation. Committee members and members of the public disagreed on whether pH checks on nonpotable water samples were useful or necessary. Ms. Geletei and a member of the public representing a commercial laboratory explained that the requirement was unnecessarily onerous and would create a huge amount of work (possibly requiring a new position) for little benefit, particularly for nonpotable water and soil samples. Ms. Cappellini and a second member of the public representing a commercial laboratory explained that their laboratories have already been performing this pH check on all incoming samples, including nonpotable water, and have found that it has occasionally uncovered an improperly preserved sample.

Ms. Alger explained that the requirement to check the pH of all incoming drinking water samples to be analyzed for chemistry was a requirement of the Department's drinking water program and could not be removed. However, the requirement to check pH of soil samples was not intended by the Department, and the rule could be reworded to eliminate the requirement for soil samples. Ms. Alger also explained that the intent was that the pH checks would not be required in the case

when the accredited laboratory's trained personnel collected the sample, but this was not yet appropriately articulated. The rule could be reworded to clarify this exception. Ms. Alger explained that the Department intends to develop technical guidance to explain how the laboratories can comply with the requirements for receiving and handling environmental samples.

The committee discussed whether the costs outweigh the benefits in the case of pH checks of nonpotable water samples for chemistry analysis. The committee ultimately proposed to limit the pH check requirement to whole effluent toxicity samples and drinking water samples to be analyzed for chemistry, thus removing the requirement for nonpotable water and soil samples to be analyzed for chemistry, and all samples to be analyzed for radiochemistry. Ms. Edinger added that this change could be an acceptable compromise, in that the revised rule would adequately protect public health and safety without being overly burdensome on the laboratory community. The members of the public that attended the meeting were amenable to this proposal.

The proposed language for 252.401(f)(1)(ii) would be changed to: The sample pH for all samples to be analyzed for whole effluent toxicity and safe drinking water chemistry fields of accreditation, unless the sample is collected by the environmental laboratory performing the analysis.

252.402(f)(6)

Ms. Steinman questioned the addition of the word "THE" before *Standard Methods* in various places in the proposed rule. Ms. Alger explained that this addition was due to a recommendation from regulatory review personnel, but agreed that it was not appropriate and would request to remove it. In addition to 252.402(f)(6), the affected sections are: 252.402(h)(6); 252.402(i)(4); 252.402(j)(3); 252.404(c)(9)(i); 252.404(d)(6); 252.404(e)(1) and 252.404(e)(3).

252.404(d)(7)

Ms. Dixon asked whether laboratories would now be required to hold accreditation in order to perform bacteriological water quality ratio analysis (suitability testing) on reagent water. Ms. Alger replied that the Department will begin to offer this accreditation, and laboratories performing this testing will need to acquire this accreditation.

Ms. Martin asked under which category this accreditation would fall for purposes of accreditation fees. Ms. Alger replied that it would not fall under the basic drinking water category, but would fall under either the microbiology category.

252.404(g)(2)

Ms. Alger reported that the change from “samples” to “sample aliquots” was made to clarify the frequency for sterility blanks with membrane filtration methods. As an example, if one sample is filtered using 10 different sample volumes, this would count as 10 sample aliquots, and thus a sterility blank would be required before any additional sample aliquots could be filtered.

252.404(h)(7)

Ms. Alger reported that the added language regarding requirements for processing of positive and negative culture control checks on media was based on comments received during the public comment period. The Department agreed with the comments.

252.601(h)

Ms. Alger reported that proposed added language in this section regarding correction of assessment deficiencies was being removed as it was unclear and causing confusion. This change was the result of a recommendation from IRRC.

252.706(c)(1)

Ms. Alger reported that the change from “signature” to “name” of the individual making an observation for purpose of recordkeeping was based on comments received. The Department agreed with the comments.

Other discussion

Ms. Alger noted that creation of any technical guidance documents would not begin until the second half of 2017 at the earliest, after publication of the finalized rule. A member of the public asked how technical guidance documents are handled. Ms. Alger replied that they are handled similarly to regulations, with input from the LAAC and other members of the public through an official process for approval.

Ms. Alger and Ms. Edinger reviewed the next steps. Ms. Alger will put the rulemaking package together for review. The Environmental Quality Board (EQB), the Governor’s Office of General Counsel, the Governor’s Budget Office, IRRC and the Attorney General’s office will all review and approve before it is published. Ms. Edinger predicted that publication would happen no sooner than August 2017.

Ms. Alger reported that she will prepare an official response to all written comments to the proposed rule, as published in August 2016. This response will be made available on the Department's Environmental Quality Board 2017 Meetings webpage.

Ms. Cappellini asked if there is a specific level of residual chlorine that is known to compromise the validity of tests, as related to the requirement of 252.401(f)(1)(iii). She stated that the New York Department of Health requires a residual chlorine level of < 0.1 mg/L. Ms. Alger replied that it is not appropriate to include any level in the regulations because the level will depend on the specific test being performed.

Wrap-up to discussion of draft Chapter 252 proposed changes

Ms. Alger and Ms. Edinger asked the committee whether it will recommend concurrence with the DEP recommendation to move the rulemaking forward, with the amendments as agreed to during this meeting. Mr. Morse made a motion to make this recommendation. Ms. Dixon seconded the motion. All present were in favor and the motion carried.

Ms. Alger reviewed the tentative dates for meetings in 2017. These are: June 7, 2017; September 13, 2017 and December 5, 2017.

OTHER BUSINESS AND CONCLUSION

There was no other business to discuss.

ADJOURN

Ms. Geletei motioned to adjourn the meeting, Ms. Martin seconded the motion. The meeting was adjourned at 11:20 am.

The next meeting is scheduled for June 7, 2017 in Harrisburg.