

Laboratory Accreditation Advisory Committee
Minutes for December 5, 2018 – Harrisburg, PA

MEMBERS PRESENT

Anita Martin, Chester Water Authority (Municipal Authority)
Danielle Cappellini, A.E. Kirby Memorial Health Center (Commercial Environmental Laboratory) via phone
John Stolz, Duquesne University (Academic Laboratory) via phone
Joel Jordan, PA Rural Water Association (Association of Community Water Supply 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
Dwayne Burkholder, Laboratory Accreditation Program
Michael Deighan, Laboratory Accreditation Program
Emily Meilott, Laboratory Accreditation Program
Martina McGarvey, Director, 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 4/12/18 MEETING MINUTES

A motion was made to approve the minutes, and the motion was seconded. All present were in favor and the meeting minutes were approved.

PA DEP SECRETARY PATRICK MCDONNELL

Dr. McGarvey introduced Secretary McDonnell to the committee. He expressed appreciation for the service of LAAC and the excellent work they do to aid the Department. Secretary McDonnell noted that the process to approve the most recent regulation update of Chapter 252 was very smooth because of the effort of the committee.

TECHNICAL GUIDANCE DOCUMENT FOR MICROBIOLOGY

The committee first reviewed the Technical Guidance Document for Microbiology. Ms. Alger introduced the technical guidance document and gave a brief outline of the document. Ms. Alger explained that the guidance document is to explain the regulatory requirements and to give members of laboratories tools so that they can ensure that they meet the requirements. In addition, Ms. Alger requested examples of temperature distribution studies from any laboratories that have successfully performed a temperature distribution study and would be willing to share it so that it could be included in the guidance document.

After introducing the guidance document, Ms. Alger guided the committee through the document section by section and gave opportunity for comments or questions in each section.

The first question came from a member of the public concerning Section 3.1.1, which addresses incubation units. The question was whether aluminum heating blocks used for biological indicator checks for autoclaves need a temperature distribution study. Ms. Alger responded that this question would be addressed in a later section of the document.

In section 3.2.1, Ms. Martin suggested specifying which version of Standard Methods is referenced. Ms. Alger and Mr. Burkholder replied that this citation is only referring to the temperature of the incubation which stays the same in each edition.

Mr. Burkholder explained that in Section 3.2.4, the 22nd edition of Standard Methods is cited because it was the most recent edition at the time the document was written and the section that it is referring to may change between editions. Ms. Alger agreed that it would be beneficial to add a statement to the guidance document which notes that other versions of Standard Methods may be used.

In Section 3.2.4.2, Ms. Martin asked if there was an established time for how long it takes a cold sample to come to temperature in the incubator for the Colilert method. Mr. Burkholder answered saying that it depends on the type of sample as well as the incubator. It was also noted that only Colilert 18 has a pre-incubation step. A member of the public asked if laboratories should do a study on how long it takes samples to come to temperature in the incubator. Another member of the public asked how that could be enforceable? Ms. Alger replied that determining how long it takes samples to come to temperature in the incubator is the responsibility of the laboratory.

Also, in this section, a member of the committee via phone pointed out that the quote from Standard Methods says to bring "cold sample in media to room temperature." Mr. Burkholder confirmed that samples should be brought to room temperature before adding media. Ms. Alger agreed that this directive from Standard Methods should be explained. This prompted a question from a member of the public about whether samples collected and transported to the laboratory on ice need to be warmed up again at the laboratory. Ms. Alger replied that the member of the public was correct but noted that cooling of drinking water samples for microbiology is only recommended. Another member of the public asked if the prewarming step was required. Ms. Alger replied that if it is not mandated consider it a recommendation and redirected the conversation back to the guidance document.

In Section 3.2.4.6, Ms. Martin noted that there was a typo "or" instead of "of."

In Section 3.3 Equipment Records, Ms. Steinman requested to bold or underline the statement "Even laboratories that only have one refrigerator, one incubator, or one drying oven must uniquely identify each item, and the records must reflect these unique identifications." Ms. Alger agreed.

In Section 3.3.3, Ms. Alger reminded the audience that the last sentence indicates that laboratories should consider "the risk" when developing procedures. The procedures laboratories put in place now will inform decisions that may need to be made in the future. The more clear and thorough the records of the equipment are, the easier it will be to determine any effects of equipment failure on the data.

Section 4.1, Ms. Alger reminded the audience that the laboratory can monitor the temperature of the incubators more frequently than two times per day 4 hours apart.

Section 4.2, Ms. Alger explained that this section gives practical examples for monitoring microbiological incubation units and reminded the audience that monitoring of the incubation unit is not required on holidays or weekends if no samples are in the incubator.

Section 4.3, Ms. Alger recommended applying these principles to the entire laboratory not just equipment for microbiology. A committee member on the phone asked if this section addressed what to do with samples if the incubator goes down while they are being incubated. Ms. Cappellini pointed out that Section 4.3.3 discusses this issue. Ms. Alger informed the audience that the Laboratory Accreditation Program is working to improve the process of responding to qualified drinking water microbiology and chemistry requests.

Section 5.0, Ms. Alger explained that the standard is short concerning temperature distribution studies, but this document has many recommendations and elaborates on the standard requirements. A member of the public asked if it is necessary to perform a temperature distribution study on heating blocks used for biological indicator tests. Ms. Alger and Mr. Burkholder agreed that it would not be necessary to do a temperature distribution study on the heating block. Another member of the public pointed out that Section 5.1.1.1. indicates that it is required. Ms. Alger replied that the Section would discuss it.

Ms. Alger explained that some sections (5.2 and 5.3) are redundant but are included because they apply to different aspects.

Ms. Martin asked if the DEP needs to be contacted if a temperature distribution study "fails" or is not acceptable. Ms. Alger replied that it would depend on the laboratory's procedures and what samples are affected. Ms. Alger gave the example that at least one laboratory does a temperature distribution study continuously while analyzing samples. In that case, a problem could be identified and corrected immediately thus not affecting many samples. Ms. Martin illustrated the concept with an analogy of a failed PT. If a PT fails, it does not mean everything else is wrong, but an investigation is necessary to determine the extent of the problem. Mr. Burkholder gave an example of a laboratory that did a temperature distribution study and found the bottom shelf was 0.5°C lower than the top shelf. The laboratory did not keep track of what samples were on the lower shelf, so they were unable to know which samples were affected.

The review of the document was complete. Ms. Alger again requested members of the public send in examples of temperature distribution studies to be included in the guidance document. Ms. Steinman requested that any examples be put in an appendix.

OTHER BUSINESS AND CONCLUSION

Ms. Alger discussed the next steps for the committee. Ms. Alger acknowledged that the LAP was aware the document uses the term "must" frequently and will evaluate the use of "must" in the document. There was discussion about whether the document should be approved now and then amended when the appendix is added. The committee agreed that they would like to review it again before it goes out for public comment if examples will be added to the document. It was noted that the public can view the document in draft form on the LAP website.

Ms. Alger informed the committee that the next meeting is scheduled for May 1, 2019, but an additional meeting could be scheduled if the committee wants to review the document again

before May. The committee discussed it and decided to wait and see if the LAP receives some examples of the temperature distribution study. Ms. Alger said she will wait until January to see if any examples are submitted and if none are received she will reevaluate the timeline and contact the committee. A member of the public requested that the discussion of the microbiology guidance document and sample collection document be staggered in future meetings so that each one could receive equal focus.

Ms. Alger provided three updates to the audience that were unrelated to microbiology. First, upon discussion with the Bureau of Safe Drinking Water, the LAP discovered an error. Only public water systems have the right to Accreditation by Rule for DW SDWA compliance. Ms. Alger prepared a letter to send to all Drinking water accredited laboratories which explains the requirements and deadlines. Second, Ms. Alger informed the audience that there is a new requirement for laboratories testing reagent water for microbiology. The LAP will be adding new methods and analytes and specifically accrediting for HPC and the bacteriological water quality test on reagent water. There will be no PT requirement for this accreditation. Ms. Alger stated that a letter is being written to notify all the laboratories of the new requirement. Ms. Alger clarified that if a lab is already accredited for HPC they do not also need to be accredited for HPC in reagent water. Finally, Ms. Alger announced that the LAP will begin scoring and tracking PTs electronically and requested that laboratories pay specific attention to ensure that the TNI codes are entered appropriately. If the TNI code is inaccurate, the software will next look at the method, so it is also important to make sure that the method is entered exactly as it appears on the laboratories' scope of accreditation. However, if the TNI code is accurate it is not as important that the method is entered the same as on the scope of accreditation. Ms. Alger also noted as this is a new procedure the LAP will be accepting wrong digits that are mistakenly entered for at least one year. A member of the public asked if the PT for chlorine should be analyzed using SM 4500 or EPA 334. Ms. Alger replied that the LAP does not accredit for EPA 334 because it is not a promulgated method and therefore no PT is required.

Ms. Steinman asked the public and committee members for any other business. There was no other business to discuss.

ADJOURN

A motion was made to adjourn the meeting, and it was seconded. The meeting was adjourned at 10:10 AM.