Pennsylvania Department of Environmental Protection
Bureau of Laboratories

MICROBIOLOGY INCUBATION UNITS
(DEP ID: 150-4200-001)

COMMENT RESPONSE DOCUMENT
May 2, 2020

LIST OF COMMENTATORS

1. Anne Harvey
   220 Monroe Street
   Philadelphia, PA 19147

2. Dean Minnich
   Nazareth Borough Municipal Authority
   872 Tatamy Road
   P.O. Box A
   Nazareth, PA 18064

3. Glenn DeBernardi
   200 Ross Street
   Plymouth Meeting, PA 19462

4. Linda O'Donnell
   Philadelphia Water Department
   1500 East Hunting Park Avenue
   Philadelphia, PA 19124

COMMENTS AND RESPONSES

General Comments

1. **Comment:** I have a concern about the language in the DISCLAIMER on the title page of this document. The disclaimer states: "...The policies and procedures herein are not an adjudication or a regulation. DEP does not intend to give this guidance that weight or deference." HOWEVER, the last part of this disclaimer states that the state reserves the right to use its "discretion" and IMPLIES that there WILL BE enforcement of "recommendations" by the state even if these recommendations are not accounted for in the state code, specifically Chapter 252. It does not seem legally enforceable to treat a "recommendation" in a guidance document the same as a requirement in the State Code, but the language seems to leave some wiggle room as to the weight this this guidance document carries when considered by an accredited laboratory. Can the PA DEP assure accredited laboratories that the state will NOT enforce "recommendations" when they conduct audits? If a lab is currently in compliance with the microbiology incubator standards based on the minimum requirements stated in the State Code, can that lab be assured that they will not receive any "surprises" at audit time (i.e., violations based solely on a "recommendation")? If a lab does not implement "recommendations" (i.e., does not purchase thermocouples, but continues to use liquid-filled, glass thermometers) will they still be in compliance at audit time? Or will the stated "discretion" entail enforcement of recommendations, even though those recommendations are not codified in Chapter 252? (1)

Response: A technical guidance document (TGD) serves as a baseline of standardized guidance between the Department, regulated entities, and the public with recommended methods that achieve regulatory compliance. This TGD does not affect the regulatory requirements published in 25 Pa. Code Chapter 252 and the Laboratory Accreditation Program only enforces regulatory requirements, not recommendations. The disclaimer printed on the cover page is standard language issued on all of the Department's TGDs and is intended to provide flexibility with the understanding that unique scenarios may exist where alternative methods may be appropriate.

2. **Comment:** Most WWTPs use a one (1) cubic foot dry air incubator. The proposed Temperature Distribution study that would be required for dry air incubators contains a couple of questions and issues as presented. 1. What type of thermometer would be necessary. A wireless thermometer? The use of a thermometer in solution would not work because the door on the incubator would have to be opened every half hour to record the temperature. This does not represent how an incubator is designed to operate. 2. Who has the staffing to perform this test. We do not have the luxury of being able to dedicate an employee for an 8 hour day to log temperatures every half hour. (2)

Response: § 252.306(j)(2) states, "At a minimum, the laboratory shall monitor and record the temperature of each shelf." An incubation unit with an internal space of one cubic foot and a single shelf would meet this definition. In this case, if the incubation unit maintains constant temperature as documented through daily temperature logs, it would pass the temperature distribution study.

3. **Comment:** I feel there should be some type of exemption for small air incubation units such as a single chamber Millipore units that only have a space of 0.1 cubic foot. It would be very difficult to conduct a temperature study on cavity of that size. I currently use a circulating water bath daily for my fecal coliform samples as required by the Ch. 252 requirements and use the

smaller Millipore incubator about once every 10 months or so for the appropriate sterility and growth checks at 35 degrees C. This rule seems more geared towards a commercial lab with very large incubators that are opened and closed many times a day and hence, subject to temperature swings and not towards a typical wastewater laboratory in which the incubator would be opened once a day. (3)

Response: § 252.306(j)(2) states, "At a minimum, the laboratory shall monitor and record the temperature of each shelf." An incubation unit with an internal space of one cubic foot and a single shelf would meet this definition. In this case, if the incubation unit maintains constant temperature as documented through daily temperature logs, it would pass the temperature distribution study.

4. **Comment:** The draft technical guidance document cites section 252.401(i)(3) as the rationale that a laboratory must determine the effect of non-conformances on past data if an incubator study reveals that one or more areas in the incubation unit does not maintain the necessary temperature range. PWD disagrees with that rationale and requests that section 5.3.3. be wholly removed from the technical guidance document. Section 252.401(i)(3) states that a laboratory will establish a procedure to "define how the analyst shall treat the results of testing or analysis of environmental samples if the associated quality control measures fail to meet the requirements of the method." This is written in the active tense. The analyst is currently evaluating both the quality control and the analytical batch results. The quality control measures, including incubator temperatures, are part of the laboratory records. If at the time of analytical batch evaluation, all the quality control measures met the specifications of the method and applicable regulations, a laboratory would have no basis to retract previously reported data. Additionally, the laboratory cannot invalidate certain results per PA-DEP directive. If the samples in question were analyzed for SDWA compliance, the laboratory has one hour to make its evaluation of the results before PA-DEP regional office must be contacted and other notification activities are triggered. The consequence of retracting analytical data or otherwise stating that past analytical data is suspect, would have a wide-ranging ripple effect. The laboratory could be in violation of other state or federal regulations, depending to which program the analytical results were reported. (4)

Response: 25 Pa. Code Chapter 252 does not currently require documentation of where samples are located in an incubator. To reflect this suggestion, DEP removed this example from the TGD. Without knowing where the samples are located in the incubator, the laboratory may not be able to properly qualify past sample results.