Commonwealth of Massachusetts
Executive Office of Energy & Environmental Affairs

Department of Environmental Protection
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June 17, 2020

RE: Laboratory Certification Program Policy on Microbiology Proficiency Testing (Policy # WES-2020.002)

Dear Laboratory Director or Other Interested Party:

Enclosed is the updated Massachusetts Department of Environmental Protection (MassDEP) Laboratory Certification Program (LCP) Policy on Microbiology Proficiency Testing (PT). This policy replaces Policy # WES-14.002.

The revised policy updates regulatory citations, division and program titles, and web links.

If you have any questions concerning this policy, please contact Lisa J. Touet, Director of the LCP, at 978-242-1364.

Sincerely,

Oscar C. Pancorbo, Ph.D.
Division and Station Director
Division of Environmental Laboratory Sciences
Senator William X. Wall Experiment Station

cc: Ann Lowery, MassDEP, BPE
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MassDEP Certified Laboratories
Proficiency Test Providers

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Massachusetts Department of Environmental Protection
Division of Environmental Laboratory Sciences
Senator William X. Wall Experiment Station

Laboratory Certification Program
Policy on Microbiology Proficiency Testing
Policy # WES-2020.002

Effective Date: June 17, 2020
Replaces the Policy on Microbiology Proficiency Testing # WES-14.002

1.0 Introduction

1.1 The Massachusetts Department of Environmental Protection (the Department or MassDEP) regulations for the certification and operation of environmental analysis laboratories at 310 CMR 42.04(3) state that a laboratory applying for certification as an environmental analysis laboratory must satisfactorily analyze samples from a proficiency testing (PT) program approved by the Department for the matrices, disciplines, and categories for which certification is sought. Also, 310 CMR 42.10(1) states that a laboratory wishing to maintain certification must satisfactorily analyze samples from a PT program administered or approved by the Department.

1.2 This policy outlines the requirements for providers of and participants in a microbiology PT program. The Department reserves the right to determine acceptable performance of a laboratory in a PT program which includes, but is not limited to, the elements outlined in this policy.

2.0 General Requirements

2.1 As specified in 310 CMR 42.08(5)(a)8, in order to meet the minimum standards for certification, certified laboratories must use acceptable analytical methods. The acceptable methods are those defined or referenced in the current regulations at 40 CFR Part 141, 40 CFR Part 143, 40 CFR Part 136, and 310 CMR 22.00 for the environmental matrix being tested. All samples, including PT samples, that are or that may be used for certification purposes must be analyzed using approved methods only. All PT samples are to be analyzed and the results reported in a manner consistent with the analysis and reporting requirements of compliance samples and any other samples analyzed according to the requirements of 310 CMR 42.00. The laboratory participating in a PT study (participant) must report the specific analytical method(s) and media (e.g., SM9222B/m-Endo, SM9223B/Colilert®, etc.) used for each PT round to the vendor providing the PT samples (provider).

2.2 Except when otherwise specified by the Department, all PT studies being used to obtain or maintain certification must meet the criteria set by the National Environmental Laboratory Accreditation Program (NELAP) and implemented by the Proficiency Testing Provider Accreditor (PTPA) or its successor body for accredited PT providers.

2.3 Before the close of a PT study, a laboratory must arrange with the PT provider so that the study results are sent directly from the PT provider to the MassDEP Laboratory Certification Program (LCP) before or at the same time that results are released to the laboratory. With the exception of those being used to obtain certification for the first time for a specific analyte/method within a matrix or to regain certification following revocation, PT study results must be submitted to the LCP by December 31st of the same calendar year in which the test was performed to meet the requirements of this policy.

2.4 A laboratory must not send any PT sample, or a portion of a PT sample, to another laboratory for any analysis for which it is certified or seeking certification.

2.5 A laboratory must not communicate with any other laboratory (including other laboratories within the same company) or person regarding the results obtained from the analysis of the PT sample before the PT provider releases the study results.

2.6 Frequency

2.6.1 Laboratories Requesting Initial Certification or Modification of Certification: A laboratory seeking initial MassDEP certification must obtain a laboratory identification number from the USEPA. A laboratory seeking certification for microbiology analyte(s)/method(s) through application for initial microbiology certification or modification of existing microbiology certification must successfully complete two PT studies, within the three most recent (i.e., within the last eighteen months) studies attempted, for each analyte/method in a matrix for which the laboratory is requesting certification as part of the application process. The PT studies must be separated by a minimum of 15 calendar days as determined by the analysis dates and the study closing dates.

2.6.2 Laboratories Seeking to Maintain Certification: Laboratories seeking to maintain certification must successfully participate in a PT study at least once each calendar year for each analyte/method/matrix in which the laboratory wishes to maintain certification. The laboratory must participate in a Water Supply (WS) PT study for potable water analytes and a Water Pollution (WP) study for non-potable water analytes. If a participant fails a PT study for an analyte/method in a matrix, it must participate in an additional PT study for that analyte/method/matrix as described below (see "Certification Status" below). A laboratory that reports no PT study data in a calendar year for a microbiological analyte/method for which it is certified will have its certification status downgraded to “Not Certified” for that analyte/method.

2.7 Acceptable/Unacceptable Results: The PT provider will determine acceptable/unacceptable results for each PT sample. If the participant believes that a provider’s evaluation is incorrect, it is the responsibility of the participant to contact the PT provider and inform it of the problem.

2.8 Summary Reports: The PT provider must identify and explain unusually high failure rates among study participants in the report.

2.9 For all enumerative methodology, the laboratory must correctly analyze all samples in the PT sample set.

2.10 The laboratory must have available and maintain for five years all of the raw data and calculations for all PT analyses and the associated quality control analyses conducted by all methods.

3.0 Reporting and Scoring of Total Coliform and *E. coli* in Water Treatment and Distribution PT Samples

3.1 The participant must report results of each sample analysis to the provider as total coliform present (positive) or absent (negative) and either present or absent for *Escherichia coli*. Laboratories using enzyme substrate methods (SM9223B) must specify the medium used (e.g., SM9223B/Colilert® or SM9223B/Colisure®).

3.2 Acceptable performance for total coliform and *E. coli* is defined as the participant correctly analyzing at least 90% of the samples in each testing round with no false negatives. "Correct" analysis is defined by the provider's evaluation or a validation process as approved by the National Environmental Laboratory Accreditation Program (NELAP) Proficiency Testing Provider Accreditor (PTPA) or its successor body.

3.3 A laboratory must be certified for at least one approved total coliform analytical method plus one *E. coli* analytical method if the laboratory analyzes finished drinking water samples for compliance purposes. Because of this interdependency of the methodologies, a correct PT analysis is needed for both the total coliform assay and the *E. coli* assay within the analytical method system being used. Therefore, if a participant passes one parameter but fails the other, this is considered a system failure and the laboratory must pass a follow-up PT study for both parameters. Any change in certification status as a result of a laboratory’s performance in PT studies will affect all parameters in the total coliform and *E. coli* system.

Note: A set of 10 potable water PT samples, when analyzed as samples for enumeration, may be used to satisfy the requirements for both, enumerative methods for potable water source water and

the corresponding presence/absence methods for potable water treatment and distribution samples.

4.0 Reporting and Scoring of Total Coliform, Fecal Coliform, *E. coli*, Enterococci, and Heterotrophic Plate Count in Source Water PT Samples

4.1 Heterotrophic Plate Count (HPC)

4.1.1 A laboratory seeking to obtain or maintain certification for heterotrophic plate count in source water must obtain acceptable results in a potable water PT study that consists of a minimum of one enumerative sample. Wastewater PT samples are not acceptable due to the higher counts in these samples that are not representative of source water samples.

4.1.2 Results are to be reported quantitatively as colony-forming units per milliliter (CFU/mL) or as most probable number per milliliter (MPN/mL).

4.1.3 A PT study is considered acceptable when the results reported for all positive samples are scored acceptable by the PT provider and any blank samples are reported as ≤ 2 CFU/mL or ≤ 2 MPN/mL.

4.2 Total Coliform, Fecal Coliform, and *E. coli*

4.2.1 A laboratory seeking to obtain or maintain certification for total coliform, fecal coliform or *E. coli* in source water must participate in a potable water PT study that consists of a minimum of one enumerative sample. Wastewater PT samples are not acceptable due to the higher counts in these samples that are not representative of source water samples.

4.2.2 Results are to be reported quantitatively as colony-forming units per 100 milliliters (CFU/100 mL) or as most probable number per 100 milliliters (MPN/100 mL); reporting as Presence/ Absence is not acceptable.

4.2.3 A PT study is considered acceptable when the results reported for all positive samples are scored acceptable by the PT provider and any blank samples are reported as ≤ 2 CFU/100 mL or ≤ 2 MPN/100 mL.

4.3 Enterococci

4.3.1 A laboratory seeking to obtain or maintain certification for enterococci in source water (ground water) must participate in a PT study that consists of a minimum of ten samples; all shipped at the same time, in either a lyophilized, dehydrated, or aqueous state. The set must include samples, in various combinations, that are enterococci positive (e.g., *Enterococcus faecium* or *Enterococcus faecalis*), enterococci negative (e.g., *Serratia marcescens* or *E. coli*), and at least one blank. The PT samples must be representative of potable source water samples (i.e., low counts of organisms).

4.3.2 The laboratory must analyze a PT sample set with a single analytical method and specify the method/medium used (e.g., EPA 1600/MEI or Enterolert®). The laboratory must report the results of each sample analysis as present (positive) or absent (negative) for enterococci.

4.3.3 Acceptable performance for enterococci is defined as the participant correctly analyzing at least 90% of the samples in each testing round with no false negatives. “Correct” analysis is defined by the provider’s evaluation.

5.0 Reporting and Scoring of *E. coli* and Enterococci in Ambient Water, and Fecal Coliform, *E. coli*, and Enterococci in Wastewater PT Samples

5.1 A laboratory must participate in a non-potable water PT study that consists of a minimum of one sample. Potable water PT samples are not acceptable due to the lower counts in these samples that are not representative of ambient water and wastewater samples.

5.2 Laboratories that are maintaining certification or applying for certification for the same analyte, using the same methodology, in both ambient water and wastewater may participate in one non-potable water PT study. If the result is acceptable, it will fulfill the PT requirements for both areas of

certification. If the result is unacceptable, the failure will apply to the specific analyte/method for both ambient water and wastewater.

5.3 Results are to be reported quantitatively as colony-forming units per 100 milliliters (CFU/100 mL) or as most probable number per 100 milliliters (MPN/100 mL); reporting as Presence/Absence is not acceptable.

5.4 A PT study is considered acceptable when the results reported for all positive samples are scored acceptable by the PT provider and any blank samples are reported as ≤ 2 CFU/100 mL or ≤ 2 MPN/100 mL

6.0 Certification Status

6.1 Laboratories seeking initial certification or modification of an existing certification must demonstrate acceptable performance in two PT studies for each analytical method requested (see Section 2.6.1 above) before certification in microbiological analytical methods can be granted.

6.2 For laboratories that are seeking to maintain certification, the results of proficiency tests will be used to determine the certification status as follows:

6.2.1 A laboratory that is certified for a particular microbiological analyte/method and fails a PT study for that analyte/method (i.e., results determined by the PT provider to be "not acceptable") must, within 30 days of receiving notice of the PT failure, determine the cause(s) of the error, take corrective action(s), and notify the LCP in writing describing the corrective action(s) taken.

6.2.2 After taking corrective action(s), a laboratory must participate in a new PT study. This follow-up PT study must be completed within the same calendar year, a minimum of 15 days but no more than 90 days after the initial failed PT notice (note: due to the acute health effects of microbial contaminants, the 90-day limit is specified for microbiology certification and not for chemistry certification). In order to ensure meeting this requirement, laboratories should participate in PT studies no later than the spring of each year in order to allow enough time for a possible repeat PT study to be completed within the same calendar year. The PT provider will then evaluate the analytical results and report the findings to the participant laboratory and to the LCP. The certification status of the laboratory will remain “Certified” during this period and after successful analysis of the follow-up PT study provided that all deficiencies noted in an on-site inspection that would affect certification status have been corrected satisfactorily and that no other deviations from 310 CMR 42.00 have been noted.

6.2.3 If a certified laboratory fails to take corrective action(s), to complete a follow-up PT study as required in Section 6.2.2 above, or to notify MassDEP as described in Section 6.2.1 above, it will have its certification status downgraded to "Not Certified" for the microbiology analyte(s)/method(s) associated with the initial PT round failure.

6.2.4 A laboratory that fails two PT studies in a row for a particular microbiology analyte/method will have its certification status downgraded to "Not Certified" for that analyte/method pursuant to 310 CMR 42.12(3)(a)3.

6.2.5 A laboratory's failure of two PT studies in a row indicates that the corrective action taken earlier by the laboratory was inadequate and may signal major problems with the microbiological analytical system in the laboratory. Further corrective action must be taken by the laboratory and documentation of that action sent to the LCP for approval before the laboratory may participate in another PT study.

6.2.6 After reviewing the corrective action documentation submitted by a laboratory (now "Not Certified") and prior to approving its participation in a new PT study, the LCP may decide to conduct an on-site inspection/audit of the laboratory, may provide or recommend training for laboratory staff, and/or may recommend that the laboratory seek third-party assistance in microbiological laboratory operation.

6.2.7 The LCP will upgrade the certification status of a laboratory from “Not Certified” to “Certified” provided that: the laboratory received MassDEP approval to participate in follow-up PT studies; the laboratory successfully performed two follow-up PT studies (see Section 2.6.1

above); the laboratory has satisfactorily responded to all deficiencies noted in an inspection that would affect certification status; and no other deviations from 310 CMR 42.00 have been noted.

6.2.8 If a laboratory submits to the LCP results of more than one PT study per analyte/method in a calendar year, the above certification rating scheme and criteria will apply to all studies (i.e., a laboratory submitting results of one PT study must pass one study; a laboratory submitting results of two studies must pass two studies, etc.).

7.0 REQUIREMENTS FOR PT PROVIDERS

7.1 A PT provider of microbiology proficiency tests must be accredited by and continue to meet the requirements of NELAP PTPA or its successor body for the microbiology parameters in which accreditation is available. Where accreditation is not offered, the provider must be approved by the MassDEP LCP. The list of accredited PT providers is available at:

http://www.nelac-institute.org/ptproviders.php.

7.2 Review of Providers: MassDEP reserves the right to review each provider's PT program and withdraw approval if these program requirements are not met or for any other factors that MassDEP deems relevant to the determination of the ability of the provider to operate a satisfactory PT service.

NOTE: It must be emphasized that a laboratory's certification status is determined not only by its performance in acceptable proficiency tests but by a combination of criteria including qualifications of personnel, its performance in inspections, and, in the case of laboratories located outside of Massachusetts, the status of its certification from its resident state. For more information about the Massachusetts laboratory certification process and requirements, consult the MassDEP regulations for the *Certification and Operation of Environmental Analysis Laboratories* at 310 CMR 42.00.

Approved:

June 17, 2020

Oscar C. Pancorbo, Ph.D. Date
Division and Station Director
Division of Environmental Laboratory Sciences
Senator William X. Wall Experiment Station