

SUMMARY OF PUBLIC COMMENTS AND DEPARTMENT’S RESPONSE

MAINE COMPREHENSIVE AND LIMITED ENVIRONMENTAL LABORATORY ACCREDITATION RULE 10-144 CMR, Chapter 263

The Department of Health and Human Services, Maine Center for Disease Control and Prevention (CDC) hosted a public hearing on July 30, 2018 on, 10-144 CMR, Ch. 263, the rule proposed to repeal and replace 10-144 CMR and 06-096 CMR Chapter 263. Representatives from Maine CDC and the Department of Environment Protection (DEP) facilitated the public hearing for this rulemaking. On July 11, 2018, a notice of agency rulemaking was published in five major newspapers; announced on the Secretary of State website; and sent to stakeholders, electronically or by U.S. mail. Also on this date, the proposed rule and notice of rulemaking were uploaded to the Maine CDC Rules website. Comments were accepted through August 9, 2018.

Commenter ID #	Name	Date	Representing	Format
1	Nicole Ingalls	7/30/18	DHHS; Maine Center for Disease Control and Prevention, HETL	Written
2	Walter A. Lach	7/30/18 8/08/18	Maine Coast Lab	Oral and Written
3	Paul Morin	8/02/18	Sabattus Sanitary District and Water Division	Written
4	Jody Frymire	8/07/18	IDEXX	Written
5	Paula Drouin	8/08/18	Maine Water Environment Association	Written
6	Christopher Montagna	8/09/18	DHHS; Maine Center for Disease Control and Prevention, HETL	Written
7	Andy Wendell	8/09/18	ClearWater Laboratory	Written
8	Jackie Villinski	8/09/18	Maine Environmental Laboratory, LLC	Written

Table 1.

Commenters 1 – 8 are identified in Table 1 above. Commenters presented oral and/or written comments during the comment period. Comments have been summarized below and each summary is followed by the Department’s response that explains whether the changes were made based on the comment(s), and, if not, the reason why the Department did not make changes. Changes made following public comments and review by Office of the Attorney General for form and legality are contained in the adopted rule.

GENERAL

SECTION 1

1. Comment: Commenter 3 identified as a certified licensed operator that uses EPA approved methods for in-house sampling and testing for *E.coli*. Commenter 3 submitted that, for reasons including short holding times for the samples and because contracting with outside labs could place a hardship on treatment plants, sampling and testing for *Enterococci* using EPA approved methods should also be allowed in-house by certified, licensed operators.

Commenter 4 and 5 proposed language to amend Section 1(B)(2). Commenter 4 and 5 also recommended that *Enterococci* be added to Section 1(B)(2). Commenter 5 stated that Maine’s water quality criteria include *Enterococcus* limits and monitoring requirements and that it would be “financially burdensome” if testing for *Enterococcus*, which is similar to other bacteria compliance testing done in-house, requires labs to complete certification or contract for this testing.

Commenter 4 suggested further changes to Section 1(B)(2) to remove fecal coliform. Commenter 4 submitted "...Maine's bacteria indicators as listed in Title 38 MRS 465, are *E. coli* for all freshwaters and *Enterococci* for marine/estuarine waters."

Response: The Department has determined that suggested changes are outside the scope of this rulemaking and require legislative action. The Department refers the commenter to 22 MRS § 567(1) and made no change based on this comment.

SECTION 2

2. **Comment:** Commenter 6 suggested adding trip blanks to final sentence in Section 2(A)(12).

Response: The Department amended Section 2(A)(12) to include trip blanks to the list of blanks.

3. **Comment:** Commenter 6 referenced Section 2(A)(55) and requested clarification regarding "no detectable concentration." Commenter 6 asked, "What if you *detect* something below the detection limit?" and whether blanks with an analyte <RL are acceptable.

Response: The Department has determined, unless specified in the method, blanks with an analyte concentration below the reporting level are acceptable. No change was made based on this comment.

SECTION 3

4. **Comment:** Comment 6 referenced Section 3 and stated, "I don't see references for microbiological methods for drinking water, i.e. Total Coliform Rule (40 CFR 141.21(f)), and Surface Water Treatment Rule (40 CFR 141.74(a))."

Response: The Department confirmed that the proposed rule does not cite correctly the applicable sections of the CFR. The Department has amended Section 3(C) by revised language as follows:

1. Methods for the Drinking Water Program test category are as provided under the 2015 version of the Code of Federal Regulations: 40 CFR Part 141, Subpart C, Appendix A and 40 CFR §§ 141.21(f), 141.23(k), 141.24(e), 141.25, 141.27, 141.40(n)(11), 141.25(a), 141.131(a)(1), 141.131(b), 141.131(c), 141.131(d), 141.74(a), 141.402, 141.704, and 141.852(a), and 143.4(b), as amended up to July 1, 2017.

SECTION 7

5. **Comment:** Commenter 2 submitted "Over the years, government has forced the private sector to do data entry for it. Labs should be able to report in whatever formats they use. The DWP and DEP should do their own data entry."

Response: The Maine DEP does data entry, but requires that the data be provided in a format suitable for entry. The Electronic Data Delivery (EDD) is a required standard template for laboratory and field data submittals to EGAD (Environmental and Geographic Analysis Database). Authority for this requirement is granted under Maine's Uniform Electronic Transaction Act, 10 MRS § 9418 (2) (A). The ME DEP EDD Version 6.0 should be used for all data submissions. The DEP EGAD webpage can be accessed at <https://www.maine.gov/dep/maps-data/egad/index.html>. No changes were made to the rule based on this comment.

6. **Comment:** Commenter 7 referenced Section 7(H)(3) and expressed the opinion that requiring labs that voluntarily withdraw to notify "current clients" is not appropriate for the following reasons: 1) labs voluntarily withdrawing certification are still obligated to inform clients on a case-by-case basis under the applicable MLAP rules; 2) the requirement is moot as labs may subcontract a compliance sample without informing the client; 3) the use of the term "current clients" implies all those listed as clients by the lab, including those clients who have not used the lab for the related method, and this creates undue burden; 4) the outcome of requiring labs to submit a copy of each notification will result in the Department receiving thousands of notices; 5) this requirement is a disincentive for labs to be transparent about relinquishing certification in order to avoid the burden of thousands of notices; 6) it is not clear if this applies when a lab chooses not to seek re-certification for a given method; 7) it is more appropriate and efficient that MLAP notifies DEP and Drinking Water Programs; and 8) "unless the lab has failed to meet any of the other

applicable MLAP rules when handling samples or reporting results from voluntarily relinquished methods, no crime has been committed.”

Response: The Department confirms this provision applies, regardless of the number or type of methods withdrawn, or whether re-certification is sought. The Department agrees that labs may use contracted services and states that, to the contrary, laboratories must indicate on reports that results were obtained from a subcontracted laboratory. The Department understands that the majority of labs inform clients prior to sending samples to another lab and the Department supports this practice of informing clients of change in the lab’s certified methods. Labs cannot report results as “certified analysis” if the method is withdrawn. Currently, the MLAP notifies the DEP and DWP and information is updated on the Drinking Water Program website, <https://www.maine.gov/dhhs/mecdc/environmental-health/dwp/partners/labCert.shtml>. The language in the rule provides a safeguard to ensure that even those clients being served outside of these programs are notified that they are not receiving a ‘certified analysis’ if the method is withdrawn. The Department determined that the potential adverse impact of this requirement on the administrative level does not outweigh the importance of transparency and quality customer service. The Department amended Section 7(H)(3) to clarify that the labs are required to submit to the Department one copy of the notification and the list of clients who received notice of withdrawal.

SECTION 8

- 7. Comment:** Commenter 2 asked whether the management review has any added value, considering there is already an internal audit and the management review would be an additional step. Commenter 2 submitted that, previously, an internal audit was required and the additional management review proposed is an “administrative burden that add not value to data quality.”

Response: The Department supports the addition of a management review described in Section 8(G) of the rule as a necessary and effective quality assurance measure. No change was made based on this comment.
- 8. Comment:** Commenter 1 noted that, in Section 8(K)(2)(b) of this rule, the initial demonstration of capability (IDC) is run at one to four times the reporting level (RL). Commenter 1 submitted “A typical LCS is a mid level standard and may be more than four times the reporting level. Many use 4 LCS as the IDC.” Commenter 6 also referenced Section 8(K)(2)(b) and asked for the basis for spiking an IDC at one to four times the RL, suggesting this is a low threshold and that, generally, IDC’s are spiked mid calibration range.

Response: In response to this comment, the Department amended Section 8(K)(2)(b) by changing the reference to concentration from “one to four times the reporting limit” to requiring the laboratory to use the mid-level standard, unless otherwise specified by the method.
- 9. Comment:** Commenter 7 referenced Section 8(K)(2)(d) and suggested that (n-1) refers to *sample standard deviation* and that (n) refers to *population standard deviation*. Commenter 9 requested that the Department “verify wording and intent and correct reference if appropriate from ‘population’ to ‘sample.’”

Response: The Department amended this section by replacing the reference to population sample with “sample standard deviation.”
- 10. Comment:** Commenter 6 referenced Section 8(K)(3) and asked for clarification on acceptable concentration levels, because the rule did not specify a concentration.

Response: The Department responds that the concentration levels will vary by method and should be documented according to the lab’s QA protocols. No changes were made based on this comment.
- 11. Comment:** Commenter 6 referenced Section 8(L)(2)(a)(i) and asked that the Department define “reasonable timeframe.”

Response: The Department amended Section 8(L)(2)(a)(i) to clarify the standards of an “reasonable timeframe” for receiving a sample collected that are specific for Maine CDC only. The Department added language further in rule to address the timeframe expected for DEP samples. See response to Comment 12 below.
- 12. Comment:** Commenter 6 referenced Section 8(L)(2)(a)(ii) and stated that the requirement for labs to call and document every client discussion places an undue burden and suggested the following change:

(ii) *Samples that are not received shortly after collection (e.g., received through the mail), that do not arrive at the proper temperature may be analyzed, ~~at the client's discretion~~, if the following criteria are met:*

(1) *The sample arrived with evidence of an attempt to thermally preserve;*

or

(2) *The client is notified that the sample did not arrive at the proper temperature and the outcome of the conversation is documented; and*

~~(3)~~ *The report is annotated to indicate that the sample arrived outside of the acceptable range and was run at the client's request.*

Response: The Department confirmed that the language proposed in Section 8(L)(2)(a)(ii) requiring contact with the client regarding a sample received at an improper temperature is intended to establish a reasonable standard based on an understanding that this practice reflects the majority of accredited labs and serves as a safeguard for labs conducting sample testing. The Department determined the protection that these provisions affording labs to report results outweighs the potential administrative burden of client contact. The Department amended Section 8(L)(2) by clarifying requirements, based on whether the sample is submitted to the Drinking Water Program or a different program. Section 8 is amended to include the following language regarding sample receipt protocol:

b. Samples received for any programs other than the Drinking Water Program must be verified and documented per the following:

i. All samples that require thermal preservation are considered acceptable if the arrival temperature is verified and within the range required by either the approved method or by the applicable permit, program or rule.

ii. Sample temperature must be recorded at the time of sample receipt.

iii. Samples that do not arrive at the proper temperature may be analyzed at the client's discretion, if the following criteria are met:

(1) The sample arrived with sufficient coolant to indicate adequate support for the thermal cooling process;

(2) The client is notified that the sample did not arrive at the proper temperature and the outcome of the conversation is documented; and

(3) The report is annotated to indicate the temperature of the sample at the time of sample receipt, that the sample arrived outside the acceptable range and was run at the client's request.

13. Comment: Commenter 6 referenced Section 8(M)(4) and asked whether this pertained to "new lots of purchased chemicals or the prepared reagents made in the laboratory." Commenter 6 stated that some reagents cannot be tested prior to use and that purchased chemical lots can be tested.

Response: The Department disagrees with the commenter and finds that Section 8(M)(4) pertains to both new purchased lots and lab-prepared reagents. Testing reagents prior to use is a necessary quality control measure. No change was made based on this comment.

14. Comment: Commenter 8 referenced Section 8(N)(3) and asked whether certified weights are included in the support equipment that must be calibrated or verified at least annually and whether the Department would consider a five-year calibration or verification interval, since certified weights are not susceptible to mass loss or gain.

Response: The Department reviewed language in Section 8(N)(3), the Manual for the Certification of Laboratories Analyzing Drinking Water (MCLADW) and ASTM and determined that this language is consistent with standards. MCLADW states that weights used to verify balance each day of use should be verified annually against ASTM weights, Class I or II. The ASTM, Class I or II need to be calibrated every five years. No change was made based on this comment.

- 15. Comment:** Commenter 6 referenced Section 8(O)(4)(b) [*sic*] and asked the Department to clarify whether two consecutive passing calibration verifications (CVs) are needed. Commenter 6 submitted that most methods require only one after failing CV and asked, “What if the corrective action is to only refill the standard vial as it was empty?”

Response: The Department amended language in Section 8(O)(4)(e), to clarify that corrective action is required when the CV is run twice and fails consecutively. A successful calibration verification must follow the corrective action, or the lab must perform a new instrument calibration.

- 16. Comment:** Commenter 6 referenced Section 8(P)(2) and stated that language specific to non-compliance analysis seems to be outside the scope and intent of the rule because non-compliance samples do not fall under the specified regulations. Commenter 6 suggested striking all references to non-compliance samples.

Response: The Department notes that this section was developed in consultation with other states’ rules, and finds that this language assures that public health is protected at the same level, regardless of the purpose of analysis (compliance versus non-compliance. Labs accredited by the Department are intentionally held to a standard of applying the known and appropriate quality of precision and accuracy required for all samples. The Department also encourages transparency in lab reporting, so that clients can be assured that public health is protected, whether the samples are for compliance purposes or not. Further, the Department would be concerned about fraudulent conclusions, if the public chose an accredited laboratory, expecting that the standards and methods to achieve such an accreditation, would be applied to their samples. Although the accredited lab is not required to analyze by a method specified by MLAP, is the lab is required to report those analyses performed using methods for which the lab is not accredited. This language serves as a safeguard against potential misunderstanding by a client “acting reasonably under the circumstances” (5 MRS § 207), or misrepresentation, fraudulent or deceptive practices by an accredited laboratory. The Department refers the commenter to the Consumer Law Guide housed on the website of Office of the Attorney General (https://www.maine.gov/ag/consumer/consumer_law_guide.shtml). No changes were made, based on this comment.

- 17. Comment:** Commenter 6 referenced Section 8(P)(7)(c) and asked whether the requirement to report by the tenth day of the month apply to quarterly and yearly samples, or only to monthly samples. Commenter 6 asserted that this language needs to be revised, to account for testing that requires extended testing time (i.e. gross alpha). Commenter 6 suggested adding the following change: “shall be reported or a status up-date provided by the tenth day of the month.”

Response: The Department does not consider the language as proposed in this section as critical to this rule and has amended Section 8(P)(7) by removing language proposed in paragraph c.

SECTION 9

- 18. Comment:** Commenter 6 referenced Section 9(B)(1) and stated that, in practice, the lab director or quality assurance officer (QAO) may *approve* changes, whereas the proposed language directs that only the director or QAO makes changes to standard operating procedures (SOPs).

Response: The Department has amended Section 9(B)(1) to clarify that, while changes to an SOP may be drafted by others, only the laboratory director or quality assurance officer may approve changes and finalize SOPs.

SECTION 11

- 19. Comment:** Commenter 6 referenced Section 11(A)(2)(d)(i) and asked what the basis was for the following language: “greater than 1/10 of amount measured in any sample.” Commenter 6 stated that this has not been seen in organic methods and asked whether this applies to other sections.

Response: The Department confirms that this section applies to all chemistry methods. This same language may be found in the lab accreditation rule effective April 2010. This language is a data validation

requirement, to ensure that blank contamination can be identified, in order for the data user to determine if data is acceptable for the intended use. Method blank acceptance criteria was developed from the National Functional Guidelines and the EPA New England Environmental Data review supplement. Commenters may access current versions of these documents by using the following links:

<https://www.epa.gov/clp/superfund-clp-national-functional-guidelines-data-review> and <https://www.epa.gov/quality/epa-new-england-environmental-data-review-supplement>. No change was made based on this comment.

20. Comment: Commenter 6 referenced Section 11(A)(3)(b)(ii) and stated that clarification is needed, as this appears to simply define a batch.

Response: In response to this comment, the Department amended this language by clarifying that the exception applies when the method does not require the LCS.

21. Comment: Commenter 6 referenced Section 11(A)(4) and asked the Department to clarify whether this language applies to SM methods that do not require MS/MSD, or to state that they are not applicable and provided solids, alkalinity and color as examples.

Response: The Department finds that there are methods that do not require MS/MSD for which this requirement does not apply. The Department has amended Section 11(A)(4), by adding the following language to further clarify: "..., when applicable."

22. Comment: Commenter 8 referenced Section 11(A)(4) and asked, "Would it be acceptable to perform a matrix duplicate instead of a matrix spike duplicate?"

Response: The Department will not accept a matrix duplicate instead of a matrix spike duplicate as a quality control for calculating the recovery. One reason includes the potential inaccuracy, due to the amount of concentration in the matrix duplicate. The Department did amend Section 11(A)(4) to clarify that this requirement applies, unless the lab was not provided with a sufficient sample amount.

23. Comment: Commenter 6 referenced Section 11(A)(8)(c) and asked, "Why 100 +/- 40%?" with regard to the percent recovery of the standard.

Response: The Department had determined that it is the acceptance criteria contained in the lab certification rule effective April 2010 and, considering the calibration curve, +/- 40% of the true value is the RL that is the lowest calibration standard, unless otherwise stated in the method. No change was made based on this comment.

24. Comment: Commenter 1 referenced Section 11(A)(8)(d) and asked "whether the reporting level must be raised when the reporting level is high (bias high) and the analyte is not in the sample."

Response: The Department confirms that the reporting level (RL) must be raised if acceptance criteria is outside range, to ensure accuracy of reporting low level. The Department made no change based on this comment.

25. Comment: Commenter 6 referenced Section 11(A)(8)(d) and asked the Department to explain why RL cannot be reanalyzed before "harsh measures" are implemented, considering reanalysis is permitted for CVs which are analyzed at a much higher concentration.

Response: The Department states that RLs should and may be analyzed a second time. If the RL fails consecutively, a lab may re-calibrate and re-analyze the RL. Otherwise, the RL must be raised for subsequent sample analysis.

26. Comment: Commenter 8 referenced Section 11(B)(7) and asked, "Is individual packaged, commercially prepared media with manufacturer shelf-lives of greater than 90 days, such as Colilert media, subject to the quarterly positive and negative controls?"

Response: The Department confirms that individually packaged, commercially prepared media with manufacturer shelf-lives of greater than 90 days are subject to requirements in Section 11(B)(7).

27. Comment: Commenter 6 referenced Section 11(B)(10)(b) and stated that the requirement to use thermometers from an accredited third party or a National Metrology Institute seems to imply that

thermometers must be sent out for calibration. This is at odds with Section 8(N)(3)(f). Section (N)(3)(f) requires that the accuracy of thermometers be verified by comparing devices with a certified reference thermometer.

Response: The Department confirms that devices must be calibrated using thermometers from an accredited third party or NIST, which is consistent with Section 8(N)(3)(f). The Department amended Section 11(B)(10)(b) to further clarify, by replacing “using with “against.”

LIST OF CHANGES IN RESPONSE TO COMMENTS AND AAG REVIEW

- Minor grammatical and format corrections throughout the rule.
- Section 2 (A)(12) amended to include trip blanks.
- Section 3(B) amended to include reference to where the CFR can be accessed.
- Section 3(C)(1) revised by replacing references to federal regulations with the following citations: 40 CFR Part 141, including Subpart C, Appendix A and 40 CFR §§ 141.21(f), 141.23(k), 141.24(e), 141.131(b), 141.131(c), 141.131(d), 141.74(a), and 40 CFR §143.4(b) updated in the Annual Edition of July 1, 2017.
- Revised language in Sections 5 and 7 to include reference to sections of Maine’s Administrative Procedure Act at 5 MRS §10051 or applicable law.
- Section 7(G)(1) amended by replacing “suspend or revoke accreditation” with “deny an application for accreditation or make an accreditation provisional,” based on statutory authority.
- Section 7(G)(3) amended by removing the following sentence: “This section governs...5 MRS §9051-A.”
- Section 7(G)(3) amended by adding “the Commissioner.”
- Section 7(H)(3) amended to clarify that the labs are required to submit one copy of the letter template and the list of clients who received the notice of change in accredited methods.
- Section 8(K)(2)(b) amended by changing the reference to concentration from “one to four times the reporting limit” to requiring the IDC to be run at a mid-level standard, unless otherwise specified.
- Section 8(K)(2)(d) amended by replacing the reference to population sample with “sample standard deviation.”
- Section 8(L)(2) amended by adding language to distinguish and clarify protocols for receipt of samples submitted to the Drinking Water Program and those samples that are specific to other programs.
- Section 8(O)(4)(e) amended to clarify that corrective action is required when the CV fails consecutively and that a successful calibration verification must follow the corrective action or the lab must perform a new instrument calibration.
- Section 8(P)(7) amended by removing paragraph c.
- Section 9(B)(1) amended to clarify that, while changes to an SOP may be drafted by others, only the laboratory director or quality assurance officer may approve changes and finalize SOPs.
- Section 10(K)(1)(a) replaced “second failed proficiency test” with “suspension”
- Section 11(A)(3)(b)(ii) amended to clarify that the exception applies when the method does not require the LCS.
- Section 11(A)(4) amended by adding the following language: “..., when applicable.”
- Section 11(A)(4) amended to clarify that this requirement applies unless the lab was not provided a sufficient sample amount.
- Section 11(B)(10)(b) amended by replacing “using” with “against.”