



COMMONWEALTH OF MASSACHUSETTS
 EXECUTIVE OFFICE OF ENERGY & ENVIRONMENTAL AFFAIRS
 DEPARTMENT OF ENVIRONMENTAL PROTECTION
 Senator William X. Wall Experiment Station

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 Governor

TIMOTHY P. MURRAY
 Lieutenant Governor

IAN A. BOWLES
 Secretary

ARLEEN O'DONNELL
 Commissioner

Response to Comments for 310 CMR 42.00

8/2/07

MassDEP received comments from 3 groups/individuals:

#	Name	Affiliation
1	David Knowlton	Nashoba Analytical, LLC
2	Mark Warren	Accutest Laboratories of New England
3	Robert E. Bentley	Independent Testing Laboratories Association

**#1—Nashoba Analytical, LLC
 David Knowlton**

Comment: The commenter offered suggestions regarding the use of microbiology proficiency tests. The commenter expressed concern regarding the number of proficiency test (PT) studies needed to obtain certification in various matrices by various analytical methods

Response: Until now, MassDEP has offered certification for microbiological parameters in potable water only. Once the proposed regulations are promulgated, MassDEP will offer certification in potable water, wastewater, ambient water, and sewage sludge (biosolids). Each of these matrices has different regulatory requirements regarding acceptable methods and the reporting of analytical results (e.g., Presence-Absence or enumeration). In addition, there are discussions taking place nationally among state and EPA regulators regarding the appropriate number of samplings in a microbiology PT study for methods requiring enumeration. MassDEP will carefully review these requirements and the commenter's concerns regarding the number and cost of PT studies when updating the MassDEP PT program. Note that MassDEP is no longer proposing certification for fecal coliform in ambient water as a USEPA notice in the March 26, 2007 Federal Register indicates that this parameter in ambient water is not needed.

Comment: The commenter expressed concern regarding the schedule of implementation of the regulations stating that PT studies would not be available and that there would not be any laboratories certified for the new parameters at the time the regulations become effective. The commenter was especially concerned with testing of beaches.

Response: Promulgation of the laboratory certification regulations does not create any requirement for laboratories to become certified or for regulatory entities to require certification. Once the regulations are in effect, laboratories wishing certification for the newly offered parameters may apply to be considered for such certification. MassDEP programs and other agencies that require the use of certified laboratories may decide to update their regulations to require the additional certification areas. The beaches testing program is administered by the

Massachusetts Department of Public Health (DPH), which currently approves the laboratories participating in its program. Once MassDEP certification is available, DPH, if it chooses, may require such certification for laboratories participating in its beaches testing program.

The USEPA recently published a final rule approving new microbiological test methods for wastewater, ambient water, and sewage sludge. PT providers are aware of this publication and of MassDEP's proposed revisions to its certification regulations. Issues related to microbiology PTs, including PTs for enumeration studies are being discussed nationally among states that certify and accredit laboratories and EPA. Once MassDEP promulgates the regulations expanding the scope of certification, information will be sent to laboratories regarding the application procedure and participation in PT studies.

Comment: The commenter suggested that MassDEP considerably expand the scope of laboratory certification to a larger number of analytes and cites the National Environmental Laboratory Accreditation Conference (NELAC).

Response: The LCO certifies laboratories to meet the requirements and needs of MassDEP programs. Before the public comment period opened, MassDEP programs, including the Drinking Water Program, carefully reviewed the proposed regulations and requested that certification be offered for some additional analytes and methods. Other than what is currently proposed, MassDEP is not considering a further expansion of its scope of laboratory certification at this time.

Note that states that are recognized as accreditation bodies using the NELAC standard are not required to offer a specific scope of accreditation. While several states offer lengthy lists of analytes and matrices for which accreditation is available, other states offer a smaller scope of accreditation. MassDEP is carefully reviewing the national laboratory accreditation program as it develops, especially with regard to some of its requirements that may be particularly onerous for small laboratories.

#2—Accutest Laboratories of New England, Inc. Mark Warren

Comment: 310 CMR 42.08(5)(b)2f Accutest requests that this requirement be removed. There is no mention of this three day period in 40 CFR Part 136 Appendix B. Additionally, this requirement would adversely affect the already intensive and rigorous MDL study process by adding an unnecessary step. The management of MDL studies using this approach becomes untenable in a multiple instrument setting.

Response: It is precisely because there is no mention of a specific time period in 40 CFR Part 136 Appendix B that MassDEP is adopting the procedure cited in the 5th edition of EPA's *Manual for the Certification of Laboratories Analyzing Drinking Water*. MassDEP is specifying that method detection limit (MDL) studies be determined over at least three days in order that day-to-day variations affecting laboratory analyses be taken into consideration. It appears that the commenter believes that the regulation requires an MDL be determined on each instrument used for a method (i.e., run seven replicates on each and every instrument). Note that the regulation addresses method detection limits, not instrument detection limits. The regulation requires that the laboratory determine MDLs using instruments and analysts representative of those used in the analysis of samples. Therefore, a laboratory must determine an MDL using data generated by a combination of its instruments (i.e., run one or more replicates on one instrument, one or more on another). If the instruments are run on at least three different days, the requirement of the regulation will be met.

Comment: 310 CMR 42.13(1)(b) This information is difficult to report on a result page due to LIMS limitations including the fact that the lab holds certification/accreditations from several regulatory agencies. Accutest suggests that optional alternative methods for communicating certification be employed.

Response: In this regulation, MassDEP is prescribing the content, not the format, of the report. Note that 310 CMR 42.13(4) leaves the format of the report to the discretion of the laboratory. A laboratory may append a page to an analytical report or otherwise report to its client information that clearly describes its certification status.

Comment: 310 CMR 42.08(5)(a)6ev Accutest uses an electronic application to record thermometer accuracy monitoring, and suggests the option of using electronic means of documentation for the analyst performing the check. Secure data entry using login password is universally accepted as a signature equivalent.

Response: A unique identifier such as a PIN# or protected password specific to identify each lab employee and used only by that employee would be sufficient for internal tracking of internal laboratory raw data not usually submitted to the Department. The laboratory must be able to certify the employee identity when submitting requested data. MassDEP will add the phrase “or equivalent electronic signature” to the definition of signature in 310 CMR 42.03. Electronic submissions to the Department requiring signatures will require a Department approved certification statement.

Comment: 310 CMR 42.03 Since electronic data management is becoming more prevalent in the industry, Accutest suggests that an electronic signature (such as the secure data entry procedure mentioned above) be included in the definition of signature.

Response: MassDEP will add the phrase “or equivalent electronic signature” to the definition of signature in 310 CMR 42.03

#3—The Independent Testing Laboratories Association Robert E. Bentley

Comment: 310 CMR 42.08(5)(b)2f -this section relates to method detection limit studies, and in sections, talks about appropriate methods (including 40CFR136, Appendix B). Since most methods do not specify the actual number of days over which the MDL is to be made over, it is not clear why the department is saying in 42.08(b)2(b) (*sic*) that 40CFR136, Appendix B is to be used but in 42.08(b)2(f) (*sic*) is saying that sample preparation and analysis must be made over at least three days.

Response: In January 2006, The Independent Testing Laboratories Association (ITLA) requested clarification of this section in an earlier draft of the regulations, stating that the earlier draft was “too vague.” To determine method detection limits (MDLs), the laboratory must use the procedure described in the analytical method it is using. Some analytical methods that describe the procedure for determination of the MDL state that the analyses to determine the MDL are to be “conducted over several days;” other methods provide no specific time frame. If an analytical method being used by the laboratory does not specify a procedure for determining MDLs, the laboratory must use the procedure described in 40 CFR Part 136 Appendix B. The procedure described in 40 CFR Part 136 Appendix B does not specify a time frame for the analysis of replicates. To provide clarity and to ensure a valid determination of MDLs, MassDEP is adopting the procedure cited in the 5th edition of EPA’s *Manual for the Certification of Laboratories Analyzing Drinking Water*. MassDEP is specifying that method detection limit (MDL) studies be determined over at least three days in order that day-to-day variations affecting laboratory analyses are taken into consideration when determining MDLs. The adoption of a time frame of at least three days does not conflict with procedures for the determination of MDLs that are described in analytical methods or in 40 CFR Part 136 Appendix B.

Comment: 310 CMR 42.10(3)—this section states that on sample reports, “...the laboratory must clearly distinguish between analyses for which it is certified or provisionally certified by the Department and those for which it is not certified...” It is our understanding that the Department is not asking for a distinction of the provisional or fully certified, only certified versus not certified. We ask for clarification on this point.

Response: Your understanding is correct; the Department is not requiring a laboratory to distinguish the kind of certification it has, only to indicate whether or not it is certified. Certification status includes provisional certification status.

Comment: 310 CMR 42.13(3)—although the changing of a maximum contaminant level demands much publicity, it has been the experience of ITLA members that changes to drinking water guidelines by the Department's Office of Research and Standards receive little publicity. ITLA requests the Department confirm its intent to disseminate to all certified laboratories in the future any proposed changes to the guidelines.

Response: MassDEP publishes an updated list of standards and guidelines annually. Each year in early May, the list is published on MassDEP's website at: <http://mass.gov/dep/water/laws/regulati.htm#chems>. For this year's report, please refer to a report called Chemicals in Massachusetts Drinking Water, 2007 Standards & Guidelines. This report also has contact information should further assistance be needed.

Comment: 310 CMR 42.13(3)—ITLA requests clarification as to whether this section means to include the ORS "Secondary Maximum Contaminant Levels."

Response: MassDEP does not currently offer certification for all of the secondary contaminants in drinking water. Until such certification is available, 310 CMR 42.13(3) does not refer to secondary maximum contaminant levels.

Comment: 310 CMR 42.13(10(a))—ITLA suggests that this requirement is overly broad. For example, a courier having his/her driver's license suspended may affect a laboratory's operations, but has no real relevance to the overall operation of the laboratory. Further, we suggest that this may constitute an invasion of this person's privacy. A report by a local Fire Department for having a box too close to a sprinkler head would seem to have little or no relevance to the laboratory's operation, but under this mandate, could be construed as to having to be reported. ITLA requests that this requirement either be eliminated or more clearly bounded to eliminate the potential for mis-reading and confusion.

Response: MassDEP is re-wording 310 CMR 42.13(10)(a) and (b) as noted below. The re-wording clarifies that 42.13(10)(a) refers to the laboratory as a whole, 42.13(10)(b) refers to specific, key laboratory personnel or owners, and 42.13(10)(c) refers to reporting requirements for an applicant for certification. The 10 year period has been reduced to 5 years. The reporting deadline in 310 CMR 42.13(10)(b) is reduced to 30 days from receipt of documents by the laboratory.

In the example that ITLA presents, the courier's loss of license is outside the scope of what must be reported to the Department because it is not a violation of the laboratory's conditions, equipment, or operations. The Fire Department citation, however, must be reported because it relates to the laboratory's conditions. In the wake of a devastating explosion and fire at a Massachusetts chemical plant, conditions at laboratories and other facilities where chemicals are stored are under greater scrutiny. Well-run laboratories will want all laboratories to be functioning at a high level of reliability so as to maintain a high level of public confidence in their operation.

310 CMR 42.13(10) A laboratory shall submit to the Department a copy of the following kinds of documents:

(a) within 30 days of receipt by a Department-certified laboratory of a citation, settlement agreement, judgment, order, enforcement notice or report, or inspection report that is issued by any local, state, or federal government agency that cites violations of that laboratory's conditions, equipment, or operations.

(b) a Department-certified laboratory must supply a copy within 30 days of receipt of documents from its director, supervisor, and owner holding greater than 5% equity. The documents include a citation of violations or settlement agreement issued by any local, state, or federal government agency naming the individual and documents evidencing a civil or criminal conviction of that individual involving operations of any other environmental laboratory certified or accredited by EPA or any state. The Department-certified laboratory must ensure that its director, supervisor, and owner are required to submit a copy to it within 30 days of receipt of such documents by the individual.

(c) a laboratory applicant for certification shall provide a copy pursuant to 310 CMR 42.13(10)(a) of documents received within the last five years, and pursuant to 310 CMR 42.13(10)(b) of documents received by a current owner, director, and or supervisor within the past five years.

Comment: 310 CMR 42.13(10)(a)—Further, we note that in the “Summary of Proposed Amendments,” there is a requirement under Notifications to the Department that “...for a certified laboratory...to notify the Department in writing of a violation affecting an associated laboratory for which it has been cited by a government agency...” This does not seem to be supported in the regulations themselves in 42.13(10)(a) or (b). We are also concerned that this is vague. For example, if there is an “associated lab” not certified in Massachusetts, it is unclear as to why those citation/violations would be applicable to the Massachusetts laboratory.

Response: MassDEP will enforce the language in the regulations as re-worded above.

310 CMR 42.13(10)(a) refers to violations by that laboratory as a whole and would affect, for example, a Department-certified laboratory operating in New York that is cited by the state of New York so that the laboratory must submit a copy of the New York citation to the Department.

310 CMR 42.13(10)(b) has been narrowed to refer solely to violations committed by key personnel or owner of a Department-certified laboratory; the violations include those committed by the laboratory owner, director or supervisor while associated with any EPA- or state-certified or accredited environmental laboratory for which a citation was issued to that individual. For example, a supervisor at a Department-certified laboratory may also currently work for (or have worked in the past) for another laboratory only certified by New Hampshire and be individually cited for violations by New Hampshire. The supervisor must supply a copy of the citation to the Department-certified laboratory which must submit copy to the Department.

Comment: 310 CMR 42.14(2)—ITLA requests that either signatures or initials of the person making the correction be allowed.

Response: The definition of signature in 310 CMR 42.03 includes “any mark, such as initials, printed or handwritten name....”