

MARYLAND REGISTER

Proposed Action on Regulations

Comparison to Federal Standards Submission and Response

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In accordance with Executive Order 01.01.1996.03 and memo dated July 26, 1996, the attached document is submitted to the Department of Business and Economic Development for review.

The Proposed Action is not more restrictive or stringent than corresponding federal standards.

COMAR Codification: 26.08.05..01-.17

Corresponding Federal Standard:

40 CFR § 142.10(b)(3)(i)

Discussion/Justification:

The Laboratory Certification Program is required by the Safe Drinking Water Act. These regulations support the implementation of this activity. The Program ensures that the Laboratories that analyze drinking water are providing accurate test results that are used to evaluate and determine the risk to public health from the drinking water.

TO BE COMPLETED BY DBED

- Agree

-Disagree

Comments:

Name: Sally Kenyon Grant

Date: 2/20/2014

-Submit to Governor's Office

Governor's Office Response

Comments:

Transmittal Sheet PROPOSED OR REPROPOSED Actions on Regulations	Date Filed with AELR Committee	TO BE COMPLETED BY DSD
	02/25/2014	Date Filed with Division of State Documents
		Document Number
		Date of Publication in MD Register

1. Desired date of publication in Maryland Register: 4/4/2014

2. COMAR Codification

Title Subtitle Chapter Regulation

26 08 05 .01-.17

3. Name of Promulgating Authority

Department of the Environment

4. Name of Regulations Coordinator

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5. Name of Person to Call About this Document

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6. Check applicable items:

New Regulations

Amendments to Existing Regulations

Date when existing text was downloaded from COMAR online: .

Repeal of Existing Regulations

Recodification

Incorporation by Reference of Documents Requiring DSD Approval

Reproposal of Substantively Different Text:

: Md. R

(vol.) (issue) (page nos) (date)

Under Maryland Register docket no.: --P.

7. Is there emergency text which is identical to this proposal:

Yes No

8. Incorporation by Reference

X- Check if applicable: Incorporation by Reference (IBR) approval form(s) attached and 18 copies of documents proposed for incorporation submitted to DSD. (Submit 18 paper copies of IBR document to DSD and one copy to AELR.)

9. Public Body - Open Meeting

OPTIONAL - If promulgating authority is a public body, check to include a sentence in the Notice of Proposed Action that proposed action was considered at an open meeting held pursuant to State Government Article, §10-506(c), Annotated Code of Maryland.

OPTIONAL - If promulgating authority is a public body, check to include a paragraph that final action will be considered at an open meeting.

10. Children's Environmental Health and Protection

Check if the system should send a copy of the proposal to the Children's Environmental Health and Protection Advisory Council.

11. Certificate of Authorized Officer

I certify that the attached document is in compliance with the Administrative Procedure Act. I also certify that the attached text has been approved for legality by Nancy Young, Assistant Attorney General, (telephone #410-537-3042) on January 31, 2014. A written copy of the approval is on file at this agency.

Name of Authorized Officer

Robert M. Summers, Ph.D.

Title

Secretary

Telephone No.

410-537-3084

Date

February 4, 2014

Title 26

DEPARTMENT OF THE ENVIRONMENT

Subtitle 08 WATER POLLUTION

26.08.05 Certification of State Water Quality Laboratories

Authority: Environment Article, Title 9, Annotated Code of Maryland

Notice of Proposed Action

□

The Secretary of the Environment proposes to repeal Regulations .01 - .16 and adopt new Regulations .01 - .17 under COMAR 26.08.05 Certificate of State Water Quality Laboratories.

Statement of Purpose

The purpose of this action is to repeal existing Regulations .01 - .16 and replace them with new Regulations .01 - .17. The proposed regulations include revisions: to correct technical references and agency designation, to modify the timeline for the submission of annual renewal applications for certification, to assess a penalty for late renewal applications, and to clarify the education and experience requirements for laboratory personnel who are employed at laboratories that analyze drinking water pursuant to the Safe Drinking Water Act. The proposed regulations include language to clarify requirements, and provide a more technically correct standard.

Comparison to Federal Standards

There is a corresponding federal standard to this proposed action, but the proposed action is not more restrictive or stringent.

Estimate of Economic Impact

I. Summary of Economic Impact.

The proposed regulatory changes to the Certification of State Water Quality Laboratories regulations have one area where an economic impact can be determined. The proposed changes will require water quality laboratories to enhance education and training of laboratory staff.

New standards for laboratory staff education and training will be required based on the criteria listed in the Manual for the Certification of Laboratories Analyzing Drinking Water. Laboratories may need to pay higher salaries to compensate a higher level of education, experience and training and incur costs providing additional education and training for their staff. Water quality laboratories may be able to obtain a waiver from the certification officer for minimum education requirements on a case-by-case basis for highly experienced analysts or water quality laboratory supervisors.

II. Types of Economic Impact.	Revenue (R+/R-) Expenditure (E+/E-)	Magnitude
	Benefit (+) Cost (-)	Magnitude
A. On issuing agency:	(E-)	Minimal
B. On other State agencies:	(E-)	Minimal
C. On local governments:	(E-)	Minimal
D. On regulated industries or trade groups:	(+)	Minimal
E. On other industries or trade groups:	(-)	Minimal
F. Direct and indirect effects on	NONE	

public:

III. Assumptions. (Identified by Impact Letter and Number from Section II.)

A. Assumes a negative revenue to the issuing agency, State and local Agencies, and industry trade groups. The assumed expense for the issuing agency and State and local Agencies is based on a higher cost of doing business due to workload. The assumed expense for the industry trade groups is based on the need for water quality laboratories to educate and train current staff or to acquire new staff that meet the minimum requirements for qualified water quality personnel stated in this regulation.

B. Assumes a negative revenue to the issuing agency, State and local Agencies, and industry trade groups. The assumed expense for the issuing agency and State and local Agencies is based on a higher cost of doing business due to workload. The assumed expense for the industry trade groups is based on the need for water quality laboratories to educate and train current staff or to acquire new staff that meet the minimum requirements for qualified water quality personnel stated in this regulation.

C. Assumes a negative revenue to the issuing agency, State and local Agencies, and industry trade groups. The assumed expense for the issuing agency and State and local Agencies is based on a higher cost of doing business due to workload. The assumed expense for the industry trade groups is based on the need for water quality laboratories to educate and train current staff or to acquire new staff that meet the minimum requirements for qualified water quality personnel stated in this regulation.

D. Assumes positive revenue to industry trade groups based on the additional services that would be performed for compliance with the proposed regulations. Industries that offer the training or education that is required for qualified water quality personnel may benefit if the water quality laboratory personnel utilize their services.

E. Assumes that the public will ultimately bear the costs related to directly complying with the proposed regulatory changes. The public may be affected if the water quality laboratories raise their rates for sampling and/or analysis due to the expenses of maintaining qualified staff.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Nancy Reilman, Division Chief, Maryland Department of the Environment-Water Supply Program, 1800 Washington Boulevard, or call 410-537-3710, or email to Nancy.Reilman@maryland.gov, or fax to 410-537-3157. Comments will be accepted through April 14, 2014. A public hearing will be held, The Department of the Environment will hold a hearing concerning the adoption of these regulations on April 8, 2014 from 10:00 a.m. to 12:00 p.m. in the Maryland Department of the Environment

Gunpowder Falls Conference Room, 1800 Washington Boulevard, Baltimore, Maryland 21230.

All interested persons are invited to attend and give their views. Any hearing impaired person may request an interpreter to be present at the hearing by giving five (5) working days notice to Nancy Reilman, 410-537-3710.

Economic Impact Statement Part C

A. Fiscal Year in which regulations will become effective: FY

B. Does the budget for the fiscal year in which regulations become effective contain funds to implement the regulations?

C. If 'yes', state whether general, special (exact name), or federal funds will be used:

D. If 'no', identify the source(s) of funds necessary for implementation of these regulations:

E. If these regulations have no economic impact under Part A, indicate reason briefly:

F. If these regulations have minimal or no economic impact on small businesses under Part B, indicate the reason and attach small business worksheet.

G. Small Business Worksheet:

Attached Document:

.01 Scope.

The purpose of these regulations is to provide a procedure by which the Department of the Environment may certify that water quality laboratories are capable of performing in an acceptable manner, microbiological, chemical, physical, and radiochemical analyses on water samples from public water supplies. Since owners of public water supplies are required through various State and federal programs to monitor the quality of drinking water in their systems, it is necessary to have available water quality laboratories which produce data recognized as valid by the enforcement agencies. These regulations establish standards of operation for these water quality laboratories.

.01-1 Incorporation by Reference.

In this chapter, the following documents are incorporated by reference. A. Documents Incorporated.

(1) Code of Federal Regulations (CFR) -40 CFR § 141 (July 1,2013)

(a) Record Maintenance (40 CFR §141.33) revised July 1,2010

(b) Lead and Copper Rule (40 CFR §§ 141.80 - 141.91) revised July 1,2010

(c) Reporting Requirements (40 CFR § 141.31)

(2) Manual for the Certification of Laboratories Analyzing Drinking Water (EPA 815-R-05-004, January 2005)

and Supplement 1 to the Fifth Edition of the Manual for the Certification of Laboratories

Analyzing Drinking Water
(EPA 815-F-08-006, June 2008)

.02 Definitions.

- A. "Analyst" means a person responsible for performing tests and reporting analytical results.
- B. "Certification Authority" means the Secretary or his/her designee who has signature authority for all certification decisions.
- C. "Certification Officers" means the Department personnel who have the responsibility of certifying water quality laboratories under their purview.
- D. "Denial" means a refusal of certification for a specific method or the analysis of specific parameters, or refusal of initial certification for a water quality laboratory.
- E. "Department" means the Department of the Environment
- F. "Director" means director of a laboratory.
- G. "Laboratory" means a "Water Quality Laboratory."
- H. "Laboratory quality assurance" means an integrated system of management activities involving planning, quality control, quality assessment, reporting and quality improvement to ensure that laboratory results meet defined standards of quality with a stated level of confidence.
- I. "NELAP" means National Environmental Laboratory Accreditation Program- a program operated by TNI to provide certification for environmental laboratories.
- J. "Person" means an individual, corporation, company, association, partnership, state, county, municipal corporation, federal agency, special taxing area, or any other entity.
- K. "Provisionally certified" means a certification status for a laboratory that has deficiencies but demonstrates its ability to consistently produce valid data within the acceptance limits specified in the National Public Drinking Water Regulation (NPDWR), and within the policy required by their certification authority.
- L. "Quality Assurance Manual" means a document that describes the water quality laboratory's Quality Assurance Program, which includes the organizational structure, policies and procedures for training, sampling, reporting, corrective action, ethics, preventative maintenance, pollution control, and disposal.
- M. "Quality Assurance Officer" means the laboratory personnel responsible for keeping the laboratory's Quality Assurance Manual updated, and ensuring that the quality assurance practices are implemented.
- N. "Revocation" means a cancellation of a valid laboratory certification or for a specific approved drinking water method.
- O. "Secretary" means the Secretary of the Department of the Environment
- P. "TNI" means The NELAC Institute. The institute is a non-profit organization for the development of standards for the accreditation of laboratories and the evaluation and approval of Accreditation Bodies.
- Q. "Water quality laboratory" means a facility which examines public drinking water for the purpose of identifying or measuring microbiological, chemical, physical, or radio-chemical parameters to determine its compliance with, or produces laboratory data for enforcement of, the federal Safe Drinking Water Act or State standards or public drinking water.
- R. "Water quality laboratory supervisor" means a person who directs the day-to-day activities of a water quality laboratory and is responsible for assuring the quality of laboratory results.

.03 Certification for a Water Quality Laboratory.

- A. A water quality laboratory shall obtain a certification from the Department before the water quality laboratory may analyze compliance samples in this State.
- B. The Department shall certify a water quality laboratory that meets the requirements of this chapter and Environment Article Title 9, Subtitle 10 of the Annotated Code of Maryland.

C. The Department shall identify in the certificate the parameters and test methods for which a water quality laboratory is certified.

(1) A water quality laboratory shall conspicuously display its certificate in a location visible to the public at the laboratory.

(2) The Department may approve, deny, or classify as provisional parameters and test methods requested for certification by the water quality laboratory.

D. A water quality laboratory shall obtain a USEPA identification number from the Office of Ground Water and Drinking Water Technical Support Center.

E. A laboratory shall analyze a minimum of one drinking water compliance sample per year to be eligible for certification or recertification as a water quality laboratory.

F. Certificates are non-transferable between water quality laboratories, laboratory locations, or water quality laboratory supervisors.

G. Only a water quality laboratory certified pursuant to these regulations may be called a certified water quality laboratory, and a water quality laboratory may not represent to the public by title, description of services, methods or procedure, or otherwise make any statement, written or oral, intended or likely to mislead the public with respect to its certification status.

H. The Department may not approve the initial certification for a parameter or test method for an in-state laboratory until the Department has inspected the laboratory. An on-site evaluation will be performed in accordance with Regulation .07 of this chapter.

.04 General Requirements for a Certified Water Quality Laboratory.

A. The water quality laboratory shall incorporate the following minimum criteria in its Quality Assurance Manual.

(1) Space Requirements. A certified water quality laboratory shall have adequate space, facilities, and equipment to provide test results with accuracy, precision, and safety.

(2) Use of Approved Procedures. All certified water quality laboratories shall use analytical procedures approved by the Certification Authority or the U.S. Environmental Protection Agency.

(3). Collection and Preservation Procedures.

(a) A water quality laboratory shall collect and preserve water samples in accordance with procedures approved by the U.S. Environmental Protection Agency for the analysis of drinking water samples as incorporated by reference in COMAR 26.08.05.01-1 A(l), and "Standard Methods for the Examination of Water and Wastewater" as approved by U.S. Environmental Protection Agency, American Public Health Association, National Technical Information Service, or other approved agency.

(b) A water quality laboratory shall identify and describe its sample collection procedures in its Quality Assurance Manual.

(c) Water samples collected for the purpose of compliance with these regulations shall be collected by an individual approved by the Department

(d) A water quality laboratory that is certified shall accept only samples that are properly labeled, and for which there is assurance that the samples have been collected, preserved, processed, stored, and transported in such a manner as to assure the identity and the stability of the sample with respect to the requested tests or analyses, or if the stability of the sample has not been assured, the water quality laboratory shall refuse the sample.

(e) A supervisor of a certified water quality laboratory shall implement and document sample rejection policies and procedures for each sample that is not suitable for analysis.

(4). Reporting of Laboratory Results.

(a) A water quality laboratory report of analytical results shall be signed by the water quality laboratory supervisor or the supervisor's designee.

(b) Internal water quality laboratory records shall identify the person actually performing the analyses and its Maryland Laboratory Identification Number. The water quality laboratory shall make internal water quality laboratory records available to the

Department

(c) When a water quality laboratory reports compliance results on behalf of a public water system, the water quality laboratory shall comply with the reporting requirements specified in 40 CFR § 141.31.

(5). Tests to be Performed by Qualified Analysts. The water quality laboratory supervisor shall assure that all tests are performed by qualified analysts.

(6). Supervisors Limited to Two Laboratories. A water quality laboratory supervisor may not be responsible for the supervision of more than two certified water quality laboratories.

(7). Maintenance of Laboratory Records. Each certified water quality laboratory shall comply with the following requirements:

(a) A suitable record of each test result is kept for a period of at least 5 years or until the next certification data audit is completed.

(b) If the laboratory reports on behalf of a public water system, records for chemistry and radiochemistry shall be held for 10 years (40 CFR § 141.33) and records for lead and copper shall be held for 12 years (40 CFR § 141.91).

(c) All records shall be maintained in a manner which permits ready identification and accessibility.

(d) Certified water quality laboratory records and reports shall identify samples sent to other certified water quality laboratories for analyses, and shall identify the certified water quality laboratory performing the test

(e) Laboratory records shall be available to the Department for inspection.

(f) Changes in ownership, mergers, or laboratory closures do not eliminate these requirements.

B. The laboratory shall implement the provisions of the Quality Assurance Manual.

.05 Application for Certification.

A. An application is required for:

(1) Certification for Microbiology, Chemistry or Radiochemistry, or

(2) Renewal of certification

B. An application for Water Quality Laboratory certification shall be submitted to the Department on a form provided by the Department, and shall include, but not be limited to, the following information:

(1) Name, address, and valid phone number of the water quality laboratory;

(2) Name of the water quality laboratory owner or director;

(3) A listing of the tests for which certification is requested;

(4) Description of facilities, equipment, and methodology;

(5) The name, education, experience, and training of the water quality laboratory supervisor,

(6) The name, education, experience, and training of all water quality laboratory analysts;

(7) The approximate number of tests by category performed annually by the water quality laboratory;

(8) The laboratory's Quality Assurance Manual;

(9) Valid Federal Employer Identification Number (FEIN) as required by § 1-203 of the Environment Article, Annotated Code of Maryland;

(10) A copy of the valid and current water quality laboratory certification that has been issued by any other State or by NELAP, as applicable;

(11) Proficiency test results for each certified parameter and approved test method; and

(12) Fees, if applicable.

C. The laboratory owner, director, or quality assurance officer shall complete fully and sign the application.

.06 Fees.

A. A certified water quality laboratory in the State of Maryland, except a federal, State, or a local government laboratory, shall pay an annual certification fee of \$250 plus \$10 for each specific test and parameter combination for which certification is requested.

B. An out-of-state water quality laboratory shall pay an \$400 annual certification fee for all parameters certified by their home State or NELAP accrediting body.

C. A water quality laboratory shall pay the fee at the time an application for certification or renewal of certification is submitted to the Department

D. If a water quality laboratory submits its renewal application after the expiration date of its certification it shall pay a late fee of \$100.

.07 On-Site Evaluation.

The Department may perform, announced or unannounced, on-site evaluations of the premises and operations of a water quality laboratory that is currently certified or that has applied for certification.

B. During an on-site evaluation, the Department may evaluate the adequacy of the quality assurance program, qualifications of personnel, adequacy of equipment the adequacy of the supervision, and compliance with these regulations.

C. An in-state water quality laboratory may not analyze regulated drinking water contaminants until the Department has conducted an on-site evaluation.

D. The Department may revoke the certification of a laboratory that refuses access for the on-site evaluation.

E. A water quality laboratory shall notify the Department of any on-site evaluations performed by other States or third-party organizations that include the review of drinking water test methods.

.08 Personnel Qualifications.

A. A water quality laboratory shall have staff that is trained in the approved drinking water methods to ensure that the water quality laboratory generates valid and accurate test results.

B. To maintain certification, a water quality laboratory shall continue to meet the education and training criteria identified in the Manual for the Certification of Laboratories Analyzing Drinking Water, which is incorporated by reference in COMAR 26.08.05.01-1 A(2).

C. Water Quality Laboratory Supervisor.

(1) The supervisor of a certified water quality laboratory performing chemical analyses on water samples shall have a bachelor's degree in chemistry or a bachelor's degree in a closely related science with a minimum of 12 semester hours of chemistry work and a minimum of 2 years experience in the performance of chemical tests routinely performed by the water quality laboratory except as allowed under §D of this regulation.

(2) The supervisor of a certified water quality laboratory performing microbiological analyses on water samples shall have a bachelor's degree in microbiology or a bachelor's degree in a closely related science with a minimum of one college level microbiology course or equivalent and a minimum of 2 years experience in the performance of microbiological tests routinely performed by the water quality laboratory except as allowed by §D of this regulation.

D. The certification officer may waive the minimum education requirements as specified in the Manual for the Certification of Laboratories Analyzing Drinking Water on a case-by-case basis for experienced analysts or water quality laboratory supervisors.

(1) If a waiver is granted, the certification officer shall document the decision and justification for the waiver in writing.

(2) The waiver is not transferrable to another water quality laboratory and may be subject to additional review or approval.

(3) A water quality laboratory shall keep a copy of the waiver available for inspection.

.09 Laboratory Quality Assurance Program.

A. Each certified water quality laboratory shall establish a quality assurance program consistent with U.S. Environmental Protection Agency Laboratory Certification Manual criteria or with TNI standards, if applicable.

(1) A water quality laboratory's Quality Assurance Manual shall include a description of its quality assurance program.

(2) The quality assurance officer for a laboratory is responsible for maintaining the quality assurance manual.

(3) A water quality laboratory shall submit its Quality Assurance Manual for review to the Department as part of the initial certification application.

(4) A water quality laboratory shall submit in writing any revisions to a Quality Assurance Manual if there is a change in laboratory operations or if the Quality Assurance Manual is requested by the Department

B. An acceptable quality assurance program shall include the following:

(1) A preventive maintenance program that ensures proper functioning of all instruments and equipment.

(2) Regular operational checks and calibrations to assure proper operation and standardization of equipment, instruments, and reagents.

(3) Routine testing of standard reference samples and other quality control materials. Quality control checks on reagents and media utilized in the performance of tests.

(4) Maintenance of quality control records which will support the reliability of all procedures performed. These records shall be kept on file and readily available for a period of 5 years.

(5) Satisfactory participation in a proficiency test program administered under NELAP or a TNI approved accredited proficiency test body. An acceptable proficiency test shall be performed for every method and parameter requested for certification.

(6) The analysis of proficiency testing samples at a frequency necessary to evaluate the performance of any certified water quality laboratory.

C. The water quality laboratory supervisor shall assure that a copy of the results of the proficiency testing analyses are forwarded directly to the Department from the approved proficiency test provider within 30 days of receipt

D. If there is not a valid proficiency test for each parameter and test method combination for the review period, the Department shall downgrade the laboratory's certification to a provisional status for the parameter and test method.

(1) Provisional certification for a parameter and test method is valid for 90 days.

(2) If the laboratory does not submit passing proficiency test results within the review period, the Department may revoke or deny certification for the parameter or test method that does not have a valid proficiency test report

E. Test results may not be reported on samples when quality control samples included in the analysis are found to be outside acceptable analytical limits. The entire batch of samples in the test run shall be retested and analytical data may not be reported unless quality control samples for the test run are within acceptable limits.

F. The supervisor shall certify that each test or analysis is accurate and valid and that the test-or analysis was performed in accordance with approved EPA methods for drinking water

.10 Evaluation Procedure.

A. Documentation of Corrective Action. If a certified water quality laboratory is found to be in non-compliance with these regulations, the water quality laboratory shall submit documentation of corrective action to the Department

(1) If a certified water quality laboratory is found to be in non-compliance with an on-site evaluation by another State or third party organization, the laboratory shall forward copies of the associated on-site evaluation report or reports, the laboratory's follow up corrective actions, and notifications of certification status.

B. Adequacy of Corrective Action. On receipt of documentation of corrective action, the Certification Authority shall determine the adequacy of the action taken. If the corrective action is not adequate, the water quality laboratory may be required to test supplemental proficiency test samples or submit to an on-site inspection, or both. If the results of the on-site inspection or the results obtained through testing of unknown samples are unacceptable, the water quality laboratory shall be downgraded for the specific tests for which results are unacceptable or procedures, facilities, or records are not in compliance.

C. Continued Certification of Other Tests. A certified water quality laboratory shall continue to be certified for performance of all tests for which it has demonstrated satisfactory performance through testing of unknown samples and through compliance with these regulations.

D. Notification about Discrepancies. The Department shall advise owners and water quality laboratory supervisors in writing of all certified water quality laboratory discrepancies which may lead to revocation of certification, or a downgrade to provisional status.

.11 Downgrading of Certification for Performance of Specific Tests.

A. If a water quality laboratory is subject to a change in certification status, the Certification Authority shall notify the laboratory in writing of the intent to downgrade the parameter list for the certificate.

B. The Department may deny, make provisional, or revoke approval for one or more tests for the following reasons:

(1) The certified water quality laboratory fails to satisfactorily participate in an approved proficiency test program as indicated, or to pass the test for each parameter and test method combination;

(2) Failure to pass two or more consecutive proficiency tests;

(3) Failure to implement a Quality Assurance Program required under Regulation .09 of this chapter,

(4) Failure to pass an on-site evaluation;

(5) Failure to submit or implement a corrective action plan that addresses the deficiencies identified by an on-site evaluation report; or

(6) Failure to report compliance data in a timely manner, as specified in COMAR 26.04.01.

C. A water quality laboratory that is subject to a change in certification status under this section may not analyze those drinking water compliance samples for which approval has been denied or revoked by the Certification Authority.

D. A certified water quality laboratory that has been denied or revoked approval for performance of certain tests may regain approval by documenting corrective actions taken and by requesting a review of the corrective actions.

E. The Certification Authority may require an on-site evaluation prior to reinstatement

(1) Within 30 days after completion of the on-site review, the certification officer shall make a recommendation on the status to the laboratory and submit his report to the laboratory.

(2) The water quality laboratory shall respond with corrective actions within 30 days of the receipt of the on-site report.

(3) If the corrective actions are acceptable, the Certification Authority may reinstate approval subject to continued compliance with these regulations.

(4) If the corrective actions are not acceptable, the Certification Authority may require additional corrections.

F. If the Certification Authority does not reinstate approval for specific tests under this regulation, the Certification Authority shall provide the water quality laboratory supervisor with written notice of actions to be taken to correct deficiencies.

(1) The certified water quality laboratory supervisor may request a new review after 60 days from the date of the last review.

.12 Laboratory Certification Denial, Provisional Certification, and Revocation of Certification.

A. Denial of Initial Certification

(1) The Department may deny initial certification to a water quality laboratory for any of the following reasons:

(a) Failure to comply with the minimum standards and qualifications required by these regulations;

(b) Failure to participate in or analyze proficiency test samples;

(c) Submittal of another water quality laboratory's results for proficiency tests;

(d) Intentionally false statements made on the application forms or any document associated with the certification application;

(e) Conviction of any violation of the laws of Maryland related to water quality;

(f) Fraudulently or deceptively obtaining or attempting to obtain a certification;

- (g) Failure to pay the prescribed certification fees; or
 - (h) Failure to submit or complete acceptable corrective actions to an on-site evaluation
- (2) The denial of initial certification because a water quality laboratory does not satisfactorily meet certification criteria is not appealable.

B. Provisional Certification

- (1) The Department may downgrade a certification of a water quality laboratory for any of the following reasons:
- (a) Violation of any provision of these regulations;
 - (b) Failure to report compliance data in accordance with COMAR 26.04.01 to the public water system or the Department in a timely manner, thereby preventing compliance with federal or State regulations or endangering public health;
 - (c) Failure to participate in or analyze proficiency test samples in a timely manner;
 - (d) Failure to report a change in ownership, management, location of facilities, or name of a water quality laboratory within a period of 30 days after the change has occurred; or
 - (e) Failure to submit or complete acceptable corrective actions to an on-site evaluation.
- (2) Procedure for Downgrading Laboratory Status to Provisional

(a) If a laboratory is subject to downgrading on the basis of criteria in §B of this regulation, the Certification Authority shall notify the laboratory director or owner by certified mail of its intent to downgrade within 30 days from becoming aware of the situation warranting downgrading.

(b) The laboratory director shall send a written response to the Certification Authority within 30 days of receipt of the letter specifying what immediate corrective actions are being taken and any proposed corrective actions that need the concurrence of the Certification Authority.

(c) The Certification Authority shall notify the laboratory in writing, by certified mail, within 14 days of receipt of the laboratory's response whether the corrective action taken is adequate or if the laboratory is being downgraded to provisionally certified status.

(d) Provisionally certified status may not exceed 90 days.

(3) If the Certification Authority determines that the laboratory results are reliable, a provisionally certified laboratory may analyze drinking water samples for compliance purposes.

(a) The laboratory shall notify its clients of its downgraded status in writing on any report

C. Revocation of Certification for the Water Quality Laboratory

(1) The Department may revoke certification to a water quality laboratory for one or more of the following reasons:

(a) Failure to comply with the minimum standards and qualifications required by these regulations;

(b) Failure to participate in or analyze proficiency test samples, or to obtain acceptable laboratory results of tests required on the samples annually;

(c) Operation in such a manner as to endanger the public health or safety;

(d) Intentionally false statements made on the application forms or any document associated with certification;

(e) Fraudulence, deliberate falsification, or misrepresentation of federal and State laws when reporting test results;

(f) Conviction of any violation of the laws of Maryland related to water quality laboratories or public drinking water systems;

(g) Documentation of repeated episodes of unethical conduct of water quality laboratory operation;

(h) Failure to pay the prescribed fees associated with certification or renewal of certification;

(i) Fraudulent or deceptive use of a certification;

(j) Fraudulently or deceptively obtaining or attempting to obtain a

certification; (k) Submittal of another water quality laboratory's results for proficiency tests; or (1) Failure to implement corrective actions to an on-site evaluation.

(2) Procedure for Revocation

(a) The Certification Authority shall notify the laboratory, by certified mail, of the intent to revoke certification. The notification shall state the reasons that the laboratory's certification is being revoked and set forth corrective actions when applicable.

(b) The laboratory shall have 30 days from receipt of the notice of intent to revoke to submit documentation that shows the decision does not meet the criteria in §C of this Regulation. The documentation and a letter of explanation shall be sent by certified mail to the attention of the certification officer.

(c) If the laboratory has not responded within 30 days of the notification of the intent to revoke the certification, the Certification Authority may issue a notice of revocation. A copy of the Department's Judicial Review Process shall be included with each notice of revocation.

(d) If the laboratory provides documentation and an explanation within the required time, the Certification Authority shall review the submission and determine whether to proceed with revocation.

(e) Within 30 days of receipt of the laboratory's submission, the Certification Authority shall either notify the laboratory that the documentation is satisfactory to address the reasons for revocation or that certification shall be revoked.

(f) If the Certification Authority determines after review of the laboratory's submission to revoke the certification, the revocation date shall not be sooner than 30 days from the Certification Authority's notification to the laboratory. A copy of the Department's Judicial Review Process shall be included with each notice of revocation.

(3) Upon Revocation

(a) A water quality laboratory shall return its certificate and parameter list and

(b) A water quality laboratory may not analyze drinking water samples for compliance.

D. Reinstatement of Certification. The laboratory may request reinstatement of certification that has been revoked

or expired. The process for reinstatement is as follows:

(1) Revoked certification. Through a written request, a laboratory may seek reinstatement of certification if a laboratory can demonstrate to the Certification Authority's satisfaction that the deficiencies which resulted in revocation have been corrected. The Certification Authority may require an on-site evaluation, successful analysis of unknown samples or other measures before determining that a laboratory's certification should be reinstated.

(2) Expired Certification. If a water quality laboratory demonstrates that it meets all renewal requirements, the Department may reinstate the certification of the water quality laboratory.

.13 Expiration and Renewal of Certification.

A. Expiration Date.

(1) Certification expires on the date shown on the certificate and is renewable annually.

(2) The expiration date of a certificate may be amended upon the written request of a water quality laboratory and the approval of the Certification Authority.

B. Annual Certification. The Department shall notify a water quality laboratory not less than 120 days before the expiration date shown on the face of the existing certificate that the laboratory shall submit a renewal application and fees, as applicable.

C. A water quality laboratory shall submit an application and fees as applicable, for renewal of its certification annually at least 90 days prior to the expiration date on the certificate.

D. A water quality laboratory that has an expired certification may not analyze drinking water compliance samples.

.14 Certification of Out-of-State Water Quality Laboratories.

A. An out-of-state water quality laboratory may be certified to perform drinking water analyses pursuant to Environment Article, Title 9, Subtitle 10, Annotated Code of Maryland, provided it is certified by the U.S.

Environmental Protection Agency, TNI or the State in which it is located, if certification criteria are at least as stringent as the requirements of these regulations. Proof of this certification shall be provided to the Department by the out-of-state water quality laboratory.

B. An out-of-state water quality laboratory shall submit acceptable proficiency test results for each certified parameter and method.

.15 Changes in Personnel, Analytical Procedures, or Location of Water Quality Laboratory.

A. A water quality laboratory shall report a change in ownership, water quality laboratory supervisor, or analyst in writing to the Department within 30 days after its occurrence.

B. A water quality laboratory shall submit in writing to the Department any proposed changes in analytical procedures, instrumentation and in location of a certified water quality laboratory before the change is implemented.

C. The Department may perform an on-site evaluation within 30 days of notification by the laboratory that a change in location has occurred.

.16 Certification Refusal, Revoked Certification and Provisional Certification.

A. A certification may be downgraded to provisional certification or revoked by the Department, following an opportunity for a hearing before the Secretary or a designated hearing officer, pursuant to COMAR 26.01.02.

(1) Written notification will be issued to the water quality laboratory or person, or persons, responsible for its operation, specifying one or more reasons for refusal, downgrade to a provisional certification, or revocation.

(2) If certification is downgraded to provisional certification, full certification is withdrawn until the cause for non-compliance with these regulations has been removed or addressed.

(3) A provisional certification status continuing for more than 90 days without correction may be followed by revocation.

(4) After revocation of its certification, a water quality laboratory may apply for recertification after demonstrating an ability to comply with these regulations.

.17 Penalty.

A person who violates any provision of the Annotated Code, Environment Article Title 9, Subtitle 10 is guilty of a misdemeanor and on conviction is subject to a fine not exceeding \$1,000 or imprisonment not exceeding 1 year or both.

STATE OF
MARYLAND
EXECUTIVE
DEPARTMENT

**OFFICE OF THE SECRETARY OF
STATE DIVISION OF STATE
DOCUMENTS**

MARTIN O'MALLEY
Register
Governor

Regulations
ANTHONY G. BROWN
Lt. Governor

JOHN P. MCDONOUGH
Secretary of State

Maryland

Code of Maryland

(COMAR)

Incorporation by
Reference
APPROVAL
FORM

Date:
September 19,
2013 COMAR:
26.08.05.01-1

Allison Tritt
Maryland Department of the Environment
WMA
1800 Washington Boulevard
Baltimore, MD 21230

Dear Ms. Tritt:

The following documents are approved for incorporation by reference:

- (1) EPA 815-R-05-004, January 2005 Manual for the Certification of Laboratories Analyzing Drinking Water, Criteria and Procedures Quality Assurance, Fifth Edition; and
- (2) EPA 815-F-08-006, June 2008 Supplement 1 to the Fifth Edition of the Manual for the Certification of Laboratories Analyzing Drinking Water, Supplement 1 to EPA 815-R-05-004.

Please note the following special instructions: None.

Attach a copy of this approval form when submitting an emergency or proposed regulation to the AELR Committee and when submitting a proposed regulation to DSD

for publication in the Maryland Register. If submitting through ELF, include as part of the attachment.

Any future changes to the incorporated documents do not automatically become part of the regulation. If there are subsequent changes to the incorporated documents, and the agency wishes those changes to become a part of its regulations, the agency must amend the regulation incorporating the documents.

Please call us if you have any questions.

Sincerely,
Gail S.
Klaking
Senior
Editor

Office of the Secretary of State, Division of State Documents, State House,
Annapolis, MD 21401 410-974-2486, 800-633-9657; Fax 410-280-5647;
email statedocs@sos.state.md.us