

**Maryland General Assembly
Department of Legislative Services**

**Proposed Regulations
Department of the Environment**
(DLS Control No. 14-017)

Overview and Legal and Fiscal Impact

These regulations clarify and update requirements for the certification of water quality laboratories by the Maryland Department of the Environment. The regulations correct technical references, modify the timeline for the submission of annual certification renewal applications, implement a penalty for late renewal applications, and clarify the educational and experience requirements for laboratory personnel employed by certified water quality laboratories. Relevant federal regulations and standards are incorporated by reference.

The regulations present no legal issues of concern.

The regulations may result in a minimal increase in expenditures for any State agency or local jurisdiction that operates a water quality laboratory and a negligible increase in general fund revenues collected by the department from late fees.

Regulations of COMAR Affected

Department of the Environment:

Water Pollution: Certification of State Water Quality Laboratories:
COMAR 26.08.05.01-.17

Legal Analysis

Background

The federal Safe Drinking Water Act was passed in 1974 to protect public health by regulating the nation's public drinking water supply. Under the act, public drinking water supplies must be tested periodically to ensure that contaminants in the water do not exceed permissible amounts. These tests are performed by water quality laboratories, which must be certified by the U.S. Environmental Protection Agency (EPA) or a state certification authority to ensure that the laboratories follow certain protocols and produce accurate water quality analyses.

The department is authorized to act as certification authority for certifying laboratories that analyze drinking water samples in Maryland. Federal law requires State certification programs to have standards in place that are at least as stringent as the federal standards. In

Maryland, in order to qualify for certification by the department, a water quality laboratory must meet the minimum criteria specified in the EPA Manual for the Certification of Laboratories Analyzing Drinking Water, as well as department regulations.

As of June 2013, 108 water quality laboratories were certified to process compliance samples from Maryland drinking water supplies. Of these laboratories, 47 were located in the State.

Summary of the Regulations

The regulations clarify and update requirements for the certification of water quality laboratories by the department, consistent with the requirements of the federal Safe Drinking Water Act. A description of the regulations follows.

Scope: The scope of the chapter is unchanged, providing for the establishment of standards of operation for water quality laboratories.

Incorporation by reference: Regulation .01-1 is new. The regulation incorporates relevant federal regulations on record maintenance, testing for lead and copper, and reporting requirements for certified drinking water laboratories. The regulation also incorporates the EPA's Manual for the Certification of Laboratories Analyzing Drinking Water and Supplement 1 to the Fifth Edition of the manual, which establish criteria for evaluating and certifying drinking water laboratories.

Definitions: Regulation .02 updates existing definitions and defines new terms used in the chapter. Among the new definitions are entries for "Certification Authority" and "Certification Officers." These terms clarify the department's role under federal regulations as the body responsible for certifying water quality laboratories in the State.

Certification for a Water Quality Laboratory: Regulation .03 requires all water quality laboratories operating in the State to be certified by the department. New provisions specify that a water quality laboratory must obtain an identification number from the EPA and must analyze at least one compliance sample per year to maintain certification. A water quality laboratory may not be certified until an on-site evaluation has been conducted.

General Requirements for a Certified Water Quality Laboratory: Regulation .04 is substantially the same as current Regulation .02. It requires a certified water quality laboratory to maintain a Quality Assurance Manual that contains, at a minimum, criteria pertaining to space requirements, approved analytical procedures, collection and preservation procedures, reporting of laboratory results, qualified personnel, supervisors, and the maintenance of laboratory records.

Application for Certification: Regulation .05 specifies the information that must be provided in an application for initial or renewed certification by the department. A new provision requires proficiency test results to be submitted for each parameter and test method for which the laboratory is seeking certification.

Fees: The certification fee for an in-state water quality laboratory that is not run by State, federal, or local government, remains \$250 per year under Regulation .06, plus \$10 for each specific test and parameter combination for which certification is requested. A fee of \$400 per year is codified for out-of-state water quality laboratories certified by their home state or another accrediting body. A new late fee of \$100 is established for any water quality laboratory that submits its renewal application after the expiration date on its certificate.

On-Site Evaluation: Regulation .07 updates requirements for announced and unannounced on-site evaluations of water quality laboratories that have applied for or received certification. In-state water quality laboratories are prohibited from beginning to analyze regulated drinking water contaminants until the department has conducted an on-site evaluation, and the department may revoke the certification of any laboratory that denies the department access for on-site evaluation.

Personnel Qualifications: New language in Regulation .08 requires a water quality laboratory to meet education and training criteria for laboratory staff identified in the EPA Manual for the Certification of Laboratories Analyzing Drinking Water. The department is authorized to waive minimum education requirements on a case-by-case basis for certain experienced personnel.

Laboratory Quality Assurance Program: Regulation .09 establishes more specific criteria for quality assurance programs at certified water quality laboratories. New provisions require a laboratory to develop a Quality Assurance Manual describing its quality assurance program and to submit the manual to the department as part of the laboratory's certification application. As part of a laboratory's quality assurance program, the laboratory must participate in a certain independent proficiency test program. Proficiency testing analyses must be forwarded to the department, and the department may revoke or provisionally downgrade a laboratory's certification status based on the results of proficiency tests.

Evaluation Procedure: Regulation .10 describes procedures water quality laboratories may take to correct violations of department regulations and standards. A new provision clarifies a water quality laboratory's responsibility to forward certain reports to the department if the laboratory is found to be in non-compliance with an on-site evaluation by another State or third party organization.

Downgrading of Certification for Performance of Specific Tests: Regulation .11 clarifies the department's authority to deny, make provisional, or revoke approval for a certified laboratory to perform a specific test or use a specific test method. The regulation also establishes a procedure for the reinstatement of approval to perform specific tests or use specific test methods.

Laboratory Certification Denial, Provisional Certification, and Revocation of Certification: Regulation .12 is similar to current section .13D, but provides more information on provisional certification, the procedure for revocation of certification, and the reinstatement of certification.

Expiration and Renewal of Certification: Regulation .13 alters the timeline for the submission of annual renewal applications for certification. Under Regulation .13, the department must notify a water quality laboratory at least 120 days (rather than 30 days) before the expiration of the laboratory's certification. The laboratory must then submit its application for renewal at least 90 days before its certification expires.

Certification of Out-of-State Water Quality Laboratories: Regulation .14 is similar to current Regulation .15, but contains more detailed requirements for the certification of out-of-State water quality laboratories.

Changes in Personnel, Analytic Procedures, or Location of Water Quality Laboratory: Like current regulation .16, Regulation .15 requires a water quality laboratory to notify the department of certain changes within certain timeframes. However, while the current regulation requires the department to perform an on-site evaluation of a laboratory within 30 days of being notified of a change in location, the new regulation makes such evaluation discretionary.

Certification Refusal, Revoked Certification, and Provisional Certification: Regulation .16 contains new provisions specifying the procedure for downgrading or revoking a laboratory's certification.

Penalty: Regulation .17 restates the statutory penalty for violations of Title 9, Subtitle 10 of the Environment Article, which outlines the State's water quality laboratory certification program. This text is consistent with § 9-1026 of the Environment Article.

Legal Issue

The regulations present no legal issues of concern.

Statutory Authority and Legislative Intent

The department cites Title 9 of the Environment Article as authority for the regulations. Title 9 broadly describes the department's responsibilities with respect to water, ice, and sanitary facilities. More specifically, § 9-1003 authorizes the department to adopt regulations to carry out the provisions of Subtitle 10 of Title 9 and to develop a proficiency testing program to assess the performance of certified water quality laboratories; Subtitle 10 establishes certification requirements for water quality laboratories.

This authority is correct and complete. The regulations comply with the legislative intent of the law.

Technical Corrections and Special Notes

The Department of Legislative Services has notified the department of numerous punctuation and stylistic errors in the submitted regulations. The department was also advised to specifically cite § 9-1003 as authority for the regulations, which contains the relevant statement of the department's authority to regulate water quality laboratories. Finally, the department has

agreed to submit a fee justification form, which was submitted to the Department of Legislative Services.

Fiscal Analysis

The regulations may result in a minimal increase in expenditures for any State agency or local jurisdiction that operates a water quality laboratory and a negligible increase in general fund revenues collected by the department from late fees.

Agency Estimate of Projected Fiscal Impact

The department advises that the regulations have minimal impact on State and local governments. Specifically, the department indicates that the regulations result in a minimal decrease in *revenues* on the department, State agencies, and local governments. The Department of Legislative Services disagrees, as the regulations result in several changes that may affect the operations, and potentially the *expenditures*, of a laboratory operated by a State agency or local government, but, with the exception of the department, they do not appear to affect revenues. The regulations may take effect prior to July 1, 2014; thus, any impact may begin in fiscal 2014.

Water quality laboratories are operated by private businesses, local governments (particularly local boards of public works and sanitary districts), and two State agencies. Several of the regulations, and particularly the regulations that appear to impose the most significant changes, such as the personnel training and qualification requirements and changes to the laboratory quality assurance program, merely codify federal requirements or current practices. Other changes, such as the establishment of a late fee and enforcement procedures and penalties, are either relatively minimal, a restatement or clarification of current law, or procedural in nature. Thus, the regulations do not appear to result in a significant impact on State agency or local government water quality laboratories.

General fund revenues increase minimally from the collection of a new late fee (\$100) established by the regulations. The department advises that, in fiscal 2013, only two laboratories submitted a renewal application late. Accordingly, any increase in general fund revenues from late fees is anticipated to be negligible.

Impact on Budget

There is no material impact on the State operating or capital budget.

Agency Estimate of Projected Small Business Impact

The department advises that the regulations have minimal or no economic impact on small businesses in the State. The Department of Legislative Services generally concurs that the regulations have minimal impact on small businesses, for the reasons discussed above for the State and local impact.

Contact Information

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