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Proposed Regulation
Agency Background Document

Agency name	Department of General Services, Division of Consolidated Laboratory Services
Virginia Administrative Code (VAC) citation(s)	1VAC30-45
Regulation title(s)	Certification for Noncommercial Environmental Laboratories
Action title	Revise regulation to update procedural and fee requirements
Date this document prepared	February 22, 2013; June 18, 2015

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

1VAC30-45 sets out the Division of Consolidated Laboratory Services (DCLS) program requirements to certify noncommercial laboratories that analyze environmental samples used to determine compliance with the State Water Control Law, Virginia Waste Management Act, and the Virginia Air Pollution Control Law.

The proposed action does the following:

1. Streamlines the procedures for application and renewal of certification.
2. Reduces the requirement to perform proficiency test studies to one study annually for each field of certification.

3. Eliminates requirements for specialized testing that noncommercial laboratories currently do not perform.
4. Adds procedures for suspension of certification to provide a laboratory time to correct problems to avoid decertification.
5. Makes explicit the requirements to notify a laboratory that the agency has cause to deny certification or to decertify.
6. Simplifies the appeal procedure language.
7. Restructures and modifies the fee system and the fees paid by laboratories.
8. Eliminates or provides increased flexibility for a number of quality system (Article 4) provisions.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

"DCLS" is the Division of Consolidated Laboratory Services of the Department of General Services.

"DGS" is the Virginia Department of General Services.

"DEQ" is the Virginia Department of Environmental Quality.

"FoPT" is field of proficiency testing.

"Matrix" or "matrices" is the substrate or substrates of interest of a test sample.

"NELAC" is the National Environmental Laboratory Accreditation Conference.

"TNI" is the NELAC Institute, the organization whose standards commercial environmental laboratories must meet to be accredited in Virginia.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

Virginia Legal Authority

Section 2.2-1102 A 1 of the *Code of Virginia* authorizes the Department of General Services (DGS) to prescribe regulations necessary or incidental to the performance of the Department's duties or execution of powers conferred by the *Code*.

Section 2.2-1105 A of the *Code of Virginia* authorizes the Division of Consolidated Laboratory Services (DCLS) to establish and conduct a program for the certification of laboratories conducting any tests, analyses, measurements, or monitoring required pursuant to Chapter 13 (§ 10.1-1300 et seq.) of Title 10.1 [Air Pollution Control Law], the Virginia Waste Management Act (§ 10.1-1400 et seq.), or the State Water Control Law (§ 62.1-44.2 et seq.). Section 2.2-

1105 C of the *Code of Virginia* authorizes DCLS to establish a fee system to pay for the costs of the certification program.

Promulgating Entity

The promulgating entity for this regulation is the Division of Consolidated Laboratory Services of the Department of General Services.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

Environmental laboratories are required by §2.2-1105 of the *Code of Virginia* to be certified before submitting data to the Department of Environmental Quality (DEQ) under Virginia's air, water, and waste laws and regulations. This statutory requirement is carried out by DCLS under the regulatory requirements of 1VAC30-45 (noncommercial laboratories) and 1VAC30-46 (commercial laboratories).

Certifying environmental laboratories to a single set of standards has several benefits. Certification promotes continuous quality improvement. Certification gives confidence that work is performed properly and to a known standard. Under the certification program, assurance is provided that all environmental laboratories meet the same proficiency testing and quality assurance and quality control standards. Meeting these standards ensures that the laboratories have the ability to produce environmental test data of known quality and defensibility for levels of pollutants in environmental samples. The limits set by DEQ for air and water pollutants and for solid and hazardous waste help protect our environment and public health. Laboratory measurements of environmental samples determine compliance with Virginia's environmental laws and therefore are the key to providing protection of public health and welfare. Certifying laboratories to one standard reduces the uncertainties associated with decisions made by the regulatory agencies that affect the protection of human health and the environment.

Current fees charged under the program are insufficient to support the program as required by §2.2-1105 C of the *Code of Virginia*. The current fees are inadequate for three reasons. First the fees were set initially using an estimate of the number of laboratories to be certified that was too high. Second the program fees were established in 2004 and do not account for inflation in the intervening years. Third the fee structure does not take into account the variety and amount of testing done by the laboratories DCLS certifies.

The original estimate of laboratories that would be covered by the program was based on limited information provided by DEQ and other sources. Using this information, DCLS estimated the number of in-house and commercial laboratories that were serving DEQ permit holders. This estimate proved to be too high and the resulting fees, based on these estimates, are too low. The revised fees are based on the number of laboratories currently certified under the program.

The current fee provisions do not include a factor for inflation. The fees were proposed in 2004 in regulations that did not become final until 2009. The cost of living has increased by approximately 20 percent since 2004. The revised fees have been adjusted to account for this increase in the cost of living.

The current fee provisions do not take into account the range of testing and the variety of testing done by the certified laboratories. This results in fees that do not mirror the scope of the laboratory testing. The work performed by DCLS to certify a laboratory is directly related to the number of test methods performed and the number of matrices tested by the laboratory. The revised fee structure accounts for

these differences. The revised fees are adjusted in proportion to the number of test methods a laboratory performs and for the number of matrices tested.

The agency has gained operational experience through certifying laboratories since January 2009. The proposed action revises the procedures used to certify the laboratories, eliminating provisions that no longer apply and revising some provisions to make the program more efficient. This includes the addition of procedures to suspend laboratory certification. Suspension is a benefit to the laboratory that may otherwise have its certification withdrawn.

Noncommercial environmental laboratories perform proficiency tests quite well. During a 31-month period (2010, 2011, and the first nine months of 2012), these laboratories had a 95.79 percent success rate. Through this experience DCLS has determined that reducing the annual requirement for two proficiency test studies for each Field of Certification to one proficiency test study will reduce the cost of the program for the laboratories and for the agency without reducing the benefit gained from the certification program.

The current regulation contains requirements for laboratories that perform toxicity, asbestos, or radiochemical testing. No current noncommercial environmental laboratory performs these specialized types of tests. DCLS is removing these requirements in this proposal for this reason. Only those requirements pertinent to noncommercial laboratories should be included in the regulation. The proposal does stipulate that if a noncommercial environmental laboratory decides to perform one or more of these types of tests, the laboratory would have to meet the requirements for these types of testing that are set out in the 2009 TNI Standards incorporated by reference into proposed 1VAC30-46. These laboratories would also need to pay the test category fees for these types of testing as set out in proposed 1VAC30-46.

The quality control requirements that are part of Article 4 in the current regulation are based on the 2003 NELAC Standards. The NELAC Institute (TNI) has revised the 2003 Standards and now requires TNI-accredited laboratories to meet the 2009 Standards. The 2009 TNI Standards have eliminated or increased flexibility for a number of these quality control requirements. DCLS is proposing in a separate rulemaking (1VAC30-46) that commercial environmental laboratories meet the 2009 TNI Standards. Where TNI has revised these provisions to make them more flexible or has eliminated requirements, this proposed action does the same so that the noncommercial laboratories will not be required to meet standards more stringent than the commercial laboratories.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of changes" section below.

The substantive revisions to 1VAC30-45 are listed below.

1. The definition of "environmental analysis" includes two exceptions that DCLS has previously made through guidance. 1VAC30-45-40.

2. The procedures pertinent to the initial certification period are deleted. The initial certification period was established as January 1, 2009, to January 1, 2012, when DCLS certified environmental laboratories for the first time. Because DCLS has completed the initial certification of noncommercial environmental laboratories, these provisions no longer apply. 1VAC30-45-70 B.

3. The requirement for laboratories to file an application for renewal every other year is deleted. Renewal can be efficiently done without an additional application process. 1VAC30-45-70 C.

4. A new section pertaining to suspension is added. Suspension provides the laboratory an opportunity to correct a problem that would ordinarily cause the agency to withdraw certification from the laboratory. This section sets out the procedures used to suspend laboratory certification in part or in total. DCLS also may provide extra time under these provisions for a lab to correct deficiencies before suspension occurs. 1VAC30-45-95.

5. The procedures to deny or withdraw certification are revised. The notification procedures are revised to be more explicit. The appeal process provisions are simplified, referring only to the Administrative Process Act. 1VAC30-45-110.

6. The current fees are replaced by a system and new fees that reflect the current costs of the program. The revised fees account for inflation since 2004. Revised fees represent more closely the cost of certifying each laboratory. These fees take into account the number of test methods and the number of matrices for which the laboratory seeks or maintains certification. The cost of certifying a laboratory is directly proportional to the number of methods and matrices to be certified. 1VAC30-45-130.

7. The requirement for two successful proficiency test studies every year is replaced by a requirement for one successful proficiency test study per year for each field of certification. A laboratory may participate in a second proficiency test study if the first test is unsuccessful. The revision to the proficiency test requirements includes revised procedures. 1VAC30-45-500 through 1VAC30-45-520.

8. The specific requirements for aquatic toxicity proficiency testing are deleted. Noncommercial environmental laboratories currently certified under the program do not perform this type of testing because it is specialized. 1VAC30-45-530.

9. The quality control requirements for toxicity, radiochemical, and asbestos testing are deleted. These types of testing are not performed by noncommercial environmental laboratories currently certified under the program because this testing is specialized. If a noncommercial laboratory wishes to become certified for one or more of these types of testing, the laboratory will be required to meet the 2009 TNI requirements for toxicity, radiochemical, and asbestos testing. 1VAC30-45-750 B; 1VAC30-45-780 through 1VAC30-45--789; 1VAC30-45-800 through 1VAC30-45-809; and 1VAC30-45-819 through 1VAC30-45-840.

10. Over 20 provisions in Article 4, the quality system standards, have been deleted, relaxed, or made more flexible. These provisions were revised to ensure that they are no more stringent than the accreditation standards for commercial laboratories. DCLS is proposing in a separate rulemaking to accredit commercial laboratories to the requirements of the 2009 TNI Standards replacing the currently used 2003 NELAC Standards. These changes are a result of the change to the 2009 TNI Standards for commercial laboratories.

Issues

Please identify the issues associated with the proposed regulatory action, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please indicate.

The advantage to the general public is the maintenance of up-to-date standards for the certification of noncommercial environmental laboratories. There are no disadvantages to the public.

There are two primary reasons this action is necessary for DCLS and the Commonwealth. First the revisions to 1VAC30-45 modify or reduce the program's administrative requirements making the program more efficient to operate. Second charging the revised fees will enable the agency to cover the cost of the certification program. There are no disadvantages to the agency or Commonwealth.

There are a number of advantages for the environmental laboratories certified under 1VAC30-45. Many of these proposed revisions reduce the costs for the noncommercial laboratories. The main examples of the revisions that reduce cost for the laboratories are described below.

The proposed action drops the requirement to perform proficiency test studies from two to one each year for each Field of Certification. Noncommercial environmental laboratory costs will drop as a result. In some cases this reduced requirement may offset the increase in fees proposed in this action. The noncommercial laboratories have demonstrated a high success rate in the performance of proficiency tests. These laboratories have often asked that the proficiency test study requirement be limited to one proficiency test. DCLS believes reducing the requirement from two to one PT each year will not have a negative effect on the efficacy of the program.

The noncommercial laboratories will also benefit from the changes to the quality system standards. These revisions delete or relax standards or provide flexibility in meeting the standards. These changes reduce the costs of certification for the laboratories.

The primary disadvantage of the proposed action for the affected laboratories is the increase in fees. The fee structure is revised to reflect the actual cost to the agency of certifying each laboratory. The fees are increased generally and will be charged annually rather than every other year. The increase in fees should be offset by the reduction in the proficiency test requirement.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are no applicable federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

There are 89 public laboratories currently certified under the standards of 1VAC30-45. Of these 64 are local government laboratories None of these is disproportionately affected by the revisions to 1VAC30-45. This background document was initially prepared in February 2013. At that time there were 80 local government laboratories.

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

In addition to any other comments, the agency is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so via the Regulatory Town Hall website (**http://www.townhall.virginia.gov**), or by mail, email or fax to Nancy S. Saylor, in c/o DCLS, 600 North 5th Street, Richmond, VA, 23219, nssaylor@verizon.net, 804-231-7980 (phone) or 804-371-7973 (fax). Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on the last date of the public comment period.

A public hearing will not be held following the publication of this stage of this regulatory action.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

Projected cost to the state to implement and enforce the proposed regulation, including: **a) fund source / fund detail; and** **b) a delineation of one-time versus on-going expenditures**	Cost: $620,500 per year. This is the projected cost for the overall program: to accredit commercial laboratories (1VAC30-46) and certify noncommercial laboratories (1VAC30-45). 1VAC30-46 is being revised in a separate rulemaking. The details provided below pertain only to the laboratories accredited under 1VAC30-45 unless stated otherwise. Fund source: Fees collected from all participating laboratories, both commercial and noncommercial. Expenditures: These are ongoing expenditures only.
Projected cost of the new regulations or changes to existing regulations on localities.	The projected cost of the revised regulation is the same for local government labs as it is for all affected labs and this cost is entirely in the fees. Eighty local government laboratories are currently certified under 1VAC30-45. The projected increase in fees for these laboratories ranges from 2 to 153 percent. Approximately 18-20 percent of this percentage increase in fees reflects inflation since 2004, an 8-year period. The remaining increase represents the quantity and type of testing performed by the laboratory. The fees increase for labs performing more tests under multiple matrices. See Additional Information below for more details about the fee increases.
Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	The proposed revisions to 1VAC30-45 will affect the environmental laboratories currently certified under the regulation.
Agency's best estimate of the number of such	The revisions affect 109 laboratories certified

entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	under 1VAC30-45 as of 1/9/13. Of these 109 laboratories, 56 perform only simple test procedures (STPs) and are charged a low flat fee. The remaining 53 laboratories perform a variety of tests in one or two of three matrices (nonpotable water, solid and chemical materials, air). Under the proposal these laboratories would be charged a fee based on the Fields of Certification for which they are certified and the number of matrices under which they do testing. There are 80 local government laboratories (41 STP and 39 general labs). Thirteen laboratories are owned by industrial companies (2 STP and 11 general labs). One STP laboratory is owned by a private water utility company. None of these 14 companies qualifies as a small business. Eight laboratories are owned by the Commonwealth of Virginia (7 STP and 1 general lab). Seven of these labs are run by state agencies and one lab is run by a state-owned institution of higher learning. Seven laboratories (5 STP and 2 general labs) are run by federal agencies.
All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs including: **a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and** **b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.**	The projected costs for the affected 1VAC30-45 laboratories are the increase in fees. The projected increase in fees for the 56 currently certified STP laboratories is 100% for 47 laboratories and 153% for 9 laboratories. The projected increase in fees for the 53 general environmental laboratories ranges from 2% to 56%. Most of the fee increases fall in the range between 19-28% [22 labs] and 31-48% [27 labs]. There are four other labs. Two labs will see fee increases of 2% and 6% and the other two labs will see fee increases of 50% and 56%. The proposed action reduces the requirement for proficiency test studies from two to one. The savings is substantial. See additional information below for details on the fees and the proficiency test study cost savings.
Beneficial impact the regulation is designed to produce.	The revisions to the regulation protect public health and welfare by ensuring that certified environmental laboratories continue to meet the same environmental laboratory standards. The environmental data derived from the environmental samples tested by these laboratories form the basis for determining compliance under the state's environmental laws and regulations.

ADDITIONAL INFORMATION

FEES

The current fees were set in 2004, five years before the program became effective. The current fees do not reflect the cumulative cost of living increases (@ 18-20 percent) that have occurred during this period. To determine revised fees, DCLS first determined the current costs of the program. The agency then estimated what the costs of the program would be using an effective date of 2014 for this proposed action. DCLS reviewed the costs of initially certifying a select number of laboratories. DCLS also looked at the cost to the agency of monitoring the certified laboratories. During this review, it became apparent that the agency's program costs are directly related to the amount of testing performed by a laboratory. Laboratories certified for multiple matrices and numerous test methods require more review and monitoring. DCLS determined that the fees should be based on these factors. Base fees and test category fees were set using both the number of test methods performed and the number of field of certification matrices under which the methods would be performed. This approach results in revised fees that better reflect the cost of certifying and monitoring the individual certified laboratories. Four examples follow for comparison.

Example A: A laboratory performing a total of 8 test methods on nonpotable water in four test categories (oxygen demand, bacteriology, physical, inorganic chemistry) will see a fee increase of 19% [current fee annualized is $1787.50; proposed annual fee is $2125; increase of $337.50].

Example B: A laboratory performing a total of 8 methods on nonpotable water in four test categories (bacteriology, physical, inorganic chemistry, organic chemistry) will see a fee increase of 24% [current fee annualized is $1900; proposed annual fee is $2350; increase of $450].

Example C: A laboratory performing a total of 11 methods on nonpotable water and solid and chemical materials in two test categories (physical and inorganic chemistry) will see a fee increase of 28% [current fee annualized is $1637.50; proposed annual fee is $2090; increase of $452.50].

Example D: A laboratory performing a total of 9 methods on nonpotable water and solid and chemical materials in four test categories (oxygen demand, physical, bacteriology, and inorganic chemistry) will see a fee increase of 31% [current fee annualized is $1787.50; proposed annual fee is $2345; increase of $915].

Most laboratories performing any number of tests defined as simple test procedures (STP) will see a fee increase of 100%. These laboratories currently pay $600 every two years. Under the proposal they will pay $600 annually, an increase of $300 each year. The current fee of $600 paid every two years does not cover the cost to the agency of the on-site assessment much less the cost to the agency of monitoring the laboratory's PTs.

PROFICIENCY TESTING STUDIES (PTs)

This proposal reduces the requirement for the number of PTs to be performed each year from two to one PT for each field of certification (matrix, technology/method, and analyte). This is a significant cost reduction for both the STP laboratories and the general laboratories. A typical STP laboratory performs nonpotable water testing for e. coli, total suspended solids, and biochemical oxygen demand. Some STPs perform only two of these tests; others test pH in addition to these tests. The majority of the STP labs (64%) will see a savings on average of between $149 and $245 each year.

A typical general environmental lab performs tests for simple and complex nutrients as well as those tests performed by the STP labs. Others add a test for total residual chlorine to the basic STP lab tests. The majority of the general environmental labs (64% or 34 labs) will save on average between $198 and $296 each year from the reduction in the requirement to perform PT studies. Twelve other general environmental laboratories are certified for many fields of certification, including test methods for organic chemistry and chemical metals testing. Their savings will be greater but their fees will be higher as well.

Using the four examples under Fees above, the reduction in PT costs would be as follows:

Example A=$296; Example B=$289; Example C=$362; and Example D=$341.

The PT costs set out above are an average of the prices charged by four approved PT providers that sell all the studies these laboratories need.

OVERALL CHANGES IN LABORATORY COST TO MAINTAIN CERTIFICATION

While the proposed fees will increase, the cost of maintaining certification will be reduced. The reduction in the requirement to purchase and perform PT studies from two to one each year will offset the increase in fees for all laboratories. This can be demonstrated by using the four examples shown above for general environmental laboratories.

DESCRIPTION	EXAMPLE A	EXAMPLE B	EXAMPLE C	EXAMPLE D
Current annualized fee	$1787.50	$1900.00	$1637.50	$1787.50
Current PT cost	$592.00	$578.00	$724.00	$682.00
Total current fee and PT costs	$2379.50	$2478.00	$2361.50	$2469.50
Proposed annual fee	$2125.00	$2350.00	$2090.00	$2345.00
Reduced PT cost under proposal	$296.00	$289.00	$362.00	$341.00
Total proposed fee and PT costs	$2421.00	$2639.00	$2452.00	$2686.00
TOTAL INCREASE IN COST TO MAINTAIN CERTIFICATION UNDER PROPOSAL	**$41.50 (1.7%)**	**$161.00 (6.5%)**	**$90.50 (3.8%)**	**$216.50 (8.8%)**

The laboratories performing only simple test procedures (STP) will also benefit from the reduction in the requirement to purchase and perform PT studies from two to one each year. The PT section above indicated that 64% of STP laboratories would realize average savings between $149 and $245 per year. To demonstrate the overall cost change for STP laboratories, two examples are provided using these PT cost savings. Example E will realize savings of $149 each year. Example F will realize savings of $245 each year.

DESCRIPTION	EXAMPLE E	EXAMPLE F
Current annualized fee	$300.00	$300.00
Current PT cost	$298.00	$490.00
Total current fee and PT costs	$598.00	$790.00
Proposed annual fee	$600.00	$600.00
Reduced PT cost under proposal	$149.00	$245.00
Total proposed fee and PT costs	$749.00	$845.00
TOTAL INCREASE IN COST TO MAINTAIN CERTIFICATION UNDER PROPOSAL	**$151.00 (25.3%)**	**$55 (6.7%)**

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

Two alternatives pertain to the general revision of 1VAC30-45. The first is to revise the regulation based on the experience DCLS gained while certifying laboratories during the initial certification phase of the program. The second is to retain the regulation as it is currently written. The agency believes that the first alternative is the best approach. Using this approach DCLS can apply the lessons learned in certifying laboratories in the initial phase of the program. The proposed action for example streamlines the procedures used to certify laboratories and to maintain certification of laboratories. This approach is beneficial not only to the agency but also to the affected laboratories in that it reduces their costs by reducing their application requirements.

Two alternatives pertain to the revision of fees charged under 1VAC30-45. The first is to revise the fees to cover the costs of the program as required by the program's statutory authority. The second is to leave fees as currently established. The agency believes the first alternative is the best approach. The current fees do not cover the cost of the program nor do these fees represent the costs of certifying individual laboratories. Changing the structure of the fee program benefits the laboratories as well as the agency. The laboratories under the revised fee structure are charged fees that are appropriate to their test menu. While fees will rise for all the laboratories, fees will be lower for those laboratories that perform limited testing.

Two alternatives pertain to the requirement for laboratories to perform successful PT studies to obtain certification. The first is to continue to require the successful performance of two PT studies each year for each Field of Certification (FoC). The second is to require the successful performance of one PT study each year for each FoC. The agency believes the second alternative is the best approach. The noncommercial laboratories have demonstrated a PT success rate of over 95% for almost three years. The agency believes requiring only one PT study each year will not have a negative effect on laboratory quality. This change benefits both the laboratories and the agency, reducing costs for both.

Two alternatives pertain to the changes to quality system provisions based on the 2009 TNI Standards. The first alternative is to make the changes that eliminate or relax the quality system provisions. The second is to retain the current provisions as written. The agency believes the first alternative is the best approach. This approach ensures that quality system requirements for noncommercial laboratories are no more stringent than those for commercial laboratories.

Regulatory flexibility analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

The revised regulation applies to all noncommercial environmental laboratories. None of these laboratories can be classified as small businesses. All these laboratories should meet the same certification standards. Any 1) establishment of less stringent compliance or reporting requirements; 2) establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) consolidation or simplification of compliance or reporting requirements; 4) establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; or 5) exemption of small businesses from all or any part of the requirements contained in the proposed regulation would adversely affect the benefits that would be achieved through the implementation of the regulation.

The proposed action -

- streamlines application and renewal requirements;
- lowers fees for laboratories performing fewer test methods;
- reduces PT study requirements; and
- eliminates or provides more flexible quality system requirements.

Public comment

Please summarize all comments received during the public comment period following the publication of the NOIRA, and provide the agency response.

Commenter	Comment	Agency response
SUPPORT FOR THE PROGRAM		
Hampton Roads Sanitation District (HRSD)	HRSD has been actively involved in the development and implementation of the Virginia Environmental Laboratory Accreditation Program (VELAP). HRSD's laboratory, accredited under 1VAC30-46, has found the program beneficial to full integration of a quality system for environmental analyses and supports program sustainability for continued accreditation of both commercial and non-commercial laboratories.	The agency appreciates HRSD's support of the VELAP program and its acknowledgement that the program is beneficial.
ELIMINATE INITIAL CERTIFICATION PERIOD REQUIREMENTS		
Virginia Association of Municipal Wastewater Agencies (VAMWA), HRSD, Upper Occoquan Service Authority (UOSA), Augusta County Service Authority (ACSA), Town of Luray	1VAC30-45-70, subsection B. 1, established September 29, 2009 as the deadline for timely application for certification for owners of noncommercial environmental laboratories. As this date has long-since passed, the commenters support the Department's proposal to amend the regulation by deleting this subsection.	The agency appreciates the commenters' support for this change.
VAMWA, HRSD	The commenters note that subsection B. 2 establishes the requirement that owners of noncommercial environmental laboratories that come into existence after January 1, 2009 must submit an initial application to the Department no later than 180 days prior to beginning operation. The commenters assume that the Department will retain this requirement as it continues to be applicable.	The agency has dropped the 180-day requirement from the regulation. Any new environmental laboratory that must report data to DEQ will have to be certified under the program. The owner of a well-managed laboratory will submit his application for certification in a timely manner after consultation with the agency.

ACSA	The application process should be streamlined for laboratories requesting accreditation in the future.	The process for labs applying for certification for the first time benefits from the experience gained by DCLS during the initial certification period. The regulation requirements remain essentially the same. The agency has developed procedures that make the process easier.
SIMPLIFY RENEWAL OF CERTIFICATION PROCESS		
UOSA, ACSA, Town of Luray	UOSA and ACSA support the simplification of renewal procedures to reduce the burden on laboratories and the agency. ACSA asks DCLS to consider letting the Lab Practices Committee review the changes to the renewal procedures before being implemented.	The agency appreciates the commenters' support. The renewal process as proposed will consist of the steps outlined in the response to the next comment. All proposed revisions must go through a public comment process. The noncommercial laboratory may comment on these proposed changes during the 60-day comment period.
VAMWA, HRSD	The commenters support the concept of streamlining certification renewal procedures that reduce regulatory burdens on its members. The Department has not, however, provided specifics in the NOIRA as to how certification renewal streamlining will be accomplished. Without further specific information, the commenters cannot offer unqualified support for streamlined certification renewal procedures. The commenters look forward to the opportunity to provide comments on a more particular plan for streamlining the certification renewal procedures it develops.	The agency has eliminated the need for certified laboratories to submit an application for renewal. The agency will renew certification for any laboratory that maintains compliance with 1VAC30-45, attests to this compliance by signing the Certificate of Compliance, maintains a successful PT history, and pays the required fee.
REVISE FOR FLEXIBILITY IF PROVIDED FOR THE SAME PROVISIONS IN 1VAC30-46		
UOSA, ACSA, Town of Luray	The commenters believe that the agency wants to revise the 1VAC30-45 requirements to match the 1VAC30-46 proposed requirements as revised by the 2009 TNI standards. They believe the agency wants to impose the same standards on noncommercial laboratories as are required of commercial laboratories.	The agency stated in the NOIRA that the revised 1VAC30-45 would provide the same flexibility for covered laboratories where that flexibility will be provided for 1VAC30-46 laboratories under the 2009 TNI Standards. The commenters misunderstand the agency's intent. The agency believes that the noncommercial laboratories can benefit from the flexibility for specific requirements that became available to commercial laboratories under the 2009 TNI standards. Where the requirements are the same for both noncommercial and commercial laboratories, any flexibility provided to commercial laboratories should also be provided to noncommercial laboratories. If DCLS does not make these updates to

		1VAC30-45, there will be requirements for noncommercial labs that are more stringent than those for commercial labs. The agency's intent is to avoid this possibility.
VAMWA, HRSD	In general, the commenters support the consensus-based, stakeholder informed process and less prescriptive, quality system-centered approach embodied by the NELAC Institute 2009 Standard. The commenters also appreciate the 2009 Standard's similarities with ISO 17025, a recognized international standard for laboratory accreditation. The commenters believe the following areas offer the potential to achieve the Department's stated objectives to provide flexibility and reduce burdens by modifying the Regulation to reflect the 2009 Standard: • Reduced demonstration of capability documentation requirements; • Removal of the requirement for method manuals in favor of standard operating procedures; and • Removal of requirements for documenting work cells.	The agency appreciates the commenters' suggestions for changes to 1VAC30-45. The proposed revisions incorporate numerous changes based on the flexibility found in the 2009 TNI Standards. The following are the proposed revisions to demonstration of capability (DOC) based on the changes found in the 2009 TNI Standards. For applicants for certification, no initial DOC would be required if the laboratory has used a test method for at least one year prior to applying for certification. This eliminates the date of July 1999 for grandfathering the requirement for initial DOC. The requirement for DOC certification statements to be retained in an analyst's personnel files is deleted. The proposed revision provides more flexibility for performing DOC based on the options provided in the 2009 TNI Standards. The revision also provides detailed options for microbiological laboratories separate from the DOC options for chemical testing laboratories. Microbiological laboratories have found the lack of DOC information for their laboratories to be confusing. The commenters listed two other issues which have been made to the proposed revision. The requirements for work cells are deleted throughout the proposed revision to 1VAC30-45. The 2009 TNI Standards deleted these requirements. The use of method manuals in the revised 1VAC30-45 has been deleted in favor of the use of SOPs. This change reflects the change made in the 2009 TNI Standards.
REVISE FEES TO COVER COST OF PROGRAM		
UOSA, ACSA, Town of Luray	UOSA has significant concerns about increasing certification fees. Raising fees places an increased burden on facilities and eventually to Virginia taxpayers. The NOIRA does not state	This document provides detailed information on the reasons why the current fees are inadequate to pay for the program and a detailed discussion

	the size of the shortfall. Would an independent audit demonstrate that additional funds are absolutely necessary? DCLS has not proposed any alternatives to reduce their costs. Consider the following (a-e below):	on the cost of the program. The program is run with a minimum of resources (5 instead of the originally authorized 12 FTEs). DCLS is reducing costs for the laboratories at the same time it is restructuring and raising fees.
UOSA, ACSA, Town of Luray	a. Why is it necessary for non-commercial laboratories to analyze two PT samples annually? Virginia drinking water certified laboratories are only required to analyze one PT each year. There is no legal, regulatory, or data quality need for requiring two PT samples annually to certify laboratories under Chapter 45. By reducing the number of PTs by half, the financial burden on laboratories and DCLS could be reduced.	The proposed revision reduces the requirement for proficiency test studies to one study per year for each field of certification. See the economic analysis section for the average savings for the laboratories that results from this change.
UOSA, ACSA, Town of Luray	b. DCLS should consider reducing the on-site inspection frequency from every two years to every three or four years. This would result in a significant reduction in travel expenses for inspectors as well as reducing paperwork. By doing so, DCLS should be able to reduce the number of inspectors. There are no known reports that any wide-spread or significant issues or problems in laboratories occurred such that a reduction in audit frequency would compromise the program.	DCLS believes the on-site assessment frequency of once every two years is appropriate. The on-site assessment continues to be important as a time to educate laboratory staff and to review the certification requirements. The laboratories have commented that the on-site assessments have been helpful to maintain laboratory quality. This one-on-one time at the laboratory is critical for the laboratory's understanding of and meeting the requirements of the program.
UOSA	c. DCLS could partner with existing state-wide organizations with laboratory members (such as VA-AWWA/VWEA lab Practices Committee, Virginia Rural Water Association, and Virginia Association of Municipal Wastewater Agencies) to improve laboratory performance by developing training programs and other activities. By utilizing existing resources and collaborating more with the laboratory community, continuous improvement in overall laboratory operations could be realized without added costs to the agency, facilities and taxpayers.	DCLS has responded to every training request made to date and will continue to do so. DCLS has partnered with a number of the statewide laboratory organizations to provide information and education. Continuous improvement in laboratory operations is provided on a one-to-one basis by the program's assessors during the on-site assessment of each laboratory. Developing additional training programs would take more time than is available for a program already run on minimal resources. The laboratories are limited in resources as well and many cannot afford to send staff to training sessions.
UOSA, ACSA, Town of Luray	d. Will another round of small laboratories close after this increase in fees? Will moving regulatory testing from on-site laboratories (who have a vested interest in the quality of their data) to a commercial laboratory (that is more concerned with profits) really improve data quality?	This proposed action modifies and restructures fees. These revised fees charge less for laboratories performing fewer tests. This proposed action reduces the requirement for PT studies each year, thus reducing the cost of certification for all laboratories. Commercial laboratories also have a vested interest in the quality of their data.

		Otherwise they would not stay in business.
UOSA	e. DCLS should reconsider their exemption of laboratories as spelled out in 1VAC30-45-30 C and D. By removing the exemptions, the potential pool of paying laboratories would increase.	The exemption provided in 1VAC30-45 C is for labs run by citizen monitoring groups. DEQ sets standards for these labs in lieu of certification by DCLS. The exemption provided in 1VAC30-45 D allows DEQ to determine whether a lab performing research studies for DEQ must be certified by DCLS. This occurs if the data derived from analyses done by the lab would support DEQ standards or determine compliance. There would be no benefit by requiring these labs to become certified under 1VAC30-45 because this would increase the agency's workload and therefore increase the cost to the agency.
ACSA	One cost-cutting suggestion is to reduce staff since there are less labs to inspect than estimated.	The current staff is insufficient for the current workload. Current staff size (five FTEs) is less than half that projected under the initial budget for the program (12 FTEs). Because fees were insufficient the additional staff was not hired. These five FTEs currently support both the certification program for noncommercial laboratories and the accreditation program for commercial laboratories.
VAMWA, HRSD, ACSA	The commenters request that the Department develop a transparent process for revising the 1VAC30-45 fees. It is important for the Department to be forthcoming with information as to how it plans to address the realities of the diminished scope of the certification program, such as the Department's budget revisions, its proposal for adjusting program staffing and how it is addressing other program costs and expenses, before the Department increases any fees set forth in the regulation.	DCLS is at maximum capacity to carry out both environmental laboratory programs. As noted above, staff size is less than half that authorized for the program originally. The four assessors average 24 on-site assessments each year, most of that time as a lead assessor. On-site assessments take at least one-half day not including travel time. Some on-site assessments take several days to perform. The assessor must prepare in advance for the visit. The assessor also is responsible for monitoring the laboratory's PT performance and its maintenance of certification requirements. All state agencies are continuously required to address program expenses to ensure that only necessary expenses are covered by general funds or fees.
VAMWA, HRSD, ACSA	The commenters request that the Department provide for a phase-in period for any new fees. Such a period of time (ACSA: at least a one year notice) would allow the owners of laboratories subject to the regulation to make	The revised fees are proposed through the APA's regulatory process. This allows affected parties 60 days to comment on the fees and to offer

	any necessary budgetary adjustments.	alternatives. The regulatory process is lengthy. The proposed fees give laboratories notice of what the agency intends. Once the fees are proposed and public comments received, the rulemaking process typically takes 1.5-2 years to complete. DCLS believes this is sufficient notice of the change in fees.
ACSA	There should be a cap on future fee increases.	The governing statute requires the fees charged by the program to cover the cost of certifying and accrediting labs. The costs of the program will increase gradually due at a minimum to inflation. DCLS will assess the costs of the program on a regular basis and propose changes to the fees as necessary.
RULEMAKING PROCESS		
VAMWA, HRSD, ACSA	In keeping with the stakeholder informed process advanced by the 2009 Standard, and in order to provide for feedback through peer review during the development of amendments to the Regulation that achieve the Department's goals and provide meaningful flexibility and burden reductions, the commenters recommend that the Department form a Stakeholder Advisory Group.	The current regulations were developed with the assistance of a stakeholder advisory group. DCLS is mindful of the affected laboratories' concerns. The process to revise 1VAC30-45 does not involve a restructuring of the regulation but rather an opportunity to provide flexibility where possible, to revise the fees to make them more equitable as well as to better support the program, to eliminate the initial certification requirements, and to simplify the renewal process. DCLS believed it was unnecessary to reconvene an advisory group for these purposes. The affected laboratories will have 60 days to provide comments on the proposed revisions and to suggest any other changes they feel should be made to 1VAC30-45.
TOWN OF LURAY - ELIMINATE THE PROGRAM		
Town of Luray Wastewater Treatment Plant	The interests of the Commonwealth of Virginia would best be served by the elimination of 1VAC 30-45. This would relieve the state of all monetary shortfalls incurred by the certification of non-commercial laboratories. The program requiring certification of non-commercial laboratories has already done irreparable damage to small laboratories. Increasing fees would increase this damage. For small laboratories that farmed out their testing to commercial laboratories rather than go thru the ordeal of the certification process; timely results of in-house laboratory testing that could be used to improve operational efficiency are now gone. Most results from samples sent	Many noncommercial laboratories have provided feedback to DCLS telling the agency how beneficial the certification program is for their laboratory. These laboratories find the on-site assessment to be an educational experience that helps the laboratory improve its operation. DEQ has provided feedback to DCLS that the certification program provides a clear expectation of quality from the laboratories. The proposed fees have been restructured so that the labs pay in proportion to the type and amount of testing they are performing.

	to commercial labs are only of historical value whereas real time results can actually be used to impact the environment and operational efficiency in a positive manner. For operational reasons as well as the fact that our effluent is released into our own environment, affecting ourselves and our community, valid data is important to us. We understand that data fraud was one of the reasons for initiating the program to begin with. There are programs to determine whether data is corrupt or falsified. Perhaps the agency should run the environmental data received through such a data verification program. If commercial laboratories want to be certified so they can do business in other states, 1VAC 30-46 can be maintained and the cost of that program can be borne by the entities that profit by that certification. If commercial laboratories cannot, or will not provide all of the support for the program, perhaps 1VAC 30-46 should be abandoned as well.	The laboratories are certified only for the testing required by DEQ permits. This testing determines whether the permit holder is meeting the environmental limits set out in its permit. Certification is not required for the testing used by wastewater plants or other facilities to determine operational efficiency. If the validity of data is important, then a program to assess the procedures used by the laboratory to analyze samples and derive the data from these analyses should be as important to the commenter. Good quality control is critical to the production of valid data. While the law that authorized the certification program was passed in part because of some instances of fraud in Virginia, the program itself can only prevent data falsification if it can be detected. DCLS knows of no electronic means to do so. The program's purpose is to determine whether a laboratory is capable of producing quality data by assessing its quality system and reviewing the proficiency testing required under the program.

Family impact

Please assess the impact of this regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

It is not anticipated that the proposal will have a direct impact on families. There will be a positive indirect impact on families in that the proposal will protect public health and welfare.

Detail of changes

*Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please list separately: (1) all differences between the **pre**-emergency regulation and this proposed regulation; and 2) only changes made since the publication of the emergency regulation.*

Important Note: The 2009 TNI Standards revised or deleted requirements that had previously were in the 2003 NELAC Standards. DCLS is revising 1VAC30-46 to replace the 2003 NELAC Standards with the 2009 TNI Standards and incorporate these standards by reference. When requirements are relaxed in revised 1VAC30-46 because of the changes to the 2009 TNI Standards, DCLS makes the same change to any equivalent provisions in the revised 1VAC30-45 to ensure that the noncommercial laboratories are not meeting more stringent standards than the commercial laboratories. These changes will be noted below as based on a "*relaxed TNI standard*."

Current section number (1VAC30-45-)	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
Terminology changes			Throughout 1VAC30-45, revised the designation for the agency implementing the provisions of the chapter from "DGS-DCLS" to "DCLS". This change provides consistency within all the laboratory accreditation and certification regulations carried out by DCLS.
Terminology changes			Throughout 1VAC30-45, revised the following terms to update the regulation when it refers to the TNI standards: • "NELAP" or "NELAC" has become "TNI" • "accrediting authority" has become "accreditation body" • "corrective action report" has become "corrective action plan" • "analyte group" is deleted throughout
10		Reference to 1VAC30-46 in the purpose statement	Strikes sentence because it is extraneous to the regulation.
30 D		Title	Simplifies the title.
40		Sets out the definitions used in the chapter.	Revises the introductory material in section -40 to conform to the requirements of the Registrar of Regulations.
40, various definitions		"Assessor," "Field of certification," "Finding," "Holding time," "Primary accrediting authority," "Proficiency test sample," "Quality assurance," "Quality control," "Quality system," "Standard operating procedure," "Simple test procedures" "TCLP," and "U.S. Environmental Protection Agency."	Simplifies and updates these definitions
"		"Proficiency test field of testing" and "NELAC"	Replaces and updates definitions. "Field of proficiency testing or FoPT" replaces "Proficiency test field of testing." "The NELAC Institute or TNI" replaces "NELAC."
"		"Initial certification period" and "NELAP"	Deletes definitions because they are no longer in use

Current section number (1VAC30-45-)	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
"		"Client" or "customer" currently not defined	Adds definition to make clear who the client or customer is for noncommercial labs.
"		Definition of "environmental analysis"	Adds two types of testing to the list of exempt types of testing under the definition: (1) geochemical and permeability testing for solid waste compliance and (2) materials specification for air quality compliance when product certifications are provided in lieu of laboratory testing. These exemptions are currently provided under DCLS guidance and need to be added to the regulation.
"		"Virginia Environmental Laboratory Accreditation Program" or "VELAP"	Adds definition to provide a reference to the name of the certification program for all environmental laboratories
50 C		Describes the scope of certification or what the laboratory would be certified for.	Revises the language for syntax and to eliminate the use of "analyte groups."
60 B 3		Allows laboratories with noncontiguous physical locations to apply as an individual laboratory.	Deletes the provision. This revision was also made to proposed 1VAC30-46. The provision was not used during the initial certification period.
70 B		Sets out the process to apply initially for certification under this chapter.	Revises the language eliminating the deadlines used for the initial certification period. This period has passed; the environmental laboratories that were required to apply have done so. Replaces the language with a simple statement on what first-time applicants must do to apply.
70 C		Sets out the process for renewal of certification.	Revises the language eliminating the provisions that require certified laboratories to reapply for certification by filling out an application for renewal of certification every other year. Replaces this language with the current requirements that certified labs must meet to maintain certification in alternate years. Deleting the requirement for labs to fill out an application and for DCLS to process the renewal application eliminates work for both the labs and the agency, thereby reducing costs for both.
70 E		Specifies what modifications to certification can be made and how to apply	Deletes list of modification types and adds a general phrase that covers the types of modification. Change made to simplify provision.
70 F 1		Sets out a list of information and documents that should be included in an application for certification	Adds the phrase "but not be limited to" to indicate that other materials might be required in addition to the items listed in this section. The phrase is added for clarity. The application form available on the website may include items other than those on this list.
70 F 1 j		Requires name, title and telephone number of	Deletes the requirement for the title of the contact person to be included. The person's title is

Current section number (1VAC30-45-)	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
		laboratory contact person.	unnecessary. The contact person is often someone whose name is already required to be submitted with the application.
70 F 1 n		Requires the application to include a list of the test methods to be accredited.	Deletes the requirement because it is duplicative of the requirement above it for "fields of certification."
70 F 1 o (new n)		Part of the list of information required to apply for certification: PT studies requirement.	Deletes the requirement for "the three most recent" PT studies, substituting a requirement for "one successful unique" PT study. Directs the applicant to the specific requirements in Part II of the chapter.
70 F 1 q		Part of the list of information required to apply for certification: lab ID requirement.	Deletes the requirement for a lab identification number because it is unnecessary.
70 G 1		Requirements for determination by DCLS of the completeness of an application, including during the initial certification period	Deletes all references to the initial certification period because this period is over. Full implementation of the program has begun. Deletes references to renewal applications because DCLS has decided to drop the application process for renewing certification. The section applies only to new applications received following the effective date of the chapter.
70 G 4		Deadline for DCLS to make a completeness determination on an application	Deletes provision related to the initial certification period. Increases the time for DCLS to make a completeness determination from 60 to 90 days, the same used during the initial certification period. The agency's experience with the program indicates that this time period is realistic.
70 G 5		Requirements for laboratories submitting additional application information	Deletes the requirement for DCLS to return an incomplete application if laboratory does not provide additional information in 90 days. Indicates that DCLS may inform the laboratory that the application cannot be processed. The agency's experience with the program indicates that in this case returning an application package is unnecessary.
70 H 1 c		Lists the conditions for granting certification on an interim basis.	Deletes references to initial applications because the initial application period is over. Deletes references to renewal of certification because DCLS has dropped the application process for renewal. Increases the time allowed for DCLS to schedule an on-site assessment from 90 to 120 days, providing a realistic time period for DCLS to schedule on-site assessments along with its other certification responsibilities.
70 I 2		Sets out an option for an alternative third-party on-site assessment.	The provision is deleted because it is unnecessary. The provision was included in the current regulation in case laboratories wanted their on-site assessment done quickly during the initial certification period. No

Current section number (1VAC30-45-)	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			laboratory took advantage of this provision.
70 J 2		Specifies the timing and conditions for DCLS to complete action on an application for certification during and after the initial certification period.	The provision concerning the initial certification period is deleted because DCLS has completed the initial certification process for labs. DCLS is deleting the requirement to complete action on a new application within nine months of the date DCLS deems the application to be complete. This deadline was self-imposed and can create unnecessary scheduling difficulties for the agency.
70 K 1		Specifies how the agency shall issue a certificate.	The provision is revised for syntax.
70 K 2		Describes who signs the certificate of certification.	Adds that a "designee" of the DCLS director as well as the director may sign the certificate of certification.
70 K 4		Specifies the term of certification.	Revises the term of the certification from two years to one year.
70 M 1		Requires a laboratory to wait six months before reapplying when DCLS has denied its application.	This provision is deleted. The deletion has been proposed in the revised 1VAC30-46 standards. This deletion is based on a relaxed TNI standard.
90 B 2 a		When applying for a change to its scope of certification, a lab must submit a letter.	The provision is revised to require a written request rather than a letter to make the requirement more flexible.
	90 B 6		This provision adds the requirement already stated in 1VAC30-45-130 F 1 that a laboratory must pay a fee to receive a modification to its scope of certification. The addition provides complete information to the applicant within section 90.
90 C 1		A lab must notify DCLS when the lab's ownership or location changes. The provision currently states that these requirements pertain only to fixed-based labs.	Revises the provision to clarify that the requirement on changing location pertains only to fixed-based labs and not to mobile labs. Revises the provision to ensure that mobile labs know that they do have to notify DCLS when their ownership changes. The current provision indicates otherwise and needs to be corrected.
90 C 5		Requires new owners of a certified laboratory to assure historical traceability of the laboratory certification numbers.	This provision is deleted. The deletion has been proposed in the revised 1VAC30-46 standards. This change is based on a relaxed TNI standard.
90 C 6 (new C 5)		Requires a new lab owner to keep certain records from the previous owner.	Revises language of the provision to clarify which of the previous owner's records a new owner must keep. These are the records "pertaining to certification" that must be kept for a minimum of three years.
90 D		Sets out the process for a lab to voluntarily withdraw	Deletes the deadline for a lab to withdraw in writing no later than 30 calendar days before the end of the lab's

Current section number (1VAC30-45-)	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
		from certification.	certification term. Deletes the deadline for DCLS to send the lab a written notice within 30 days of receiving the lab's withdrawal notice. These 30-day requirements are not necessary.
	95		Creates 1VAC30-45-95 on suspension of certification. DCLS currently provides for suspension through guidance and is adding these provisions to 1VAC30-45. DCLS can suspend certification prior to withdrawing certification. Suspension is beneficial to laboratories. The process allows the laboratory faced with decertification a chance to correct its deficiencies. Suspension is allowed for five specific reasons listed in subsection B. DCLS will use the procedures set out in subsection C. Prior to suspension, DCLS may allow a lab additional time to correct its deficiencies. This is especially important when a laboratory has not succeeded in its proficiency testing studies. Subsection D sets out the responsibilities for the agency and the laboratory once DCLS suspends a lab. This includes the consequences when a laboratory does not correct its deficiencies within the six-month suspension period.
100 B 2		Specifies two of the reasons for decertification	Subdivision 100 B 2 is revised to simplify the language of the requirement.
	100 B 9 and B 10	1VAC30-45-100 B lists the reasons why DCLS may withdraw certification from an environmental laboratory.	Adds 1VAC30-45-100 B 9 and B 10. These two reasons are not new and found elsewhere for withdrawing certification.
100 D		Section title	Revised to use the term "decertification."
100 D 2		States that DCLS shall issue an addendum to an certification certificate when it withdraws certification in part.	Revises the provision to state that DCLS shall issue a revised certificate rather than an addendum to the original certificate. This change reflects current DCLS practice.
	100 D 3		Adds a provision to state that the environmental laboratory shall not continue to analyze samples or report analyses for the fields of certification for which DCLS has withdrawn certification. This provision is implied by the fact that DCLS has withdrawn certification. The addition of the provision ensures clarity on this point.
100 E		States that a laboratory that has corrected the reason for certification may reapply for certification.	Adds a phrase to indicate the application would be made under 1VAC30-45-70.

Current section number (1VAC30-45-)	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
110		Sets out the procedures DCLS uses to deny or withdraw certification.	1. Revises the entire section deleting references and discussion in subsection A and entirely deleting subsections B and C pertaining to informal fact finding and informal discussions prior to an informal fact finding. Adds a new subdivision B that provides a laboratory may appeal a final decision to deny or withdraw pursuant to the Administrative Process Act (APA). 2. Rewrites subsection A, adding subdivisions 2 - 6. This subsection specifies how DCLS will notify a laboratory when the agency determines it has cause to deny or to decertify and what DCLS shall include in its notice. Subsection A also specifies the action a laboratory must take if it believes DCLS is incorrect in its determination. 3. DCLS is revising this section to simplify and make clear the actions that must take place when the agency believes it should deny or withdraw certification. The change to the appeals language, deleting the current subsections B and C and adding a new B properly references the APA rather than describing some of its provisions.
130		Sets out the provisions on fees.	The fee provisions are revised extensively. 1. The fees are charged annually instead of every two years. 2. The maximum fee is omitted. The maximum fee is currently quite low and does not reflect the cost of certification. 3. The simple test procedure (STP) laboratories will be charged an annual flat fee of $600. This amount is the current maximum fee which most STP labs pay every two years. The fee of $600 has not covered the cost of the on-site assessment of most STP laboratories much less the review and oversight of proficiency testing for these laboratories. 4. The fees for general environmental laboratories will still be structured using base fees and test category fees. These fee concepts have been expanded. Base fees as well as the test category fees are now differentiated by the number of test methods for which the laboratory is certified. The base and test category fees are revised to account for the number of field of certification matrices for which the laboratory is certified. These expanded base fees and test category fees are set out in two tables. Using this approach better reflects the true cost of certifying these laboratories. The more testing a laboratory does, the more costly it is to certify the laboratory. 5. The minimum and maximum fees for review of a

Current section number (1VAC30-45-)	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			transfer of ownership in subdivision F 2 are deleted. The actual cost of the review will be charged. 6. The additional fees described for a request to consider multiple noncontiguous laboratory sites as one site are deleted because the provision in 1VAC30-45-60 B 3 is being deleted (see above). 7. The additional fees covering applications for exemption or petitions for variance are revised to cover the cost of the review process the agency must undertake in these circumstances.
300 A		Sets out the frequency of on-site assessments	Revises the provision to indicate that on-site assessments for certified labs shall occur every two years plus or minus six months starting from the date of the previous assessment. The revision provides a clearer explanation of when on-site assessments occur.
350 B		Provisions describe what happens if on-site assessment personnel are denied access to the laboratory	Adds subdivision B 2 to address any overt antagonism or verbal or physical threats toward on-site assessors. Any hostility of this nature will be treated as a refusal to admit the assessors to the laboratory. This will result in denial of laboratory certification or decertification.
400 C 3		States that DCLS will provide the lab with the checklist used for on-site assessment with the final report.	The provision is deleted. The checklists used by the assessment personnel are already available on the DCLS website.
500		Sets out the requirements for participating in proficiency testing studies	Requires laboratories to successfully participate in one rather than two PT studies annually. Updates the reference to proficiency test provider to those providers approved by TNI. Deletes the specific requirements for environmental toxicology because current noncommercial laboratories do not perform this specialized type of testing. Updates and makes current the provisions on reporting results.
510 A		Sets out when a lab should return its PT results and the time a lab has to analyze the PT and report the results.	Requires the lab to report analytical results by the closing date of the PT study instead of within 45 days of the scheduled shipment date of the study.
520 B - G	520 B-D	Sets out the requirements for a lab to meet initial and continuing certification requirements for proficiency testing	Reduces the requirement for PTs to one instead of two PT studies per year for each field of certification (FoC). Revises time allowed for labs to perform PTs for initial certification requiring the most recent PT to be done no more than 12 months prior to the application date. For a laboratory performing supplemental testing, requires at least 15 days between the analysis dates of successive PT samples for the same FoPT. Sets out new procedures for labs to follow when the PT study result is not acceptable. These procedures are a result of the

Current section number (1VAC30-45-)	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			reduction in the requirement for PT studies to one PT each year for each FoC. Simplifies the procedure to withdraw from PT studies.
530		Special requirements for aquatic toxicity PTs.	Deletes these requirements. Current noncommercial laboratories do not perform these specialized tests.
	600 C	Requirement for personnel to know the quality system documentation and to implement its policies and procedures	Adds language to clearly require that laboratory personnel be made aware of, understand, and implement the quality system documentation including its policies and procedures in their work. While implied this requirement had not previously been stated in the regulation.
610 B and C	610 C	The elements of a quality manual are specified.	The list containing the elements of a quality manual is revised and placed into two sections. The first are required items to be included in the manual. The second are items that may either be included in the manual or referenced in the manual. This change is based on relaxed TNI standards. In addition, a new element for the quality manual is added: a policy addressing the use of unique electronic signatures, but only where applicable.
720 E		Sets out the records that must be kept for each major item of equipment.	Deletes the requirement to keep records of the date received and date placed in service and the requirement to record if available the condition of the equipment when received. This change is based on a relaxed TNI standard.
730 C 2		Sets out requirements for laboratory methods manuals.	Deletes references to laboratory methods manuals and substitutes standard operating procedures (SOPs). Makes minor revisions for clarity. This change is based on a relaxed TNI standard.
730 D1		Sets out requirements for the use of test methods.	Adds a requirement that laboratories shall use the latest valid edition of a test method unless it is not appropriate to do so. This new requirement is based on a recent EPA update to its test method requirements and list at 40 CFR Part 136.
730 E		Sets out requirements for demonstration of capability (DOC)	Adds "initial" to subdivision 1 and "ongoing" to subdivision 2 to designate the difference between the two requirements. In subdivision 3, substitutes "at least one year prior to application" for "before July 1999" as the grandfather date when an initial DOC is not required. In subdivision 5, specifies that a change in a test method also means the addition of an analyte to a certified test method (FoC). Deletes the work cell requirements in subdivision 6.
730 G		Provides the certification statement required for the DOC.	Deletes the requirement for the certification statement to be retained in the analyst's personnel file. This change is based on a relaxed TNI standard.

Current section number (1VAC30-45-)	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
730 J 2		Sets out requirements for documentation and labeling of standards and reagents.	The documented procedures required for original containers are revised to label the container with an expiration date only if the date is provided by the manufacturer. This change is based on a relaxed TNI standard.
740 D 1 d		Sets out standards for support equipment used in laboratory operations.	Clarifies language condition used for checking support equipment. "On each day the equipment is used" is substituted for "prior to use on each working day." This change is based on a TNI standard that clarifies the requirement.
750 B		States that 1VAC30-45-760 through 1VAC30-45-829 set out the essential quality control requirements for specific types of testing.	Currently certified noncommercial laboratories do not perform toxicity, radiochemical, or asbestos testing. Those specific sections are deleted in this proposal (see below). The revision here substitutes the 2009 TNI Standards requirements for any noncommercial laboratory that wishes to become certified for these types of testing.
760 A 1		Requires labs to follow quality control protocols specified by the lab's method manual.	Substitutes "method SOPs" for "method manual." This change is based on a TNI standard that clarifies the requirement. Laboratories must have methods SOPs for their test methods but these SOPs do not have to be gathered into a methods manual.
770 B 3 b and D 3 b(2)		Sets out positive controls for chemical testing	Corrects errors. The provisions currently indicate for methods that include 11-20 targets, components should be spiked "at least 10% or 80%, whichever is greater." The provision is corrected to read "at least 10 or 80%, whichever is greater."
771 B 3		Sets out limit of detection for chemical testing	Deletes the requirement for established procedures to relate limit of detection with limit of quantitation. This change is based on a relaxed TNI standard.
775 B		Chemical testing. Requires glassware to be cleaned to meet the sensitivity of the test method.	Deletes the requirement. The requirement is not needed because method blanks verify cleanliness. This change is based on a relaxed TNI standard.
780 through 789		Sets out quality control requirements for toxicity testing.	Deletes these requirements because current noncommercial laboratories do not perform this type of testing. If any noncommercial laboratory wants to become certified for toxicity testing, the lab will need to meet the 2009 TNI standards for toxicity testing. See revision to 1VAC30-45-750 B.
791 A 2		Sets out sterility checks and balances for the filtration technique for microbiological testing.	Revises procedure to require one beginning and one ending sterility check for each filtration series rather than each laboratory sterilized filtration unit used in the filtration series. This change is based on a relaxed TNI standard.

Current section number (1VAC30-45-)	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
791 A 4		Sets out requirements for sterility checks on sample containers for microbiological testing.	Requires labs to perform sterility checks on sample containers using nonselective growth media. The current provision is not clear with respect to what a lab should use to perform the sterility check for purchased, presterilized containers.
796 F		Sets out requirements for procedures for media, solutions and reagents for microbiological testing.	Deletes the requirement to document the amount of the media received when the lab purchases it pre-prepared and ready to use. This change is based on a relaxed TNI standard.
798 B 2 d		Sets out requirements for autoclave maintenance for microbiological testing.	Relaxes the requirement for annual maintenance of autoclaves if a laboratory can demonstrate regular monitoring of pressure and annual calibration of the maximum registering thermometer.
798 B 6 a		Sets out requirements for incubators and water baths for microbiological testing.	Revises the provision on temperature distribution in incubators and water baths to require only that the uniformity (and not the stability) of temperature be established. Eliminates need to determine the time required to reestablish equilibrium conditions. This change is based on a relaxed TNI standard.
800 through 808		Sets out quality control requirements for radiochemical testing.	Deletes these requirements because current noncommercial laboratories do not perform this type of testing. If any noncommercial laboratory wants to become certified for radiochemical testing, the lab will need to meet the 2009 TNI standards for radiochemical testing. See revision to 1VAC30-45-750 B.
811 B		Requirements for laboratory control samples for air testing.	Deletes the requirement to notify the client prior to the start of analysis if a calibration solution must be used for the laboratory control sample. This change is based on a relaxed TNI standard.
820 through 829		Sets out quality control requirements for asbestos testing.	Deletes these requirements because current noncommercial laboratories do not perform this type of testing. If any noncommercial laboratory wants to become certified for asbestos testing, the lab will need to meet the 2009 TNI standards for asbestos testing. See revision to 1VAC30-45-750 B.
850 3 b		Sets out thermal preservation requirements for samples.	Revises the requirements. Thermal preservation in the field is not required if the lab receives the sample and either begins the analysis or refrigerates the sample within 15 minutes of collection. This change is based on a relaxed TNI standard.