Virginia Regulatory Town Hall

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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	1VAC30-46
Regulation title	Accreditation for Commercial Environmental Laboratories
Action title	Revise regulation to meet 2009 TNI Standards and to update procedural and fee requirements
Date this document prepared	June 29, 2012

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

In a short paragraph, please summarize all substantive provisions of new regulations or changes to existing regulations that are being proposed in this regulatory action.

1VAC30-46 identifies the requirements used by the Division of Consolidated Laboratory Services (DCLS) to accredit commercial 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. An existing requirement is the use of the 2003 NELAC Institute (TNI) Standards to accredit these laboratories. These standards were updated by TNI in 2009. The proposed action will replace the 2003 NELAC Standards with the 2009 TNI Standards, which is the most current version of the standards.

The proposed action revises the process used to accredit laboratories, eliminating requirements relating to the initial accreditation period and streamlining the process to renew accreditation which reduces the cost of accreditation for both the agency and the laboratories.

The proposed action restructures the fee provisions in 1VAC30-46-150 which increases the fees charged to laboratories under the program. The current fees are insufficient to support the program. The proposed increase in fees better recovers the cost of accreditation over the full range of laboratory work performed by the accredited laboratories.

The proposed action adds provisions on suspension of accreditation. Suspension provides an opportunity for a laboratory to correct deficiencies before having its accreditation withdrawn.

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.

"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 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 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 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 (DCLS) of the Department of General Services (DGS).

Purpose

Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal, the environmental benefits, and the problems the proposal is intended to solve.

Environmental laboratories are required by §2.2-1105 of the *Code of Virginia* to be accredited 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).

DCLS accredits commercial laboratories (1VAC30-46) using the national environmental laboratory accreditation standards developed by the NELAC Institute (TNI). The TNI program standards are the only national standards developed for the accreditation of environmental laboratories. TNI periodically revises their standards to improve them and to provide the most up-to-date information available for the accreditation of environmental laboratories. DCLS currently accredits commercial environmental laboratories using the 2003 NELAC Standards. TNI replaced these standards with the 2009 and published the new standards in July 2010. To maintain its status as a TNI accreditation body and to continue to accredit commercial environmental laboratories under the TNI program, DCLS must incorporate the 2009 TNI Standards into 1VAC30-46.

Accrediting commercial environmental laboratories to a single set of standards has several benefits. Accreditation promotes continuous quality improvement. Accreditation gives confidence that work is performed properly and to a known standard. Under the accreditation 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, water, and waste pollutants 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. Accrediting 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.

Failure to update the regulation to the TNI 2009 standard may jeopardize the Virginia commercial laboratories' accreditation. In order to maintain accreditation in TNI, laboratories must adhere to the current standard. TNI-accredited Virginia commercial laboratories can easily obtain secondary accreditation in other states that utilize the TNI program to accredit laboratories. Failure to update the regulation to the TNI 2009 standard will jeopardize this commercial option for these laboratories.

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 accredited 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 accredits.

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 accredited 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 revised fee provisions also include a provision to allow DCLS to adjust the fees annually for changes 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 accredited laboratories. This results in fees that do not mirror the scope of the laboratory testing. The work performed by DCLS to accredit 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 accrediting laboratories since January 2009. The proposed action revises the procedures used to accredit 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 accreditation. Suspension is a benefit to the laboratory that may otherwise have its accreditation withdrawn.

Substance

Please briefly identify and explain new substantive provisions (for new regulations), substantive changes to existing sections or both where appropriate. (More detail about all provisions or changes is requested in the "Detail of changes" section.)

The proposed action requires laboratories accredited under this chapter to meet the 2009 TNI Standards instead of the 2003 NELAC Standards. The TNI 2009 standards are incorporated by reference into Part II of the regulation. Provisions from the 2003 NELAC standards that are currently included in Part I of 1VAC30-46 (General Provisions) have been revised or dropped entirely to meet the 2009 TNI Standards. This includes the definitions in 1VAC30-46-40.

The proposed action revises the definition of "environmental analysis" to include two exceptions that DCLS has previously made through guidance in consultation with DEQ.

The proposed action deletes the procedures pertinent to the initial accreditation period. The initial accreditation period was established in 1VAC30-46 as the period of January 1, 2009, to January 1, 2012. During this time, DCLS accredited environmental laboratories for the first time. Because DCLS has completed the initial accreditation of commercial environmental laboratories, these provisions no longer apply.

The proposed action deletes the renewal procedure that required laboratories to file an application for renewal every other year. Renewal can be efficiently done without an additional application process.

The proposed action adds 1VAC30-46-95. This section sets out the procedures used to suspend laboratory accreditation in part or in total. Suspension provides the laboratory an opportunity to correct a problem that would ordinarily cause the agency to withdraw accreditation from the laboratory. DCLS also may provide extra time under these provisions for a lab to correct deficiencies before suspension occurs.

The proposed action revises the procedures to deny or withdraw accreditation. The notification procedures are revised to be more explicit. The proposed action revises the provisions on the appeal process. The provisions are simplified, referring only to the Administrative Process Act.

The proposed action replaces the current fee system with one that reflects the current costs of accrediting commercial environmental laboratories. The revised fees account for inflation since 2004. Revised 1VAC30-46-150 charges fees that represent more closely the cost of accrediting each laboratory. These fees take into account the number of test methods and the number of matrices for which the laboratory

seeks or maintains accreditation. The agency accreditation workload is directly proportional to the number of methods and matrices to be accredited.

The proposed action adds provisions on applications for primary accreditation from out-of-state laboratories. The current regulation does not address these applications adequately.

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 the regulatory action poses no disadvantages to the public or the Commonwealth, please indicate.

There are two primary advantages to the public associated with this proposed action. The first advantage to the public is the maintenance of up-to-date standards governing the accreditation of commercial environmental laboratories. The 2009 TNI Standards are the most current version of these national accreditation standards for environmental laboratories and improve the 2003 NELAC Standards currently used by DCLS to accredit these laboratories. Accrediting environmental laboratories benefits the public because it ensures that the laboratories can produce environmental data of known quality and defensibility. DEQ uses these environmental data to determine compliance with environmental standards that protect the public health and welfare. The second advantage is for DEQ permit holders who contract with the commercial laboratories to analyze environmental samples. The permit holders are assured of the quality of the laboratories' analyses. There are no disadvantages to the public.

There are three primary reasons this action is necessary for DCLS and the Commonwealth. First TNI requires accreditation bodies to use the latest TNI standards to accredit environmental laboratories. This proposed action is necessary for DCLS to meet that requirement. Second the revisions to 1VAC30-46 reduce the program's administrative requirements and make it more efficient. Third DCLS will be able to charge fees that cover the cost of the accreditation program. There are no disadvantages to the agency or Commonwealth.

There are also advantages for the environmental laboratories accredited under 1VAC30-46. By meeting the 2009 TNI Standards, the laboratories will continue to be recognized as TNI-accredited laboratories. This enables the Virginia commercial laboratories to quickly obtain secondary accreditation from other TNI-approved accreditation bodies so that they can provide laboratory services as accredited laboratories in these other states.

The primary disadvantage of the proposed action for the affected laboratories is the increase in fees. The fee structure is revised to more closely charge for the actual cost to the agency. The fees are increased generally and will be charged annually rather than every other year.

Requirements more restrictive than federal

Please identify and describe any requirements of the proposal, which are more restrictive than applicable federal requirements. Include a rationale 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 four local government laboratories currently accredited under the standards of 1VAC30-46. None is disproportionately affected by the revisions to 1VAC30-46.

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.

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 requirements creates the anticipated economic impact.

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source, 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 both commercial laboratories (1VAC30-46) and noncommercial laboratories (1VAC30-45). 1VAC30-45 is being revised in a separate rulemaking. The details provided below pertain only to the laboratories accredited under 1VAC30-46 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.

	Four local government laboratories are currently accredited under 1VAC30-46. The projected increase in fees for these laboratories is 23, 27, 43, and 123 percent. Approximately 18-20 percent of the 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.
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 1VAC30-46 will affect the environmental laboratories currently accredited under the regulation.
Agency's best estimate of the number of such 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 (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	The revisions affect 118 laboratories currently accredited under 1VAC30-46 (as of 6/23/12). Four are local government laboratories, one is a federal laboratory, three are laboratories owned by industrial companies, and 110 are commercial laboratories. The three industrial labs are part of large industrial companies. Sixty-five (65) of the 110 commercial labs (59%) can be classified as small businesses. Forty-five commercial labs (41%) are considerably larger and are representative of the largest environmental laboratories in the U.S, including 12 of the top 20 revenue producing commercial environmental labs in the U.S. DCLS accredits multiple locations of these laboratories. Eighty-one (81) labs (69%) are located out-of-state. Of these, 32 are small businesses, one is an industrial lab, and the remaining 48 are large labs. Thirty-seven (37) labs (31%) are located in Virginia. Of these, 25 are small businesses, five are government labs, two are industrial company labs, and the remaining five are large labs. Three of these are individual locations for large laboratory concerns.
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. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. 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 1VAC30-46 laboratories are the increase in fees. The projected increase in fees for currently accredited laboratories range as follows: 1. Forty percent (40%) will see a fee increase of 7-59%. Most are Virginia labs. 2. Thirty-seven percent (37%) will see a fee increase of 60-98%. All are located out-of-state with one exception. 3. Thirty-one percent (31%) will see a fee increase of 100-194%. All are located out-of-state with the exception of six Virginia labs. 4. Three percent (3%) will see a fee increase of over 200%. These are out-of-state labs. The 2009 TNI standards list additional reasons to notify DCLS if a laboratory has changes to its operation. A laboratory however would only be responsible to provide these notifications infrequently. The cost

	associated with this change should be minimal. The proposed action reduces requirements for renewal of accreditation thus reducing the cost for all accredited laboratories.
Beneficial impact the regulation is designed to produce.	The revisions to the regulation protect public health and welfare by ensuring that accredited environmental laboratories meet the latest national 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. 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, or two years from the time the revised regulation is estimated to be proposed. DCLS reviewed the costs of initially accrediting a select number of laboratories. DCLS also looked at the cost to the agency of monitoring the accredited 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 accredited 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 accreditation matrices under which the methods would be performed. This approach results in revised fees that better reflect the cost of accrediting and monitoring the individual accredited laboratories. Three examples follow for comparison.

Example A: A Virginia laboratory performing a total of 19 test methods on nonpotable water in five test categories will see a fee increase of 27%.

Example B: An out-of-state laboratory performing a total of 30 methods on nonpotable water and solid and chemical materials in four test categories will see a fee increase of 65%.

Example C: An out-of-state laboratory performing a total of 124 methods on nonpotable water and solid and chemical materials in six test categories will see a fee increase of 96%.

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 updating the standards used to accredit environmental laboratories. The first is to revise the regulation to replace the 2003 NELAC Standards with the 2009 TNI Standards. The second is to retain the 2003 NELAC Standards to accredit laboratories. The agency believes the first alternative is the appropriate approach. This approach allows DCLS to take advantage of the improvements made to the national standards in 2009. DCLS would also retain its status as a TNI accreditation body. This enables DCLS to work as a partner with other TNI accreditation bodies to improve the quality of environmental laboratories. This approach benefits the laboratories. They will continue to meet the latest TNI standards and therefore continue to be accredited laboratories under the

TNI program. This enables these commercial laboratories to easily obtain secondary accreditation in other states with TNI programs.

Two alternatives pertain to the general revision of 1VAC30-46. The first is to revise the regulation based on the experience DCLS gained while accrediting laboratories during the initial accreditation 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 accrediting laboratories in the initial phase of the program. The proposed action for example streamlines the procedures used to accredit laboratories and to maintain accreditation 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 1VAC30-46. 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 accrediting 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.

Regulatory flexibility analysis

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 commercial environmental laboratories including small businesses. All these laboratories should meet the same accreditation 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 revised regulation does provide streamlined application and renewal requirements for all affected laboratories. This should lessen the impact on small business laboratories. The 2009 TNI Standards that will be used to accredit laboratories under this proposed action on balance do not increase laboratory requirements over the 2003 NELAC Standards.

The revised fee structure set out in this proposed action provides for lower fees for laboratories performing fewer test methods on one or two matrices. Many small business laboratories can be described in this way. Any affected laboratory should pay a fee that reflects the scope of its accreditation, i.e. the number of test methods performed and the field of accreditation matrices on which the test methods are performed.

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
Laboratory Association of Virginia (LAVA), Universal Laboratories, Coastal Bioanalysts, and Air, Water & Soil Laboratories	Increases in fees present a challenge for small businesses operating in challenging economic conditions. Increases in fees should only be considered if the benefit to all parties justifies such increases.	Commercial laboratories that meet the 2009 TNI standards have a marketing advantage over commercial labs that are not so accredited. Meeting these standards ensures that the accredited laboratories have the ability to produce environmental test data of known quality and defensibility for the levels of pollutants in environmental samples. This is beneficial to Virginians because the quality of their environment and ultimately their public health is protected.
LAVA, Universal Laboratories, Coastal Bioanalysts, and Air, Water & Soil Laboratories	LAVA asserts that DCLS has stated that the increases in fees are necessary to implement the 2009 TNI standards over the 2003 NELAC standards.	LAVA misread the NOIRA on this point. The NOIRA states the following: "The proposed action will revise the fees charged to laboratories under the program. The current fees are insufficient to support the program because fewer laboratories applied for accreditation than originally anticipated." The increase in fees in needed because fewer laboratories applied than originally estimated.
LAVA, Universal Laboratories, Coastal Bioanalysts, and Air, Water & Soil Laboratories	LAVA members agree that the program needs to be self-funding. They expect fee increases. Not knowing the extent of the fee increases makes it difficult to comment.	The purpose of the NOIRA is to provide general notice of the intended revisions to a current regulation. DCLS did not have its fee proposal available when the NOIRA was published.
LAVA, Universal Laboratories, Coastal Bioanalysts, and Air, Water & Soil Laboratories	LAVA would like the following information to be provided: total budget for the program, the total spent on the Chapter 45 labs and the total spent on the Chapter 46 labs.	See the economic impact section of this document.
LAVA, Universal Laboratories, Coastal Bioanalysts, and Air, Water & Soil Laboratories	LAVA suggests making the reciprocity fees the same for out-of-state labs with additional fees for out-of-state audits.	The fees for laboratories obtaining secondary accreditation are the same as for those obtaining primary accreditation under the current regulation and will remain so under the revised regulation.
LAVA, Universal Laboratories, Coastal Bioanalysts, and Air, Water & Soil Laboratories	LAVA would like protection from future increases such as a fixed rate increase.	The proposed regulation provides that the fees will rise with the CPI-Urban inflation factor once the revised regulation becomes effective. DCLS agrees that this approach will benefit both the agency and

		the laboratories.
LAVA, Universal Laboratories, Coastal Bioanalysts, and Air, Water & Soil Laboratories	If third party auditors are used, LAVA would like protection against the cost of such auditors which can cost $12-15 K per year for larger labs.	DCLS has proposed deleting the provision that allows a laboratory the option to use third-party auditors. See the discussion on section 1VAC30-46-70 I 2 in the "Detail of Changes" below.
LAVA, Universal Laboratories, Coastal Bioanalysts, and Air, Water & Soil Laboratories	LAVA encourages DCLS to evenly share the burden of accreditation costs among all accredited and certified laboratories.	DCLS has assessed the costs of certifying and accrediting a small sample of laboratories. The revised fees are based on these costs.
Coastal Bioanalysts	The owner of Coastal Bioanalysts is concerned that the Chapter 46 labs will bear an inequitable portion of the increased costs of running the program.	See the response above.
Hampton Roads Sanitation District (HRSD)	HRSD supports updating the VELAP program to the 2009 TNI standards from the 2003 NELAC standards.	DCLS appreciates HRSD's support.
HRSD	HRSD supports the re-evaluation and increases in fees to ensure the VELAP is funded, with comments (a) through (c) as follows.	DCLS appreciates HRSD's support.
HRSD	a. Continue to structure the fees as they are structured currently, including a base fee and a maximum fee.	The fee revisions include base fees but no maximum fee. The use of a maximum fee contributed to insufficient funding for the agency and is being eliminated.
HRSD	b. Provide at least one year notice of any fee increases to allow labs to make adequate budgetary and pricing adjustments.	The revised fee provisions set up a yearly adjustment to fees based on the CPI-Urban inflation factor. The laboratories will know the percentage increase at the same time that DCLS does.
HRSD	c. Set forth a fee structure for charges associated with scope of accreditation expansion.	DCLS is continuing to charge for applications for scope of accreditation.
HRSD	HRSD supports removal of initial accreditation period language and streamlining of the application process.	DCLS appreciates HRSD's support.
HRSD	HRSD requests DCLS consider appointing a Stakeholder Advisory Group to provide opportunities for stakeholders to provide feedback through peer review relating to proposed changes to 1VAC30-46.	The Administrative Process Act provides a 60-day public comment period once the proposed regulation is published. DCLS believes this public comment period will be adequate for all stakeholders.
Unidentified commenter - Chapter 46 laboratory	The commenter provides brief comments on his concern about the increase in fees for commercial environmental laboratories.	Please see the previous comments and responses pertinent to increased fees and concerns from the commercial laboratories.

Family impact

Please assess the impact of the proposed 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. 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.*

Current section number (1VAC30-46-)	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
Terminology changes			Throughout 1VAC30-46, 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 1VAC30-46, revised the following terms to meet the 2009 standards: • "NELAP" or "NELAC" has become "TNI" • "accrediting authority" has become "accreditation body" • "corrective action report" has become "corrective action plan" • "technical director" has become "technical manager" • "reciprocal" has become "secondary" when referring to labs accredited by other TNI accreditation bodies • "analyte group" is deleted throughout

Current section number (1VAC30-46-)	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
Changes to references			Throughout 1VAC30-46, the references to Part II are revised to reflect the revisions to Part II where the 2009 TNI standards have been substituted for the 2003 NELAC standards.
10		Purpose statement on the standards used to accredit laboratories	Moves statement on standards to new section -15. Deletes statements related to out-of-state labs and 1VAC30-45 because they are unnecessary.
	15		Adds section on the transition from the 2003 NELAC standards to the 2009 TNI standards. Sets date for DCLS to begin requiring labs to meet the 2009 standards.
30 B		Sets out the requirements and deadlines for DCLS to become accredited under NELAP and to become an accreditation body under NELAP.	Deletes the requirements because DCLS already has met the standards to become accredited and has been designated an accreditation body under NELAP and TNI.
	30 B		Requires Virginia's commercial environmental labs to obtain primary accreditation under the requirements of this chapter. States that DCLS will not offer primary accreditation to environmental labs located in states offering TNI accreditation. While not stated in the TNI standards, this policy is carried out by the other TNI accreditation bodies.
30 C		Allows any environmental laboratory to apply for accreditation under 1VAC30-46.	Adds the word "noncommercial" to the provision so that the intent of the provision is clear.
30 D		Allows a laboratory performing both drinking water and environmental testing to obtain accreditation for both under this chapter.	Revises the language for clarity. EPA allows drinking water laboratories to obtain certification under the TNI standards as an alternative to being certified under the national drinking water standards (1VAC30-40).
40		Sets out the definitions used in the chapter. Many of these are from the 2003 NELAC standards and glossary.	Revises definitions from the 2003 NELAC standards to conform to those in the 2009 TNI Standards. Revises the introductory material in section -40 to conform to the requirements of the Registrar of Regulations. The definition of "quality system matrix" is revised to alphabetize the list of matrices. No other changes were made to this definition.
40		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)

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			materials specification for air quality compliance when product certifications are provided in lieu of laboratory testing. These exemptions are currently provided under DCLS/DEQ guidance and need to be added to the regulation. In a separate exempt rulemaking, DCLS will also add another exemption to this list. The 2012 General Assembly added a new subsection G to §2.2-1105, the statute governing this regulation. Subsection G provides that "testing using protocols pursuant to §10.1-104.2 to determine soil fertility, animal manure nutrient content, or plant tissue nutrient uptake for the purposes of nutrient management" is not applicable under VELAP.
60 B 3		Allows laboratories with noncontiguous physical locations to apply as an individual laboratory.	Deletes the provision. The provision was included in the 2003 NELAC standards but omitted from the 2009 TNI standards. None of the TNI accreditation bodies have implemented this provision from the 2003 standards.
70 B		Sets out the process to apply initially for accreditation under this chapter.	Revises the language eliminating the deadlines used for the initial accreditation 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 accreditation.	Revises the language eliminating the provisions that require accredited laboratories to reapply for accreditation by filling out an application for renewal of accreditation every other year. Replaces this language with the current requirements that accredited labs must meet to maintain accreditation 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 accreditation 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 accreditation	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 laboratory contact person.	Deletes the requirement for the title of the contact person to be included. The person's title is unnecessary. The contact person is often someone whose name is already required to be submitted with the application.

Current section number (1VAC30-46-)	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
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 accreditation."
70 F 1 o (new n)		Part of the list of information required to apply for accreditation: PT studies requirement.	Deletes the requirement for "the three most recent" PT studies, substituting a requirement for "two successful unique" PT studies. Directs the applicant to the specific requirements in Part II of the chapter. Specifies that these PT studies are required for primary accreditation applications only.
70 F 1 p (new o)		Part of the list of information required to apply for accreditation: QA manual requirement.	Revises the requirement to indicate that the QA manual is required for primary accreditation applications only.
70 F 1 q (new p)		Part of the list of information required to apply for accreditation: lab ID requirement.	Deletes the requirement for a lab identification number because it is unnecessary. Substitutes a requirement for applicants applying for secondary accreditation to include a copy of their primary accreditation certificate.
70 F 3 b		Sets out the certification of compliance requirements for applicant laboratories and those wanting to maintain their accreditation.	The 2009 TNI standards added requirements to those set out in the 2003 NELAC standards to which applicant lab and accredited labs owners must attest upon application and to maintain their accreditation. These statements repeat requirements found elsewhere in the chapter. The specific provisions added to the compliance statement are numbered (2) through (7). Item (1) repeats what is in the current compliance statement: "the laboratory is required to be continually in compliance" with the regulation. Items (2) through (5) require the lab to let DCLS verify that the lab is fulfilling the requirements of accreditation. This verification is done through the on-site assessment process and review of PT studies. The requirements for on-site assessment are in 1VAC30-46-220. The requirements for PT studies are in 1VAC30-46-210 B. Item (6) requires the lab to claim accreditation only for its granted scope of accreditation. This requirement is found in 1VAC30-46-100 D and -130. Item (7) requires applicant and accredited labs to pay the fees set by DCLS. The fees are set out in 1VAC30-46-150. Labs that do not pay fees are denied accreditation and if accredited would have their accreditation withdrawn.
70 G 1-2		Requirements for determination by DCLS of the completeness of an application, including during	Deletes all references to the initial accreditation 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

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		the initial accreditation period	application process for renewing accreditation. 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 accreditation period. Increases the time for DCLS to make a completeness determination from 60 to 90 days, the same used during the initial accreditation 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 returning an application package is unnecessary in this case.
70 H 1		Lists the conditions for granting accreditation on an interim basis.	Deletes references to initial applications because the initial application period is over. Deletes references to renewal of accreditation 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 accreditation responsibilities.
70 H 2		Lists the conditions for granting interim accreditation for a lab renewing its accreditation.	Deletes this provision because DCLS has dropped the application process for renewal of accreditation.
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 accreditation period. No laboratory took advantage of this provision.
70 J 2-5		Specifies the timing and conditions for DCLS to complete action on an application for accreditation during and after the initial accreditation period. Specifies when DCLS would notify applications of their accreditation status and release on-site assessment reports.	The provisions concerning the initial accreditation period are deleted because DCLS has completed the initial accreditation process for labs. DCLS is deleting the requirement for it 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. There is no TNI requirement specifying a deadline for the determination on accreditation.
70 K 2		Describes who signs the	Adds that a "designee" of the DCLS director as well as

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		certificate of accreditation. States that the certificate shall be transmitted as a sealed and dated document.	the director may sign the certificate of accreditation. Deletes the provision stating how the certificate is transmitted to the lab. This latter provision was in the 2003 standards but omitted in the 2009 standards. Subsection 70 K 3 states that the certificate must have issuance and expiration dates. The current subsection 70 K 2 is duplicative of 70 K 3 in this regard.
70 M 1		Requires a laboratory to wait six months before reapplying when DCLS has denied its application.	This provision is deleted. The requirement was in the 2003 standards but omitted in the 2009 standards.
90 A		This provision lists those aspects of accreditation that are considered key accreditation criteria.	Adds key accreditation criteria from the 2009 TNI standards to those from the 2003 standards currently set out in 1VAC30-46. Adds "legal, commercial, or organizational status" to "laboratory ownership" describing laboratory ownership in more detail. Adds "top management" to "key personnel" describing key personnel in more detail. Two new criteria are added: (i) resources and (ii) quality system policies.
90 B 2 a		When applying for a change to its scope of accreditation, 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 1VAC30-46-150 F1 that a laboratory must pay a fee to receive a modification to its scope of accreditation. 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 an accredited laboratory to assure historical traceability of the laboratory accreditation numbers.	This provision is deleted because it was in the 2003 standards but was omitted in the 2009 standards.
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 accreditation" that must be kept for a minimum of five 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

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		from accreditation.	accreditation term. Deletes the deadline for DCLS to send the lab a written notice within 30 days of receiving the lab's withdrawal notice. Neither of these 30-day requirements is in the 2009 TNI standards and are unnecessary.
	95		Creates 1VAC30-46-95 on suspension of accreditation. Both the 2003 NELAC Standards and the 2009 TNI Standards provide for suspension of accreditation. DCLS currently provides for suspension through guidance and is adding these provisions to 1VAC30-46. DCLS can suspend accreditation prior to withdrawing accreditation. Suspension is beneficial to laboratories. The process allows the laboratory faced with withdrawal of its accreditation 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 9 and B 10	1VAC30-46-100 B lists the reasons why DCLS may withdraw accreditation from an environmental laboratory.	Adds 1VAC30-46-100 B 9 and B 10. These two reasons are not new and found elsewhere for withdrawing accreditation.
100 D 2		States that DCLS shall issue an addendum to an accreditation certificate when it withdraws accreditation 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		A lab must discontinue using certain materials when accreditation is withdrawn.	One of the materials listed is "laboratory analytical results." Revises this term to read "laboratory analytical reports." This revision is a correction to the proper term.
	100 D 4		Adds a provision to state that the environmental laboratory shall not continue to analyze samples or report analyses for the fields of accreditation for which DCLS has withdrawn accreditation. This provision is implied by the fact that DCLS has withdrawn accreditation. The addition of the provision ensures clarity on this point.
110		Sets out the procedures	1. Revises the entire section deleting references and

Current section number (1VAC30-46-)	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
		DCLS uses to deny or withdraw accreditation.	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 - 5. This subsection specifies how DCLS will notify a laboratory when the agency determines it has cause to deny or to withdraw accreditation 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 accreditation. 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.
120		Describes the information that DCLS must provide to NELAP regarding the laboratories it accredits.	This provision is revised to meet the 2009 TNI standards. The 2009 standards omit this provision pertaining to the national accreditation database. The 2009 standards do require DCLS to provide information to the public about the laboratories it has accredited. The title is revised to better reflect the revised provision.
140 A - F		Sets out the requirements for laboratories applying for reciprocal accreditation under the 2003 NELAC standards.	This section is revised to meet the requirements of the 2009 TNI standards. Subsection B is revised to indicate the exceptions for secondary accreditation applications in 1VAC30-46-70 F 1. 1VAC30-46-140 F 2 is deleted. This current provision requires DCLS to issue a certificate of accreditation within 30 calendar days of the receipt of the application. This deadline is not required by the 2009 standards.
140 G		This provision covers nonconformance issues that DCLS may see when reviewing applications for secondary accreditation.	Subsection -140 G is deleted. The 2009 TNI standards omitted these requirements pertaining to nonconformance issues.
150		This section covers fees.	The fee provisions are revised extensively. These revisions present a fee program that better reflects the true costs of accrediting these labs. The fee program charges less for those smaller commercial labs that perform few test methods for only one matrix. The fee program charges more for the largest commercial labs that are full-service, performing numerous methods across 3 or 4 field of accreditation matrices. The

Current section number (1VAC30-46-)	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			agency spends more time accrediting these larger labs, monitoring their proficiency testing, and assessing the labs on-site. The agency analyzed the costs for a select group of labs to determine how much it costs the agency to accredit the labs. The revisions can be summarized as follows: 1. DCLS will charge fees annually to accredited labs instead of every two years. This provides an even flow of income to the agency. It should benefit the labs because the fee would be half that for two years on an annual basis, becoming a regular budget item. 2. Fees will still be structured using base fees and test category fees. These fee concepts have been expanded however. Base fees are revised based on the number of test methods for which DCLS accredits the laboratory. Only the test category fees currently differentiate by the number of test methods. The base and test category fees are revised to account for the number of field of accreditation matrices for which DCLS accredits the laboratory. These expanded base fees and test category fees are set out in two tables. 3. DCLS is omitting the maximum fee. The maximum fee is currently quite low and does not reflect the cost of accrediting the larger labs. 4. Subsection E has been added to keep the fees in line with inflation in the years following the effective date of this revision. DCLS will use the fees specified in 1VAC30-46-150 for the first 12 months of the revised program. For each of the following 12 months, the fees will be increased or decreased based on the CPI-Urban average-average published by the U.S. Dept. of Labor for the preceding year. DCLS will publish the revised base fee and test category fee tables on its website. 1VAC30-46-150 E specifies how DCLS will make these annual changes to the fees. Fees under the program have not been changed since they were proposed during the fall of 2004. The cost of living has risen during this period. 5. DCLS is deleting the fee range for review of a transfer of ownership in subdivision F 2. This range may not support the cost of the review. Instead the agency will charge the actual cost of the review as it does for the other instances in subsection F. 6. DCLS is deleting current 1VAC30-46-150 F 3. The fees described in that subdivision pertain to 1VAC30-46-60 B 3 which is being deleted (see above). 7. DCLS is revising 1VAC30-46-150 H, specifying that

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			the subsection pertains to out-of-state labs applying for primary accreditation. DCLS is seeing an increase in these applications. Processing out-of-state primary accreditation applications is an expensive process for DCLS. If an out-of-state laboratory chooses to apply for primary accreditation from DCLS, DCLS shall charge the laboratory $5000 in addition to the normal application fee plus the labor cost of the on-site assessment and the travel costs associated with the assessment. The $5000 application fee will not be charged once DCLS accredits the laboratory.
Part II - Standards		Part II incorporates by reference the 2003 standards and sets out the components of these standards in more detail.	Revised Part II deletes the 2003 NELAC standards, incorporates by reference the 2009 TNI standards, and sets out the components of the 2009 TNI standards in detail. Part II includes specific requirements from Volume 2 of the 2009 TNI standards that pertain principally to accreditation bodies. Volume 2, Modules 2 and 3, do contain specific requirements that pertain to laboratories. Including these requirements in the body of Part II means that the laboratories will not need to obtain a copy of Volume 2 of the 2009 TNI Standards as well as Volume 1. See the additional information below.

Additional Information: Replacing the 2003 NELAC Standards with the 2009 TNI Standards.
The 2009 TNI Standards reorganized the 2003 NELAC Standards. Volume 1 of the 2009 Standards contains all the requirements for laboratories with a few exceptions. This volume is organized into seven modules. The first two cover general management and technical requirements and proficiency testing. The third through the seventh modules cover the various types of testing such as chemical and microbiological testing.

TNI omitted from the 2009 TNI Standards a number of requirements that were included in the 2003 NELAC Standards. The accreditation bodies were not using some of these provisions. Others were thought to be inappropriate. TNI has attempted to resolve some accreditation issues discovered in carrying out the national program using the 2003 NELAC standards. One of these concerns proficiency testing. The deadlines for proficiency testing studies were somewhat vague in the 2003 NELAC Standards. This created some confusion for the accreditation bodies. The 2009 TNI Standards include specific deadlines so that the confusion is eliminated. TNI has made information available to both the laboratories and the accreditation bodies on the differences between the 2003 NELAC Standards and the 2009 TNI Standards. The details of these changes are considerable. TNI considers most of these changes to be minor.