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Final Regulation Agency Background Document

Agency name	Department of General Services, Division of Consolidated Laboratory Services
Virginia Administrative Code (VAC) citation(s)	1VAC30-46
Regulation title(s)	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	December 9, 2013; June 10, 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 of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

1VAC30-46 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 also restructures the fee provisions; eliminates requirements relating to the initial accreditation period; streamlines the process to renew accreditation; and adds provisions on suspension of accreditation.

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.

There are no technical terms or acronyms used in this document that are not defined in the regulations.

Statement of final agency action

Please provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

The Director of the Department of General Services approved the final proposed regulations on January 2, 2014 and the revised final regulations on June 30, 2015. The regulations are entitled Accreditation for Commercial Environmental Laboratories.

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

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 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 its 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 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 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 the new substantive provisions, the substantive changes to existing sections, or both.

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 there are 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 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 will be no localities particularly affected by this regulatory action.

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.

These amendments will have no impact on the institution of the family or on family stability.

Changes made since the proposed stage

*Please list all changes that made to the text of the proposed regulation and the rationale for the changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. *Please put an asterisk next to any substantive changes.*

Section number	Requirement at proposed stage	What has changed	Rationale for change
1VAC30-46-15	These provisions stated that DCLS would continue to accredit commercial laboratories through June 30, 2014, under the 2003 NELAC Standards and begin accrediting the laboratories under the 2009 TNI standards on July 1, 2014.	1VAC30-46-15 B and C are revised to provide a 10-month transition period for DCLS and the commercial laboratories. DCLS will begin accrediting laboratories under the 2009 TNI Standards beginning on the first day of the 11 th month following the effective date of the regulation.	The dates set in the proposed regulation provisions have passed. A new timetable for the transition from accrediting under the 2003 standards to accrediting under the 2009 standards is required.
1VAC30-46-40	Definition of "accrediting authority" was struck and a new definition of "accreditation body" was added to the section.	The new definition of "accreditation body" has been struck. The definition of "accrediting authority" has been reinstated except that "accrediting authority" is now changed to "accreditation body."	The proposed definition is too general and does not indicate that DCLS, the accrediting authority or accreditation body that carries out the accreditation program in Virginia, is a governmental body. The term "accreditation body" replaces that of "accrediting authority" in the 2009 TNI Standards. There were two definitions in these standards for this term. The

Section number	Requirement at proposed stage	What has changed	Rationale for change
			one chosen for the final is the same as the current definition and specifies that a territorial, state, or federal agency carries out the program.
1VAC30-46-40	Definition of "finding" was revised to meet the definition for the term in the 2009 TNI Standards	The definition has been revised to add a phrase indicating that a standard referenced in an assessment conclusion would be a standard incorporated by reference or contained in 1VAC30-41.	The change makes clear what standards are being met by laboratories covered under this chapter.
1VAC30-46-150 B 3 and E	These provisions provided that DCLS would revise the fees annually based on the year-over-year percentage change of the CPI-Urban, a standard inflation index.	These provisions have been omitted from the regulation.	These changes were made due to concerns raised about whether this annual fee change would appropriately cover the costs of the program.

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate. Please distinguish between comments received on Town Hall versus those made in a public hearing or submitted directly to the agency or board.

Commenter	Comment	Agency response
Hampton Roads Sanitation District (HRSD) and Virginia Association of Municipal Wastewater Agencies (VAMWA)	<u>Support for regulation revisions.</u> Implementation of the Virginia Environmental Laboratory Accreditation Program (VELAP), which embodies a quality system approach, has provided benefits to accredited laboratories performing analyses in support of the Virginia Air Pollution Control Law, the Virginia Waste Management and the Virginia Water Control Law, to laboratory customers and to regulatory program data users. The Division of Consolidated Laboratory Services (DCLS) has been highly successful in implementing the program and has exemplified quality and efficient service, leadership, fairness, consistency, and professionalism in accrediting laboratories under the current program. Therefore, HRSD and VAMWA support	DCLS appreciates the commenters' support.

Commenter	Comment	Agency response
	<p>amendments to the VELAP regulation that improve program effectiveness and efficiency, and ensure program sustainability.</p>	
<p>HRSD and VAMWA</p>	<p><u>Support for regulation revisions.</u> HRSD and VAMWA support updating the VELAP reference standard from the 2003 National Environmental Laboratory Accreditation Conference (NELAC) to The NELAC Institute (TNI) 2009 standard for the following reasons:</p> <ul style="list-style-type: none"> • DCLS will be able to maintain its recognition as a NELAP Accreditation Body, and therefore will be able to continue offering NELAP Accreditation to commercial laboratories. The TNI 2009 standard was developed using a consensus standards development process, which allowed more stakeholder groups to be involved through committee participation and voting. The 2009 Standard is less prescriptive but still emphasizes the importance of a quality system. Hence, the 2009 Standard is superior to the current standard. • The structure of the TNI standard is much more practical for use by Accreditation Bodies, Proficiency Testing Providers and Laboratories, and allows an easier understanding of the requirements. • The 2009 TNI standard is based on ISO 17025, which is an internationally recognized and widely accepted standard for accrediting laboratories. 	<p>DCLS appreciates the commenters' support.</p>
<p>HRSD and VAMWA</p>	<p><u>Support for regulation revisions.</u> HRSD and VAMWA support the removal of language relating to the initial accreditation period, as the VELAP program is already established.</p>	<p>DCLS appreciates the commenters' support.</p>
<p>HRSD and VAMWA</p>	<p><u>Support for regulation revisions.</u> HRSD and VAMWA support changes to the renewal and reassessment and application</p>	<p>DCLS appreciates the commenters' support.</p>

Commenter	Comment	Agency response
	<p>processes. The streamlining of requirements will be more efficient and reduce costs for both laboratories and DCLS, and will be an improvement to the program.</p>	
<p>HRSD and VAMWA</p>	<p><u>Support for regulation revisions.</u> HRSD and VAMWA support provisions to add a process for suspension of accreditation prior to withdrawal. This will benefit citizens (ratepayers) by allowing the laboratory the opportunity to take corrective action before accreditation is withdrawn for a limited set of reasons.</p>	<p>DCLS appreciates the commenters' support.</p>
<p>HRSD and VAMWA</p>	<p><u>DCLS and the 2009 TNI requirements.</u> Deletion of 1VAC30-46-30 B.2 removes the applicability of the VELAP to DGS-DCLS as a NELAC accreditation body. Although 1VAC30-46 references TNI 2009 requirements for Accreditation Bodies, this section of the regulation does not state the applicability of the regulation to DGS-DCLS. HRSD and VAMWA recommend adding the following language to 1VAC30-46-30.B: "DGS-DCLS shall meet the requirements of the 2009 TNI standard to maintain status as a NELAP Accreditation Body."</p>	<p>DCLS cannot use the 2009 TNI Standards to accredit environmental laboratories in Virginia unless the agency maintains its accreditation body status with TNI. To do so, DCLS must meet the 2009 TNI Standards. The change suggested by this comment therefore is unnecessary. No change has been made to the regulation as a result of this comment.</p>
<p>HRSD and VAMWA</p>	<p><u>Definition of "Accreditation body."</u> "Accreditation body" or "AB" means the authoritative body that performs accreditation. This definition is inconsistent with the TNI 2009 Definition (ELV1M1 3.0 Accreditation Body). The TNI 2009 defines an Accreditation Body as "the territorial, state, or federal agency having responsibility and accountability for environmental laboratory accreditation which grants accreditation." This definition more clearly defines the types of agencies that can be accreditation bodies and could prevent the management of VELAP being moved to a nongovernmental or third party body. HRSD and VAMWA recommend changing the definition to be consistent with the</p>	<p>DCLS will make the change to the definition of accreditation body suggested by this comment. This definition is the one currently in use for "accrediting authority" which term has been replaced in the TNI 2009 definitions by "accreditation body." DCLS appreciates the suggestion made by the commenters.</p>

Commenter	Comment	Agency response
HRSD and VAMWA	<p>TNI 2009 Definition (EL-V1M1 3.0 Accreditation Body).</p> <p><u>Definition of "Finding."</u> "Finding" is defined as an assessment conclusion referenced to a laboratory accreditation standard and supported by objective evidence that identifies a deviation from a laboratory accreditation standard requirement. There is no specific reference to the TNI 2009 standard in the definition as the reference standard for laboratory accreditation. Methods are also used as regulatory references for assessment, and are not mentioned here. HRSD and VAMWA recommend adding specific language to reference the 2009 TNI standard and analytical methods to better define the scope of the assessment and ensure the program only uses the applicable standards.</p>	<p>DCLS will make a change to the definition of finding to specify that the laboratory accreditation standards are those covered by 1VAC30-46. DCLS appreciates the suggestion made by the commenters.</p>
HRSD and VAMWA	<p><u>DPB's Economic Analysis.</u> "The benefit likely exceeds the costs for one or more proposed changes. There is insufficient data to accurately compare the magnitude of the benefits versus the costs for other changes." This statement makes unreasonable assumptions on benefits exceeding costs when there is insufficient data to support the conclusion. HRSD and VAMWA recommend the DGS provide a sufficient analysis to defend the conclusion made by the Department of Planning and Budget ("DPB"). This statement should be removed if this is not possible.</p>	<p>The Department of Planning and Budget (DPB) reviewed the DGS-DCLS cost benefit analysis and approved the proposed regulation to be promulgated for public comment as a result of their review.</p>
HRSD and VAMWA	<p><u>Annual Fee Adjustment based on CPI.</u> DGS proposes to adjust fees annually based on CPI and draws the conclusion that with future fees based on CPI, the agency has incentive to get more for the dollars they have, as opposed to adjusting fees based on actual program costs. By automatically adjusting fees based on the annual CPI, there is not a process in place to promote cost saving measures</p>	<p>Making an annual adjustment to fees based on the CPI-Urban average/average percentage change should ensure that the fee income to cover the program would cover costs as they rise due to inflation. The agency already promotes a high degree of efficiency as it carries out the program. Examples of management practices currently used to maintain program efficiency include the following:</p> <ul style="list-style-type: none"> (1) pre-assessment data package review to shorten on-site assessment and travel time; (2) assessment scheduling to promote lowered travel costs by grouping multiple labs into one travel event;

Commenter	Comment	Agency response
	<p>and ensure program efficiency, as the increase/decrease will be automatic. The agency must annually base fees on actual costs and use a systematic approach that is transparent to all stakeholders to ensure fees are reflective of program revenues and costs and to promote efforts to strive for efficiency and cost saving measures in order to minimize fees.</p>	<p>(3) spreading assessment schedules near the maximum time allowed by the regulation; and (4) the use of overtime to maintain compliance with regulatory requirements.</p> <p>DCLS however is omitting from the final regulation the provision allowing an annual fee adjustment based on the year over year percentage average CPI-Urban.</p>
<p>HRSD and VAMWA</p>	<p><u>Evaluation of Need for New Assessor Lacking.</u> DGS failed to include that its basis for the proposed fee increases includes the addition of a new assessor. As a result, DPB was not able to evaluate the necessity or cost-effectiveness of adding a new assessor in its Economic Impact Analysis. The DGS should provide DPB with all the bases for the proposed fee increases so that DPB can accurately evaluate the costs and benefits, cost effectiveness, and efficiency as required by Executive Order No. 14 from the Governor's Office.</p>	<p>The certification program became effective on January 1, 2009. Twelve staff positions were originally approved for the program. This included a manager, an assistant, and ten assessors. During the initial certification and accreditation period the agency hired four assessors and a manager. This level of staffing has remained constant since inception of the program.</p> <p>The Virginia Environmental Laboratory Accreditation Program (VELAP) has 244 actively accredited or certified laboratories as of November 2013. There are currently 113 noncommercial environmental laboratories certified under 1VAC30-45. There are currently 131 commercial laboratories accredited under 1VAC30-46. Primary accreditation is held by 54 of these laboratories and the remaining 77 commercial laboratories hold secondary accreditation which requires limited monitoring by the staff. The four VELAP assessors process new applications for certification or accreditation for the noncommercial laboratories and for the primary and secondary commercial laboratories. In 2013 six new applications were received and an additional 18 have received application instructions or packages. The assessors record and review all proficiency test (PT) data from each laboratory for compliance with the regulation. Approximately 15,800 PT records were updated in the most recent 12 months. The assessors also perform an onsite assessment for each laboratory every other year. These onsite assessments require preparation prior to the onsite assessment in the form of data review to minimize travel expenses and on-site time. The onsite assessment takes from a minimum of one day to as much as a week to perform depending on the scope of the laboratory's certification or accreditation and associated travel time. For the larger laboratories, a team of assessors performs the onsite assessment. Following the site visit the assessor or assessors prepare the report documenting any non-conformances with the regulation found during the onsite assessment. This report must be prepared within 30 days of the site visit. It is generally necessary for the laboratory to respond to this report with a corrective action plan. The assessor must review the corrective actions proposed by the laboratory and make</p>

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		<p>recommendations to accept or reject the laboratory's proposed actions. The laboratory also submits documentation of all implemented corrective actions. The assessor reviews this documentation and makes recommendations to close the assessment process or require more documentation. Throughout this process rigid timelines are maintained in accordance with provisions of the regulation.</p> <p>On average, VELAP assessors each currently manage the assessment responsibilities for 52 facilities and serve as support assessors on six assessment teams for large labs managed by other assessors. The assessment activities described above with associated deadlines are consistently maintained for all facilities. The evaluation responses from laboratories consistently give high satisfaction ratings regarding the program and its staff.</p> <p>The following comparison is provided regarding a similar NELAP program and VELAP:</p> <table border="1" data-bbox="764 877 1476 1255"> <thead> <tr> <th></th> <th>Approx Total Labs</th> <th>Approx Number of Annual Site Visits Per Program</th> <th>Number of Assessors</th> <th>Average Number of Labs Per Assessor (see note)</th> <th>Average Number of Site Visits Per Assessor Per Year</th> </tr> </thead> <tbody> <tr> <td>VELAP</td> <td>244</td> <td>85</td> <td>4</td> <td>52</td> <td>21</td> </tr> <tr> <td>Similar AB</td> <td>478</td> <td>140</td> <td>10</td> <td>47</td> <td>14</td> </tr> </tbody> </table> <p>NOTE: For VELAP, the number of laboratories assigned to each assessor varies according to the scope of the laboratories' certification or accreditation. This average is of the number of laboratories assigned to the four assessors and not the approximate number of total laboratories (244) divided by the number of assessors (4).</p> <p>The VELAP group as a unit has worked extra hours averaging 45 overtime hours weekly from June 2013 to date. The group has cumulatively worked 2740 overtime hours since January 2012; this is the equivalent of more than 68 forty-hour workweeks to meet the regulatory requirements of the program. This labor has been done by extremely dedicated staff members who are committed to the ongoing excellence of the program. Additionally, the VELAP program continues to receive applications requesting accreditation. As noted above, six new applications were made to the program in 2013 and another eighteen have indicated an intention to apply. Not only is additional staff justified by comparison with another accrediting body and by</p>		Approx Total Labs	Approx Number of Annual Site Visits Per Program	Number of Assessors	Average Number of Labs Per Assessor (see note)	Average Number of Site Visits Per Assessor Per Year	VELAP	244	85	4	52	21	Similar AB	478	140	10	47	14
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VELAP	244	85	4	52	21															
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		<p>VELAP workload records, the additional staff is currently overdue. The agency has maintained the inadequate staffing level because the fees (established in 2004) are insufficient.</p>
<p>HRSD and VAMWA</p>	<p><u>Fees.</u> A major issue in this rulemaking is a proposed increase in many fees. HRSD and VAMWA believe any new fees should be based on actual costs and a transparent budgetary process that promotes efficiency and cost savings.</p> <p>Executive Order No. 14 from the Governor’s Office states the following regarding points agencies must consider in drafting regulations, including:</p> <ul style="list-style-type: none"> • “Agencies shall identify and assess the least costly means including reasonably available alternatives in lieu of regulation for achieving the goals of a regulation.” • “Regulatory development shall be based on the best reasonably available and reliable, scientific, economic, and other information concerning the need for, and consequences of, the intended regulation. Agencies shall specifically cite the best reasonably available scientific, economic, and other information in support of regulatory proposals.” • “Regulations shall be designed to achieve their intended objective in the most efficient, cost-effective manner.” <p>Accordingly, the process used to establish and adjust fees must ensure VELAP is managed in a cost effective manner. A transparent process, based on an annual calculation of costs and revenues, will promote efficiency and cost savings each and every year of the program. The approach taken by DGS lacks transparency and is not based on balancing</p>	<p>The Department of Planning and Budget (DPB) reviewed the DGS-DCLS cost benefit analysis and approved the proposed regulation to be promulgated for public comment as a result of their review. See agency responses to previous comments on fees. DCLS is omitting from the final regulation the provision allowing an annual fee adjustment based on the year over year percentage average CPI-Urban.</p>

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	<p>costs with revenues. In particular, use of an automatic annual fee adjustment based on the CPI, as proposed by DGS, will increase revenues without relevance to actual increased costs and will not acknowledge efficiencies gained over time. The CPI approach proposed by DGS will not ensure that the intended program objective is achieved in the most cost effective manner. An annual assessment of costs and revenues, much like any other government agency would conduct, will ensure that fees do not cause an undue financial burden to accredited laboratories, their customers, and data users. Furthermore, the costs savings implied in this proposed regulation, through less burdensome requirements and more efficient administrative processes, can be incorporated into the annual budgetary process used to establish fees, at the minimum appropriate level.</p>	
<p>HRSD and VAMWA</p>	<p><u>VAC30-46-150 Fees/Calculation of Fees.</u> “DCLS shall increase or decrease the fees set out in the base fee and test category fee tables using the Consumer Price Index-Urban (CPI-U) percentage change, average for the previous calendar year.” Although it is apparent that current fees do not support program costs and require revision, an automatic annual fee adjustment based on CPI will not necessarily meet the requirements of Executive Order #14 from the Governor’s Office, reflect actual program costs, ensure VELAP program sustainability, or reflect any cost savings which may be realized by DCLS as a result of streamlining administrative processes and adoption of the less burdensome 2009 TNI standard. Fees must be based on actual program revenue and costs to support program sustainability. HRSD and VAMWA recommend</p>	<p>Making an annual adjustment to fees based on the CPI-Urban average/average percentage change should ensure that the fee income to cover the program would cover costs as they rise due to inflation. The commenters suggest using the CPI-Urban average/average annual percentage change to adjust the fees as a cap for increasing fees annually. This implies that this average inflation rate will not affect the costs of the certification program. The annual adjustment is to account for inflation only.</p> <p>See previous comments and responses on fees. DCLS is omitting from the final regulation the provision allowing an annual fee adjustment based on the year over year percentage average CPI-Urban.</p>

Commenter	Comment	Agency response
	<p>developing a systematic annual budgeting approach that ensures transparency in establishing and revising fees under the regulation and meets the requirements of the Executive Order #14 from the Governor's Office. This approach must be based on annual assessments of program revenues and costs including adjustment of resources that reflect and promote efficiency in VELAP program administration and sustain the program. The provision to automatically increase or decrease fees based on the CPI-Urban index should be removed, as this does not have a relevant tie to actual revenues and costs. The CPI-Urban index should only be used as a cap for increasing fees on an annual basis to ensure increases in fees are reasonable for laboratories.</p>	
<p>HRSD and VAMWA</p>	<p><u>Revised Fee Structure- Increased Fees.</u> The proposed fee structure is based on individual laboratory size, scope, and complexity of accreditation. The new fee structure will result in significant increases to laboratory fees and program revenue. HRSD and VAMWA support a fee structure that is based on size, scope, and complexity of individual laboratory's accreditation. It is reasonable for fees to increase as the size and scope of accreditation for laboratories increases. Although it is apparent that the current fee structure does not support program costs, the new fee structure will result in substantial fee increases for many laboratories without demonstrated, commensurate increases in costs. Based on additional documents received from DGS-DCLS, dated September 19, 2013, program revenues are estimated to increase from \$723,229 received in the first two years of the program to approximately \$1.24M over two years. However, it is</p>	<p>The commenters were provided with a considerable amount of budgetary detail as a result of their FOIA request. This detail is not reflected in their comments. DCLS provided the following information setting out how the budget numbers were derived.</p> <p>The revenue received in the first two years of the program, from the start of the program when applications and fees were first due on July 1, 2009 to February 2012 (approximately two and a half years) was \$741,834. The cost of the program for the first two fiscal years (July 1 - June 30) of the program (2009-2011) was \$978,663. This is a shortfall of almost \$237,000. These calculations were made in April 2012. This cost is for the entire program: both commercial and noncommercial laboratories.</p> <p>DCLS derived the budget to use to calculate the fees as follows. The cost of the program for the first two years (\$978,663) was inflated for each of three years by 3.2 percent each year cumulatively. An additional assessor was added to the program and that cost was determined using the same approach. The result of these calculations was a final two-year budget of \$1.24 million for two years or \$620,000 per year to finance the entire program (commercial and noncommercial laboratories). DCLS projected that the revised 1VAC30-46 (and the new fee structure) would not take effect until early 2015. This is why the costs were inflated over a three-year period.</p> <p>DCLS assessed the cost to certify or accredit twelve</p>

Commenter	Comment	Agency response
	<p>unclear whether revenues need to increase by this amount in order to cover current program costs. DGS, in its Background Documents, assumes the current level of staffing will be maintained and does not consider that the number of labs covered by the program was initially overestimated, which would imply a degree of overstaffing. Because actual costs to the agency are not clearly projected in the background information, HRSD and VAMWA do not support the proposed fee increase. Further, DGS mentions that “the process to renew accreditation will be streamlined, reducing the cost for both the agency and the accredited laboratories,” but does not appear to consider these reduced costs in the calculations of the proposed fees. HRSD and VAMWA recommend that DGS develop a systematic, annual budgeting approach that ensures transparency in establishing and revising fees under the regulation and meets Executive Order #14 of the Governor’s Office. This approach must be based on an annual assessment of program revenues and costs to sustain the program, and should include an adjustment of resources that reflects and promotes efficiency of administering the VELAP program.</p>	<p>laboratories as part of the process to determine a new fee structure. The cost to certify or accredit these laboratories exceeded the fee for all but three laboratories. In the case of the two largest laboratories the cost to accredit was three times the fee received from each of these laboratories. HRSD is one of the two laboratories.</p> <p>This cost analysis showed that the effort required to certify or accredit a laboratory is dependent on the scope and complexity of the testing the laboratory performs. The revised fee structure reflects this fact. This is true whether the laboratory is commercial or noncommercial. Revisions have also been made to 1VAC30-45. The same fee structure is used. The noncommercial (1VAC30-45) laboratories generally perform fewer tests and usually perform testing in only one medium (nonpotable water). The total fees for these laboratories are lower than the total fees for the commercial (1VAC30-46) laboratories.</p> <p>The commenters recommend reviewing costs and revenues annually and setting the fees based on this review. The program as discussed previously has been essentially "in the red" since its inception. The agency is omitting from the final regulation the provision allowing an annual fee adjustment based on the year over year percentage average CPI-Urban.</p> <p>See also the responses to comments above.</p>

ADDITIONAL AGENCY COMMENTS

The comments received on the revision to 1VAC30-46 came directly from one currently accredited commercial environmental laboratory, Hampton Roads Sanitation District (HRSD), and from the Virginia Association of Wastewater Management Agencies (VAMWA) that represents three currently accredited commercial environmental laboratories including HRSD. The other two laboratories accredited under 1VAC30-46 and represented by VAMWA are the County of Henrico and Prince William County laboratories. No comments were received by the private commercial laboratories represented by the Laboratory Association of Virginia or by any private commercial laboratory located outside Virginia. Both sets of comments were submitted directly to the agency.

All changes made in this regulatory action

Please list all changes that are being proposed and the consequences of the proposed changes.

Describe new provisions and/or all changes to existing sections. Explain the new requirements and what they mean rather than merely quoting the proposed text of the 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: <ul style="list-style-type: none"> • "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
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. Provides a transition period for DCLS and the affected laboratories to begin accreditation under the 2009 standards. All other requirements of the regulation would take effect upon the effective date.
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

Current section number (1VAC30-46-)	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			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 "accrediting authority"	The 2009 TNI Standards use the term "accreditation body" instead of "accrediting authority." The definition of the term proposed in 1VAC30-46 was also changed to a more general definition found in the 2009 TNI standards. The definition has been revised in final 1VAC30-46 to return to that used currently because it specifically refers to the governmental entities that carry out accreditation programs under TNI.
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) 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

Current section number (1VAC30-46-)	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			nutrient management" is not applicable under VELAP.
40		Definition of "finding"	The definition of "finding" was revised in proposed 1VAC30-46 to conform to the definition in the 2009 TNI Standards. The definition of "finding" has been revised in the final regulation to include the phrase "incorporated by reference or contained in this chapter" to make it clear that the standards laboratories must meet are those specific to 1VAC30-46.
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.
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		Part of the list of information	Deletes the requirement for "the three most recent" PT

Current section number (1VAC30-46-)	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
(new n)		required to apply for accreditation: PT studies requirement.	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 the initial accreditation period	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 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	Deletes provision related to the initial accreditation

Current section number (1VAC30-46-)	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
		a completeness determination on an application	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 certificate of accreditation. States that the certificate shall be transmitted as a sealed and dated document.	Adds that a "designee" of the DCLS director as well as 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.

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			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 from accreditation.	Deletes the deadline for a lab to withdraw in writing no later than 30 calendar days before the end of the lab's 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

Current section number (1VAC30-46-)	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			unnecessary.
	95		<p>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.</p> <p>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.</p> <p>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.</p>
	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 DCLS uses to deny or withdraw accreditation.	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

Current section number (1VAC30-46-)	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			<p>may appeal a final decision to deny or withdraw pursuant to the Administrative Process Act (APA).</p> <p>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.</p> <p>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.</p>
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 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

Current section number (1VAC30-46-)	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			<p>to accredit the labs.</p> <p>The revisions can be summarized as follows:</p> <ol style="list-style-type: none"> 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. DCLS is deleting the fee range for review of a transfer of ownership in subdivision E 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 E. 5. DCLS is deleting current 1VAC30-46-150 E 3. The fees described in that subdivision pertain to 1VAC30-46-60 B 3 which is being deleted (see above). 6. DCLS is revising 1VAC30-46-150 G, specifying that 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.	<p>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.</p> <p>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</p>

Current section number (1VAC30-46-)	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			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.