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Proposed Regulation Agency Background Document

Agency name	Department of General Services, Division of Consolidated Laboratory Services
Virginia Administrative Code (VAC) citation(s)	1VAC30-45 and 1VAC30-46
Regulation title(s)	Certification for Noncommercial Environmental Laboratories (1VAC30-45) and Accreditation for Commercial Environmental Laboratories (1VAC30-46)
Action title	Revise 1VAC30-46 to meet 2016 TNI Standards and to update requirements in 1VAC30-45 and 1VAC30-46
Date this document prepared	March 25, 2020

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1 VAC7-10), and the *Virginia Register Form, Style, and Procedure Manual for Publication of Virginia Regulations*.

Brief Summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.

1VAC30-46 sets out the requirements 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. 1VAC30-46 uses the NELAC Institute (TNI) standards to accredit commercial environmental laboratories. The TNI standards are revised every few years. The Division of Consolidated Laboratory Services (DCLS) is replacing the current 2009 TNI standards used to accredit laboratories with the 2016 TNI standards. Commercial environmental laboratories need to meet these standards in order to remain accredited under the nationally accepted TNI program.

1VAC30-45 sets out the requirements to certify noncommercial laboratories that analyze environmental samples used to determine compliance with the State Water Control Law, Virginia Waste Management Act, and the Virginia Air Pollution Control Law. DCLS is revising 1VAC30-45 to include any proposed changes in the 2016 TNI Standards that provide more flexibility so that the noncommercial laboratories will also benefit.

DCLS is revising both 1VAC30-45 and 1VAC30-46 to reflect lessons learned from the agency's experience implementing the program since these regulations were previously revised (1VAC30-45, effective September 1, 2016; 1VAC30-46, effective November 1, 2015).

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 Virginia Department of General Services.

DEQ is the Virginia Department of Environmental Quality.

Demonstration of capability (DOC) is defined by TNI as a procedure to establish the ability of the analyst to perform analyses with acceptable accuracy and precision.

EPA is the U.S. Environmental Protection Agency.

Field of proficiency testing (FoPT) is the matrix, technology/method, analyte combination(s) for which the composition, spike concentration ranges, and acceptance criteria have been established by TNI's Proficiency Testing Program Executive Committee.

The NELAC Institute or TNI is the organization whose standards environmental laboratories must meet to be accredited as a commercial environmental laboratory in Virginia.

The National Environmental Laboratory Accreditation Conference or NELAC is a voluntary organization of state and federal environmental officials and interest groups with the primary purpose to establish mutually acceptable standards for accrediting environmental laboratories. NELAC preceded the formation of The NELAC Institute or TNI. TNI is comprised of several subparts, one of which is the National Environmental Laboratory Accreditation Program or NELAP.

Limits of detection or LOD is defined by TNI as the minimum result which can be reliably discriminated from a blank with a predetermined confidence level. Method detection limit or MDL is one way to establish a limit of detection.

Method detection limit or MDL is defined by EPA (EPA 821-R-16-006, December 2016) as the minimum measured concentration of a substance that can be reported with 99% confidence that the measured concentration is distinguishable from method blank results.

A primary accreditation body is the NELAP accreditation body responsible for assessing a laboratory's total quality system, on-site assessment, and PT performance tracking for fields of accreditation.

Proficiency testing (PT) is a means to evaluate a laboratory's performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by an external source.

A secondary accreditation body is the NELAP accreditation body that grants laboratory accreditation for a field of accreditation based on recognition of accreditation from a primary accreditation body for the same field of accreditation.

Mandate and Impetus

Please identify the mandate for this regulatory change, and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, board decision, etc.). For purposes of executive branch review, "mandate" has the same meaning as defined in Executive Order 14 (as amended, July 16, 2018), "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

DCLS accredits commercial environmental laboratories (1VAC30-46) using the national environmental laboratory accreditation standards developed by TNI. DCLS currently accredits commercial environmental laboratories to the 2009 TNI standards. TNI has replaced the 2009 standards with the 2016 standards. DCLS must incorporate the 2016 standards into 1VAC30-46 in order to continue to accredit commercial environmental laboratories under the TNI program. Commercial environmental laboratories need to meet these 2016 revised standards in order to remain accredited under the TNI standards.

Revising 1VAC30-45 at the same time DCLS revises 1VAC30-46 for new TNI standards is important to ensure that the standards for noncommercial environmental laboratories are no more stringent than the standards for commercial environmental laboratories. Revising both regulations at the same time also ensures that testing meets federal and state requirements, as appropriate.

The procedural aspects of the program are the same in the two regulations. Any changes made to the procedural aspects of the program should be made at the same time to both regulations.

Legal Basis

Please identify (1) the agency or other promulgating entity, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia or Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency or promulgating entity'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 [the 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 the Division of Consolidated Laboratory Services to establish a fee system to pay for the costs of the certification program.

Promulgating Entity

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

Purpose

Please explain the need for the regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety or welfare of citizens, and (3) the goals of the regulatory change and the problems it's intended to solve.

The TNI program standards are widely recognized standards for the accreditation of environmental laboratories and are currently incorporated by reference in 1VAC30-46. TNI revises their standards regularly to improve those standards and to provide the most up-to-date information available for the accreditation of environmental laboratories.

Accrediting commercial environmental laboratories to a single set of standards has several benefits. Environmental laboratories test environmental samples to determine whether the samples meet the air, water, and waste pollutant limits set by DEQ. Under the accreditation program, all environmental laboratories meet the same proficiency testing and quality assurance and quality control standards. Meeting these standards ensures that the laboratories are capable of providing results of known quality and defensibility for measurements of pollutants in environmental samples. The limits set by DEQ for air, water and waste pollutants protect public health and welfare. Laboratory measurements of environmental samples determine compliance with Virginia's environmental laws and therefore are the key to providing protection of public health and welfare.

Certifying noncommercial environmental laboratories to a single set of standards provides the same benefits as those described above for commercial environmental laboratories. Noncommercial environmental laboratories are certified to standards that are similar to the TNI standards.

Substance

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

In 1VAC30-46, DCLS is replacing the current accreditation standards, the 2009 TNI standards, with the 2016 TNI standards. Commercial environmental laboratories and DCLS must meet the standards in order to remain accredited under the nationally accepted TNI program. DCLS is revising the dates for the transition period for laboratories to meet the 2016 TNI standards in 1VAC30-46-15. DCLS is adding to the Certificate of Compliance a provision for the laboratory to acknowledge it has a copy of the TNI standards incorporated by reference into 1VAC30-46.

DCLS is revising the definitions in 1VAC30-46 to conform to changes in the definition of terms from the 2009 to the 2016 TNI standards. When appropriate, DCLS is revising the definitions for the same terms in 1VAC30-45. This ensures compatibility between the programs for commercial and noncommercial environmental laboratories.

In both 1VAC30-46 and 1VAC30-45, DCLS is adding as a cause for suspension, laboratory failure to submit an acceptable corrective action plan after two opportunities. DCLS currently may only withdraw accreditation or certification. This adds flexibility for DCLS and provides the possibility of a less onerous outcome for a laboratory.

In both 1VAC30-46 and 1VAC30-45, DCLS is adding as a reason to withdraw accreditation or certification, laboratory failure to correct the causes for suspension within the term of suspension. This provision currently is in the suspension provisions but not in the withdrawal provisions.

In both 1VAC30-46 and 1VAC30-45, DCLS is adding as a reason to withdraw accreditation in part or in total when a laboratory fails three consecutive PT studies. For 1VAC30-45, this reason for withdrawal is set out elsewhere in the regulation. For 1VAC30-46, TNI removed this reason for withdrawal in the 2009 TNI standards but reinstated it in the 2016 TNI standards.

In both 1VAC30-46 and 1VAC30-45, DCLS is adding as a reason to withdraw accreditation or certification when a laboratory fails to meet the provisions concerning communicating with other laboratories with regard to proficiency testing.

In both 1VAC30-46 and 1VAC30-45, DCLS is adding a statement that the agency will regularly review its budget to determine if the fees charged under the program offset its costs.

In both 1VAC30-46 and 1VAC30-45, DCLS is adding a provision requiring a laboratory to pay the cost of compliance determination when the agency has suspended accreditation or certification in total and the laboratory wishes to demonstrate that reasons for suspension have been resolved.

DCLS is revising 1VAC30-45 in two cases to provide more flexibility for the laboratory. First DCLS is revising the time between PT supplemental studies in 1VAC30-45-520 B. Second DCLS is deleting the requirement for an access log to archived records in 1VAC30-45-650 E.

DCLS is revising 1VAC30-45 to conform to a change in the 2016 TNI standards. DCLS is requiring a successful performance of the demonstration of capability procedure when the laboratory has not performed this procedure within 12 months. This change strengthens the defensibility of a laboratory's records.

DCLS is revising 1VAC30-45 to conform to EPA's 2017 Methods Update Rule. This revision applies to testing done in accordance with the federal Clean Water Act using the approved methods listed in 40 CFR Part 136. For these test methods, DCLS is eliminating the exemption to performing MDL if not reporting (a) below the reporting limit or LOD and (2) outside the calibration range. EPA's Methods Update Rule does not acknowledge this exemption.

Issues

Please identify the issues associated with the regulatory change, 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, include a specific statement to that effect.

The primary advantage to the public associated with this proposed action is the maintenance of up-to-date standards for the certification (1VAC30-45) and accreditation (1VAC30-46) of environmental laboratories. For commercial laboratories, the 2016 TNI Standards are the most current version of these national accreditation standards for environmental laboratories and improve the 2009 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.

With regard to DCLS and the Commonwealth, 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. There are no disadvantages to the agency or Commonwealth.

The primary advantage of the proposed action for the affected noncommercial laboratories is increased flexibility in one revised provision and the deletion of another provision of 1VAC30-45. The primary disadvantage of the proposed action for the affected noncommercial laboratories are additional requirements in two provisions of the revised regulation. The balance between the advantages and disadvantages should limit the impact for these laboratories.

The primary advantage of the proposed action for the affected commercial laboratories is maintaining their accreditation under TNI. By meeting the 2016 TNI Standards, the laboratories will continue to be recognized as TNI-accredited laboratories. This enables the Virginia commercial laboratories to obtain secondary accreditation from other NELAP 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 commercial laboratories is the time it may take to meet the 2016 TNI standards. DCLS is allowing six months for this transition. The length of this transition period benefits both the agency and the affected laboratories. This disadvantage should be offset for the affected commercial laboratories because of the benefits to remaining accredited under TNI.

Requirements More Restrictive than Federal

Please identify and describe any requirement of the regulatory change which is more restrictive than applicable federal requirements. Include a specific citation for each applicable federal requirement, and 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 specific statement to that effect.

There are no applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

Please identify any other state agencies, localities, or other entities particularly affected by the regulatory change. "Particularly affected" are those that are likely to bear any identified disproportionate material impact which would not be experienced by other agencies, localities, or entities. "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.

There are 64 public utilities certified under 1VAC30-45 and six public utilities accredited under 1VAC30-46. None is disproportionately affected by these regulatory revisions.

Economic Impact

Pursuant to § 2.2-4007.04 of the Code of Virginia, please identify all specific economic impacts (costs and/or benefits), anticipated to result from the regulatory change. When describing a particular economic impact, specify which new requirement or change in requirement creates the anticipated economic impact. Please keep in mind that this is change versus the status quo.

Impact on State Agencies

<i>For your agency:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources	Any administrative costs related to the transition can be absorbed within existing resources.
<i>For other state agencies:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	None
<i>For all agencies:</i> Benefits the regulatory change is designed to produce.	The benefits are described in the <i>Issues</i> section above.

Impact on Localities

Projected costs, savings, fees or revenues resulting from the regulatory change.	There are 64 public utilities certified under 1VAC30-45. There are six public utilities accredited under 1VAC30-46. There is no increase in fees. Depending on the laboratory, there is limited or no cost impact from the revisions to 1VAC30-45. The cost impact to the utilities accredited under 1VAC30-46 is the time it
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	will take to transition to meeting the 2016 TNI standards.
Benefits the regulatory change is designed to produce.	The benefits are described in the <i>Issues</i> section above.

Impact on Other Entities

Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.	The proposed revisions to 1VAC30-45 and 1VAC30-46 will affect the environmental laboratories certified and accredited under these regulations. No other entities will be affected.
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: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.	There are 85 environmental laboratories certified under the requirements of 1VAC30-45 as of December 16, 2019. Sixty-four (64) or 75% of these are public utilities; 11 are industrial laboratories; five are laboratories associated with educational institutions; one is a laboratory at a state correctional facility; and another four are laboratories run by the federal government. None of the industrial laboratories is considered a small business. DCLS, as of March 5, 2020, is the primary accreditation body for 48 environmental laboratories. DCLS has direct responsibility and authority to accredit these laboratories. These are the commercial environmental laboratories affected by this action. Thirty-three (69%) of these can be classified as small businesses. The remaining 15 laboratories (31%) are industry (3), public utility (3), university (1), and industrial company (8) laboratories. DCLS has provided secondary accreditation to approximately 89 other laboratories, recognizing TNI accreditation given by other NELAP Accreditation Bodies. These laboratories are not affected by this action.
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Please be specific and include all costs including, but not limited to: a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change; c) fees; d) purchases of equipment or services; and e) time required to comply with the requirements.	(a) The revisions to 1VAC30-45 may reduce recordkeeping costs. There are minimal changes to administrative costs under the 1VAC30-46 revisions. (b) and (d) There are no projected costs related to the development of real estate or to the purchases of equipment or services. (c) DCLS added only one fee. The fee is for a compliance review when a laboratory wishes to resume accreditation after DCLS has suspended a laboratory in total. Suspension in total seldom occurs. (e) The time to comply with the revisions to 1VAC30-45 will be minimal. The time to comply with the revisions to 1VAC30-46 will be minimal. DCLS is allowing six months for the 1VAC30-46 laboratories to make this transition.

<p>Benefits the regulatory change is designed to produce.</p>	<p>The revisions to 1VAC30-45 protect public health and welfare by ensuring that certified environmental laboratories continue to meet the same environmental laboratory standards. The revisions to 1VAC30-46 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.</p>
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Alternatives

Please describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. 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 regulatory change.

DCLS could choose to continue accrediting commercial environmental laboratories to the 2009 TNI standards instead of revising 1VAC30-46 to incorporate the 2016 TNI standards. This would not be a good alternative. First, DCLS would lose its standing as a NELAP-recognized Accreditation Body and commercial environmental laboratories would lose their standing as TNI-accredited laboratories through a nationally-recognized program. The laboratories would have to duplicate accreditation elsewhere in order to hold nationally-recognized accreditation. Second, the 2016 TNI standards provide many improvements over the 2009 TNI standards. The 2016 standards clarify the proficiency testing requirements; improve the sections on method validation, instrument calibration and detection/quantitation limits for chemistry; and contain revised sections for microbiology and radiochemistry.

DCLS could choose to make no changes to 1VAC30-45 as currently written. DCLS however believes the proposed revisions provide additional flexibility and reduction of requirements in some cases, and strengthen data defensibility in others. DCLS also believes that the noncommercial laboratories benefit from the revisions that provide clarity to definitions and consolidation of the suspension and withdrawal of certification requirements of 1VAC30-45.

Regulatory Flexibility Analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) establishing less stringent compliance or reporting requirements; 2) establishing less stringent schedules or deadlines for compliance or reporting requirements; 3) consolidation or simplification of compliance or reporting requirements; 4) establishing 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 regulatory change.

Revised 1VAC30-45 applies to all noncommercial environmental laboratories. None of these laboratories can be classified as small businesses. All these laboratories should meet the same certification standards. Any 1) establishment of less stringent compliance or reporting requirements; 2) establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) consolidation or simplification of compliance or reporting requirements; 4) establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; or 5) exemption of small businesses from all or any part of the requirements contained in the proposed regulation would adversely affect the benefits that would be achieved through the implementation of the regulation.

Revised 1VAC30-46 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.

Public Comment

Please summarize all comments received during the public comment period following the publication of the previous stage, and provide the agency response. Ensure to include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency or board. If no comment was received, enter a specific statement to that effect.

DCLS received no public comments on the NOIRA.

Public Participation

Please include a statement that in addition to any other comments on the regulatory change, the agency is seeking comments on the costs and benefits of the regulatory change and the impacts of the regulated community. Also, indicate whether a public hearing will be held to receive comments.

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 for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at: <https://townhall.virginia.gov>. Written comments must include the name and address of the commenter. Comments may also be

submitted by mail, email or fax to Rhonda Bishton, Regulatory Coordinator, Department of General Services, Attn: DCLS VELAP Revision Comments, 1100 Bank Street, Richmond, VA, 23219. Agency contact: Rhonda Bishton, (804) 786-3311, Rhonda.Bishton@dgs.virginia.gov. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

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

Detail of Changes

Please list all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation.

DCLS made the same changes to several sections in 1VAC30-45 and 1VAC30-46. These changes are described for both revised regulations at the beginning of the chart below. The changes DCLS made separately to the two regulations follow after this section.

Current section number	New section number, if applicable	Current requirement	Change, intent, rationale, and likely impact of new requirements
1VAC30-45-40 and 1VAC30-46-40 B (Definitions)			
		“Analyte” definition specifies the “substance or physical property to be determined.”	Revises definition to specify the “substance, organism, physical parameter, or chemical constituent(s) for which an environmental sample is being analyzed.” This conforms to the 2016 TNI standards definition which adds clarity and specificity.
		“Assessment” means the evaluation process used....to defined criteria.	Adds in 1VAC30-45 the following after criteria: “(i.e., to the standards and requirements of laboratory certification.” In 1VAC30-46, adds in “to” just after “(i.e.,...). These changes conform to the definition in the 2016 TNI standards, specifying the criteria in a clear fashion.
		“Field of proficiency testing” or “FoPT” means “analytes for which a laboratory is required to successfully analyze a PT sample in order to obtain or maintain certification, collectively defined as matrix, technology/method, and analyte.”	Change to “Field of proficiency testing” or “FoPT” means “the matrix, technology/method, and analyte combinations for which the composition spike concentration ranges and acceptance criteria have been established by the Proficiency Testing Program Executive Committee of TNI.” The change conforms to the 2016 TNI standards definition, provides clarity, and specifies the source of the criteria that the laboratory must meet.

Current section number	New section number, if applicable	Current requirement	Change, intent, rationale, and likely impact of new requirements
		<p>“National Environmental Laboratory Accreditation Conference (NELAC)” means a voluntary organization of state and federal environmental officials and interest groups with the primary purpose to establish mutually acceptable standards for accrediting environmental laboratories.</p>	<p>Adds the following sentence for clarity: “NELAC preceded the formation of The NELAC Institute or TNI.”</p>
		<p>“Proficiency test or testing (PT)” means evaluating a laboratory’s performance under controlled conditions...”</p>	<p>Substituted “a process to evaluate” for “evaluating” to make it clear that there are procedures for PTs.</p>
		<p>“Sampling” means the “act of collection for the purpose of analysis.”</p>	<p>Change to “Sampling” means “activity related to obtaining a representative sample of the object of conformity assessment, according to a procedure.” The change conforms to the 2016 TNI definition, provides clarity, and makes it clear that there are procedures for sampling.</p>
<p>1VAC30-45-95 B and 1VAC30-46-95 B</p>	<p>1VAC30-45-95 B 3 and 1VAC30-46-95 B 3</p>	<p>List of reasons to suspend a laboratory</p>	<p>Adds a provision allowing DCLS to suspend certification or accreditation when a laboratory has failed to submit an acceptable corrective action plan after two opportunities. Currently DCLS only has the opportunity to withdraw accreditation or to decertify. This provides DCLS with flexibility to manage the program and provides a laboratory with a less onerous outcome upon failure to correct a problem after two opportunities.</p>
<p>1VAC30-45-95 D and 1VAC30-46-95 D</p>	<p>1VAC30-45-95 D 6 and 1VAC30-46-95 D 6</p>	<p>Responsibilities of the laboratory upon laboratory suspension</p>	<p>Adds a provision requiring a laboratory that DCLS has suspended in total to pay the cost of any follow-up on-site assessments or data review to determine compliance. Total suspension is unusual; the impact should be minimal and is limited to the suspended laboratory.</p>
<p>1VAC30-45-100 B and 1VAC30-46-100 B</p>	<p>1VAC30-45-100 B 3 And 1VAC30-46-100 B 3</p>	<p>Reasons for decertification or withdrawal of accreditation</p>	<p>Adds a provision allowing DCLS to decertify a laboratory or withdraw accreditation when it fails to complete three consecutive PT studies successfully. 1VAC30-45-520 C 6 contains this provision. Adding the provision to 1VAC30-45-</p>

Current section number	New section number, if applicable	Current requirement	Change, intent, rationale, and likely impact of new requirements
			100 B is necessary to complete the conditions for withdrawal. For 1VAC30-46, the 2016 TNI standards reinstated this provision after dropping it in the 2009 TNI standards.
1VAC30-45-100 B and 1VAC30-46-100 B	1VAC30-45-100 B 8 And 1VAC30-46-100 B 8	Reasons for decertification or withdrawal of accreditation	Adds a provision allowing DCLS to decertify a laboratory or withdraw accreditation when it fails to correct the causes of suspension within the term of suspension. 1VAC30-45-95 and 1VAC30-46-95 set out this provision at D. Adding this provision to 1VAC30-45-100 B and 1VAC30-46-100 B completes the list of conditions for decertification and withdrawal.
1VAC30-45-100 B and 1VAC30-46-100 B	1VAC30-45-100 B 13 and 1VAC30-46-100 B 13	Reasons for decertification or withdrawal of accreditation	Adds a provision allowing DCLS to decertify a laboratory when it fails to meet the provisions regarding communication with others in 1VAC30-45-510 C concerning laboratory testing of PT samples. Exchanging information with other labs or asking other labs about running PT samples violates the rules for running PTs. The TNI standards prohibit such communication, making it a reason for withdrawing accreditation.
1VAC30-45-130 A and 1VAC30-46-150 A	1VAC30-45-130 A 4 and 1VAC30-46-150 A 5	Fees	Adds a provision that DCLS shall determine as part of its regular budgetary review whether the fees charged to labs offset the program costs. Section 2.2-1105 of the Code of Virginia requires that the fees charged under the program cover program costs. This provision establishes a process for DCLS to compare fees and costs regularly.
1VAC30-45-130 F and 1VAC30-46-150 E	1VAC30-45-130 F 3 and 1VAC30-46-150 E 3	Fees - Additional	Adds the cost of the review of compliance following total suspension to the list of additional fees DCLS may charge. See 1VAC30-45-95 D and 1VAC30-46-95 D above.
1VAC30-45-			
40 (Definitions)			Adds definition of selectivity. This term is found frequently in the regulation but was not previously

Current section number	New section number, if applicable	Current requirement	Change, intent, rationale, and likely impact of new requirements
			defined. This definition conforms to the 2016 TNI standards definition.
520 B 4		For labs performing supplemental testing, the PT studies shall be at least 15 calendar days apart from the closing date of one study to the shipment date of another study for the same FoPT.	Changes the required spacing of the supplemental PT studies to 7 calendar days instead of 15 days apart and from the closing date of one study to the opening date of another study instead of the shipment date of another study for the same FoPT.
650 E		Requires that “access to archived information shall be documented with an access log.”	Deletes the requirement for an access log because the requirement does not contribute to a quality system. This revision eliminates a requirement.
730 E	730 E 4	Demonstration of capability	Adds a requirement for another successful demonstration of capability following the procedure in 730 F before resumption of testing where an individual in a laboratory has not performed a test in 12 months. This requirement is included in the 2016 TNI standards and should be included for 1VAC30-45 laboratories as well.
760 B 1 a – B 1 c	780 B 1 a – B 1 d	Limit of detection (LOD)	Expands -760 B 1 a – B 1 c, inserting new subdivisions b and c. Strikes current subdivision c. Revises to require determination of the LOD when testing is done using the approved methods in 40 CFR Part 136, except when Appendix B of 40 CFR Part 136 specifies that the procedure is not applicable to a measurement. States the laboratory shall determine the LOD when test results are to be reported to the LOD (versus the LOQ or working range of instrument calibration) according to 1VAC30-45-771 and 1VAC30-45-814. Requires the validity of the LOD be confirmed and sets out how this is to be done.
760 B 2 c		Limit of quantitation (LOQ)-confirming validity of LOQ	Revises this subdivision to clarify the language specifying the concentration of the LOQ for analysis.
771 B		Chemical testing: limit of detection and limit of quantitation.	Eliminates the exception when test results are not reported outside of the calibration range. Adds the

Current section number	New section number, if applicable	Current requirement	Change, intent, rationale, and likely impact of new requirements
		The second sentence of 1VAC30-45-771 B states that “an LOD is not required for a test method when test results are not reported outside of the calibration range.”	requirement for LOD determination and validation as specified by 1VAC30-45-760 B 1.
771 B 3		Chemical testing: limit of detection and limit of quantitation. “The LOD shall be verified annually . . . according to the procedure specified in 1VAC30-45-760 B 1.”	Revises to read “The LOD shall be verified annually for each quality system matrix, method and analyte as specified in 1VAC30-45-760 B 1.
Forms			Revises reference to Application Form to bring it up to date.
Documents Incorporated by Reference			Revises TNI standards list for the 2016 Standards.
1VAC30-46-			
15 A		The current requirement for accreditation is to meet the NELAC standards.	Revises the name of the standards required for accreditation to the NELAC Institute or TNI.
15 B and C		The current language sets out when laboratories must meet the newest set of TNI standards. The current provisions are specific to the transition provided from the 2003 to the 2009 accreditation standards.	Revises the provision to set out the date of the transition from the 2009 to the 2016 TNI Standards.
40 A		The current requirement refers to the 2009 TNI Standards.	Revises the provision to indicate the 2016 TNI standards.
40 B (Definitions)			Adds a definition of the “National Environmental Laboratory Accreditation Program (NELAP).” The definition differentiates NELAP from TNI. NELAP is the program that implements the TNI standards. This addition is beneficial in that it adds clarity to the regulation.
40 B		Definition of “Quality system matrix” is specific to batch and quality control requirements.	Deletes the definition of “Quality system matrix” because it is found in the 2016 TNI standards but not in the text of 1VAC30-46. This definition is not needed in the regulation text.
40 B		Definition of “Secondary accreditation body” or “secondary AB”	Revises the definition for accuracy.

Current section number	New section number, if applicable	Current requirement	Change, intent, rationale, and likely impact of new requirements
40 B		Definition of “TNI standards” refers to the 2009 TNI standards.	Revises to replace the 2009 TNI standards with the 2016 TNI standards.
70 F 3 b		List of the items to be included in the Certificate of Compliance	Adds to the list that the laboratory “shall have access to a copy of the TNI standards incorporated by reference into this chapter.” Currently DCLS asks a laboratory to sign a separate document to this effect. Adding the requirement to the Certificate of Compliance is efficient and reduces the forms needed for application.
140 A		DCLS may grant secondary accreditation to an environmental laboratory that holds current accreditation from another <i>TNI-recognized</i> primary accreditation body.	Revises this provision to substitute “NELAP-recognized” for “TNI-recognized” accreditation body. This change corrects the term.
200 A		The current TNI standards incorporated by reference into this chapter are the 2009 standards.	Revises the incorporation by reference to the 2016 TNI standards. This change brings the accreditation standards up-to-date.
210 B 2		The current TNI standards for proficiency testing include provisions from V2M2 of the 2009 TNI standards.	Deletes the provisions from V2M2 of the 2009 standard. The 2016 TNI standards for proficiency testing at V1M1 include these 2009 provisions. A separate listing of the provisions is not necessary as a result.
220 L 5		Current requirement allows DCLS to withdraw accreditation when a laboratory’s second revised corrective action plan is unacceptable.	Revises to allow DCLS to suspend accreditation as well as to withdraw accreditation.
List of Documents Incorporated by Reference		The current TNI standards incorporated by reference into this chapter are the 2009 standards.	Substitutes the 2016 TNI standards for the 2009 TNI standards. This change brings the accreditation standards up-to-date.