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## Notice of Intended Regulatory Action (NOIRA) Agency Background Document

<b>Agency name</b>	Department of General Services, Division of Consolidated Laboratory Services
<b>Virginia Administrative Code (VAC) citation(s)</b>	1VAC30-45 and 1VAC30-46
<b>Regulation title(s)</b>	Certification for Noncommercial Environmental Laboratories (1VAC30-45) and Accreditation for Commercial Environmental Laboratories (1VAC30-46)
<b>Action title</b>	Revise 1VAC30-46 to meet 2016 TNI Standards and to update requirements in 1VAC30-45 and 1VAC30-46
<b>Date this document prepared</b>	September 18, 2019

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 VAC 7-10), 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 the subject matter, intent, and goals of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an 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) will replace the current 2009 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 intends to revise 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

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 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 combinations 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 which 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.

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.

## 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."*

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DCLS accredits the 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. The 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.

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.*

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### 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 describe the specific reasons why the agency has determined that this regulation is essential to protect the health, safety, or welfare of citizens. In addition, please explain any potential issues that may need to be addressed as the regulation is developed.*

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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 and water pollutant and waste 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 that are being considered, the substantive changes to existing sections that are being considered, or both.*

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The following revisions to both 1VAC30-45 and 1VAC30-46 are being considered:

1. Add to 1VAC30-46-95 B (and 1VAC30-45-95 B) as a cause for suspension, laboratory failure to submit an acceptable corrective action plan after two opportunities. Currently DCLS only has the option to withdraw accreditation.
2. Revise 1VAC30-46-100 (and 1VAC30-45-100) to add as a reason to withdraw accreditation in part or in total laboratory failure to correct the causes for suspension within the term of suspension. The suspension provisions currently contain this language but the withdrawal provisions do not.
3. Revise 1VAC30-46-100 (and 1VAC30-45-100) to add as a reason to withdraw accreditation in part or in total when the laboratory fails three consecutive PT studies, either by failure to participate in the required PT study or due to failure to obtain acceptable results, for the same field of accreditation. The 2009 TNI standards dropped this provision; the 2016 TNI standards reinstated this provision. 1VAC30-45-520 C 6

specifies decertification for this reason; the reason is not included however in 1VAC30-45-100.

4. Revise 1VAC30-46-100 to add as a reason to withdraw accreditation in part or in total when a laboratory violates the provisions regarding communication with others in Volume 1, Module 1, section 4.1.5 of the 2016 TNI standards. Revise 1VAC30-45-100 to add as a reason to withdraw accreditation in part or in total when a laboratory violates the same provisions regarding communication with others in 1VAC30-45-510 C.
5. Revise 1VAC30-46-150 (and 1VAC30-45-130) to include a statement that DCLS as part of its regular budgetary review of the program will determine whether the fees charged under the program offset the program costs as required under §2.2-1105 of the Code of Virginia. This additional provision signals the agency's intent to regularly make this determination and to revise fees when necessary.
6. Revise 1VAC30-46-95 D and 1VAC30-46-150 (and 1VAC30-45-95 D and 1VAC30-45-130) to require a laboratory that DCLS has suspended in total to pay the cost of any necessary follow-up on-site assessments or data review or both to determine compliance. This cost would be calculated under the provisions of 1VAC30-46-150 F (and 1VAC30-45-130 G). Program fees currently do not account for the agency's labor to determine compliance following total suspension.

The following revisions to 1VAC30-46 are being considered:

1. Revise Part II of 1VAC30-46 to incorporate by reference the 2016 TNI standards, replacing the 2009 TNI standards. Revise the definitions in 1VAC30-46-40 in Part I to meet the definitions in the 2016 TNI standards. If needed, revise 1VAC30-46-210 for changes to TNI requirements in Volume 2 of the 2016 TNI Standards.
2. Revise 1VAC30-46-15 to indicate when commercial environmental laboratories will need to meet the 2016 TNI standards.
3. Revise 1VAC30-46-70 F 3 b to add a subdivision to the certification of compliance stating that the laboratory has access to a copy of the TNI standards incorporated by reference into 1VAC30-46. Laboratories are currently required to sign a separate statement to this effect.
4. Revise terms throughout the regulation where appropriate. Along with item 1 above, the regulations will be reviewed to ensure that the terms are accurate and appropriate.

The following revisions to 1VAC30-45 are being considered:

1. Revise the standards in Part II to reflect the changes proposed for 1VAC30-46 commercial laboratories when the changes provide flexibility and reduce the burden on noncommercial environmental laboratories.
2. Add the definition of the term "selectivity" from the 2016 TNI standard to 1VAC30-45-40. This term had never been added to 1VAC30-45 despite its frequent use in the standards in Part II.

3. Revise 1VAC30-45-520 B 4 to provide that PT studies for a laboratory performing supplemental testing should be at least 7 calendar days apart, from the closing date of one study to the opening date of another study for the same field of proficiency testing. This revised requirement is consistent with the 2016 TNI proficiency testing requirement, and provides more flexibility for the laboratory.
4. Revise 1VAC30-45-650 to delete subsection E concerning the requirement for an “access log” to archived records. This requirement does not contribute to a quality system.
5. Revise 1VAC30-45-730 E, adding the requirement to successfully perform the demonstration of capability procedure outlined in 1VAC30-45-730 F, in the case where an individual has not performed a method in a 12-month period. This requirement is included in the 2016 TNI Standards and also should be included in 1VAC30-45.
6. Revise 1VAC30-45-760 B 1 c to eliminate the exemption to performing MDL if not reporting below reporting limit or LOD. Revise 1VAC30-45-771 B to eliminate the exemption to performing MDL if not reporting outside the calibration range. Calculation of MDL per 40 CFR 136 would be required or the MDL would be done by method specifications. EPA in its 2017 Methods Update Rule emphasizes the use of MDLs and does not offer exemptions if not reporting outside the calibration range.
7. Revise terms throughout the regulation where appropriate.

## 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, 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 completely rewritten sections for microbiology and radiochemistry. Second, the commercial environmental laboratories would lose their national standing as TNI-accredited laboratories and would have to reapply for accreditation elsewhere.

DCLS could choose to make no changes to 1VAC30-45 as currently written. DCLS believes however that certain aspects of the standards can be revised to be more flexible. DCLS is revising Part II of 1VAC30-46 to meet the 2016 TNI standards. DCLS believes it would be advantageous to the noncommercial laboratories to make similar changes to the standards in Part II of 1VAC30-45 when these standards provide more flexibility for the noncommercial laboratories.

DCLS is also considering making changes to the procedures in 1VAC30-46. Where these procedures are the same in 1VAC30-45, DCLS believes it is important to keep these procedures the same for both regulations so that the program may be carried out efficiently.

### Periodic Review and Small Business Impact Review Announcement

*If you wish to use this regulatory action to conduct, and this NOIRA to announce, a periodic review (pursuant to § 2.2-4017 of the Code of Virginia and Executive Order 14 (as amended, July 16, 2018)), and a small business impact review (§ 2.2-4007.1 of the Code of Virginia) of this regulation, keep the following text. Modify as necessary for your agency. Otherwise, delete the paragraph below and insert “This NOIRA is not being used to announce a periodic review or a small business impact review.”*

This NOIRA is not being used to announce a periodic review or a small business impact review.

### Public Participation

*Please indicate how the public should contact the agency to submit comments on this regulation, including ideas to assist the agency in the development of the regulation and the costs and benefits of the alternatives stated in this notice or other alternatives.*

*Also, indicate whether a public hearing is to be held to receive comments. Please include one of the following choices: 1) a panel will be appointed and the agency’s contact if you’re interested in serving on the panel is \_\_\_\_\_; 2) a panel will not be used; or 3) public comment is invited as to whether to use a panel to assist in the development of this regulation.*

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The agency is seeking comments on this regulation, including but not limited to: ideas to be considered in the development of this regulation, the costs and benefits of the alternatives stated in this background document or other alternatives, and the potential impacts of the regulation. The agency is also 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) the probable effect of the regulation on affected small businesses; and 3) the description of less intrusive or costly alternatives for 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://www.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. 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 the proposed stage of this regulatory action. A panel will not be used.