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# Final Regulation
# Agency Background Document

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| **Agency name** | Department of General Services, Division of Consolidated Laboratory Services |
| **Virginia Administrative Code (VAC) citation(s)** | 1VAC30-45 |
| **Regulation title(s)** | Certification for Noncommercial Environmental Laboratories |
| **Action title** | Revise regulation to update procedural and fee requirements |
| **Date this document prepared** | January 7, 2016 |

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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.*

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

The proposed action does the following:

1. Streamlines the procedures for application and renewal of certification.
2. Reduces the requirement to perform proficiency test studies to one study annually for each field of certification.
3. Expands the time between on-site assessments from two to three years for laboratories regularly meeting certification standards.
4. Eliminates requirements for specialized testing that noncommercial laboratories currently do not perform.

5. Adds procedures for suspension of certification to provide a laboratory time to correct problems to avoid decertification.
6. Makes explicit the requirements to notify a laboratory that the agency has cause to deny certification or to decertify.
7. Simplifies the appeal procedure language.
8. Restructures and modifies the fee system and the fees paid by laboratories.
9. Eliminates or provides increased flexibility for a number of quality system (Article 4) provisions.

## Acronyms and Definitions

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

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

"DGS" is the Virginia Department of General Services.

"DEQ" is the Virginia Department of Environmental Quality.

"FoPT" is field of proficiency testing.

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

"NELAC" is the National Environmental Laboratory Accreditation Conference.

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

## 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 regulations on February 9, 2016. The regulations are entitled Certification for Noncommercial 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 (DGS) to prescribe regulations necessary or incidental to the performance of the Department's duties or execution of powers conferred by the Code.

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

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

## Purpose

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

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

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

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

The original estimate of laboratories that would be covered by the program was based on limited information provided by DEQ and other sources. Using this information, DCLS estimated the number of in-house and commercial laboratories that were serving DEQ permit holders. This estimate proved to be

too high and the resulting fees, based on these estimates, are too low. The revised fees are based on the number of laboratories currently certified under the program.

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

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

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

Noncommercial environmental laboratories perform proficiency tests (PT) quite well. From 2010 through 2015, these laboratories had a 97.7 percent success rate performing PT studies. Through this experience DCLS has determined that reducing the annual requirement for two proficiency test studies for each Field of Certification to one proficiency test study will reduce the cost of the program for the laboratories and for the agency without reducing the benefit gained from the certification program.

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

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

## Substance

*Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both.*

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

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

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

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

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

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

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

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

8. The frequency of on-site assessment for certified laboratories is expanded to a three-year cycle for laboratories regularly meeting certification requirements. DCLS will maintain the two-year on-site assessment schedule for all other laboratories.

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

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

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

## Issues

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

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

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

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

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

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

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

## Requirements more restrictive than federal

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

There are no applicable federal requirements.

## Localities particularly affected

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

As of January 1, 2016, there are 101 noncommercial environmental laboratories certified under the standards of 1VAC30-45. Of these 67 are local government laboratories. None of these is disproportionately affected by the revisions to 1VAC30-45.

## Family impact

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

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

## 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 |
|---|---|---|---|
| 1VAC30-45-300 | Reassessment of certified laboratories is required every two years. | Reassessment of certified laboratories is required every three years except for those laboratories having difficulties obtaining acceptable PT results or difficulties in meeting the standards and those laboratories that have had their certification suspended in whole or in part. These laboratories will be reassessed every two years. | The change provides flexibility for both the agency and the laboratories in maintaining the certification standards. |
| 1VAC30-45-400 C 3 | Deletes the provision requiring DCLS to provide the checklist used by the agency during the on-site assessment to the laboratory with the final on-site assessment report. | The provision is reinstated with the addition that DCLS will provide the marked or completed checklist used during the on-site assessment upon request. | The change allows the laboratories to have a copy of the marked checklist while limiting the provision of the checklist to laboratories requesting it instead of to all laboratories. |

| Section number | Requirement at proposed stage | What has changed | Rationale for change |
|---|---|---|---|
| 1VAC30-45-520 C 1 | Requires a laboratory that has received a "not acceptable" PT study result to determine the cause for the failure and perform and document corrective action within 30 days of receiving the "not acceptable" PT study result. | Adds a provision allowing DCLS to extend the time for corrective action and documentation. | The addition gives DCLS the flexibility to provide laboratories additional time to complete a corrective action and documentation. |
| 1VAC30-45-520 C 5 | Requires laboratories to complete their annual PT studies by December 31. | Adds clarifying language indicating that the complete PT study includes any corrective action and makeup PT study. | The additional language ensures the laboratories understand what must be done by December 31 each year. |
| 1VAC30-45-730 D 1 | Requires laboratories to use the latest valid edition of a test method unless it is not appropriate to do so. | Deletes the requirement. | The requirements for test methods are sufficient without the requirement to use the latest valid edition of a test method. |
| 1VAC30-45-730 E 4 and G | Requires laboratories to document demonstration of capability (DOC) through the use of a certification statement. | Deletes the requirement for the certification statement. Retains the requirement for specific documentation that the laboratory is to maintain for the DOC. | The revision eliminates the requirement for the certification statement while retaining the current documentation requirements. |

## 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 |
|---|---|---|
| Virginia Association of Municipal Wastewater Agencies (VAMWA),<br><br>Spotsylvania County Laboratory Services Division (SCLSD),<br><br>Augusta County Service Authority (ACSA) | Support statements for various aspects of the proposed revisions to 1VAC30-45<br>• Supports removing references to the initial certification period<br>• Supports streamlining the application and renewal process<br>• Supports modifications of the certification standards to ensure that noncommercial labs are required to meet standards no more stringent that the commercial labs.<br>• Supports the addition of procedures to temporarily suspend certification in lieu of decertification. This allows laboratories time to correct deficiencies.<br>• Supports the reduction of the requirement for proficiency test studies | DCLS appreciates the commenters' support. |

| Commenter | Comment | Agency response |
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| | from two per year to one per year for each field of certification. This change has multiple benefits including cost savings. | |
| SCLSD | Program Support<br>• The commenter appreciates the hard work and dedication of DCLS staff. The program is necessary to guarantee that all noncommercial labs are held to the same standards.<br>• The commenter hopes the new fee structure brings enough additional revenue to bring on another assessor. The one-on-one time between lab and assessor is incredibly important and useful. | DCLS appreciates the commenter's support. |
| SCLSD | Onsite assessment schedule<br>The commenter supports the current schedule of inspections once every two years. The commenter would consider supporting a three-year inspection cycle but not a risk-based strategy as VAMWA and ACSA suggest. | DCLS appreciates the commenter's support. |
| VAMWA, ACSA | Onsite assessment schedule<br>VAMWA proposes modeling the schedule of inspections after the Virginia Department of Environmental Quality's (DEQ's) Risk Based Inspection Strategy. The two-year cycle of onsite assessments should be for those labs having issues.<br>ACSA agrees with VAMWA risk-based assessment strategy and suggests a 3-year cycle for those labs not having issues. This follows the assessment cycle for drinking water labs. The inspection frequency could remain on a 2-year schedule if a laboratory had specific issues. | DCLS has revised 1VAC30-45-300 A pertaining to frequency of on-site assessment. DCLS will conduct an on-site assessment for certified laboratories every three years. DCLS will maintain a two-year on-site assessment cycle for laboratories that trigger one or more of six circumstances .These circumstances include difficulty obtaining acceptable PT study results and suspension of certification. DCLS believes this flexible scheduling for on-site assessment will be beneficial for the laboratories and the agency. |
| VAMWA, SCLSD, Upper Occoquan Service Authority (UOSA) | Process to suspend certification<br>The commenters suggest the following substitution for 1VAC30-45-95 C 5*: DCLS may allow the laboratory time to implement an approved corrective action plan to remediate the problem . . ..* This change allows more flexibility for both DCLS and the laboratory to | DCLS believes the flexibility requested by the commenters already exists in the regulatory language. The language provides that "DCLS may allow the laboratory" a specific amount of time to correct the problem for which the laboratory may be suspended. |

| Commenter | Comment | Agency response |
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| | correct deficiencies. | The language does not require DCLS to limit the time allowed for the correction. DCLS "may" allow the laboratory more time based on the laboratory's history or the specific problem to be addressed by the laboratory. No change has been made to the regulation based on this comment. |
| SCLSD, VAMWA, UOSA | <u>Documentation of onsite assessment</u><br>The revised regulation deletes 1VAC30-45-400 C 3.<br>1. VAMWA and SCLSD would like assurance that the checklists completed by assessors during the onsite assessment will be available to the lab. The marked checklists are an important tool to help labs understand findings and troubleshoot solutions with assessors during the onsite visit.<br>2. VAMWA and UOSA would like to confirm that labs will continue to have advance access to current onsite assessment checklists and be permitted to read and copy completed/marked checklists before the onsite assessment personnel depart. This would be helpful to the labs to respond promptly to any noted problems and to ask clarifying questions.<br>3. UOSA proposes that the provision to provide the completed/marked checklists to labs with the final onsite assessment report remain in the regulation. | DCLS has restored 1VAC30-45-400 C 3 and added the phrase "upon request" to provide the marked checklists to those laboratories that want a copy of these checklists. |
| VAMWA, SCLSD, UOSA | <u>Procedure and requirements for "not acceptable" PT study results.</u><br>VAMWA and SCLSD suggest the following substitution for 1VAC30-45-520 C 1: *The corrective action plan shall be prepared . …*<br>The proposed language is unclear as to what must be completed within 30 days. Is this the completion of a correction action plan or the report of how the corrective action was completed? This substitution provides labs with the opportunity to develop a corrective action plan and to execute that plan prior to the established deadline of Dec. 31.<br>UOSA suggests the following substitution for 1VAC30-45-520 C 1: "Corrective action shall begin after a "not acceptable" PT study result, documented, and provided upon request by DCLS once completed." UOSA believes it is not reasonable to expect a lab to complete a corrective action on a "not acceptable" PT study within 30 days. Some labs may perform non-routine tests infrequently during the calendar year and would need more time for corrective action. | 1VAC30-45-520 C 1 states: *When a lab receives a PT study result of "not acceptable," the lab shall determine the cause for the failure and perform and document corrective action. The corrective action documentation shall be completed within 30 days of receiving the "not acceptable" PT study result and be submitted to DCLS upon request.*<br><br>While DCLS believes 30 days is sufficient time to take corrective action and document that action, the agency is providing some flexibility for the laboratories by adding language to 1VAC30-45-520 C 1 as follows: *DCLS may extend the time for corrective action and documentation.*<br><br>This addition provides an option for those laboratories that may need more time to take corrective action and document it. |

| Commenter | Comment | Agency response |
|---|---|---|
| VAMWA, SCLSD, UOSA | Procedure and requirements for "not acceptable" PT study results.<br>The commenters suggest the following substitution for 1VAC30-45-520 C 5: *DCLS shall not extend the period for makeup PT study completion . . ..* The suggestion is made to provide clarification for consistency. | DCLS has revised 1VAC30-45-520 C 5 to clarify the phrase "failure to satisfactorily complete a PT study by December 31." Language is added to indicate that satisfactorily completing a PT study includes any corrective action and makeup PT study. |
| VAMWA, UOSA | Test methods.<br>1VAC30-45-730 D 1. The addition of a requirement to use the latest valid edition of a test method appears to be inconsistent with applicable DEQ regulations and VPDES permits. This additional requirement should be deleted. | DCLS has deleted the language that had been added to 1VA30-45-730 D 1. The requirements for test methods are sufficient without the requirement to use the latest edition of a test method. |
| VAMWA, SCLSD, UOSA | Certification statement for demonstration of capability.<br>1VAC30-45-730 G. The proposed regulation retains the certification statement requirement for demonstration of capability. Instead the commenters suggest deleting the current language of -730 G and substituting the following: "Each demonstration of capability will be documented and certified according to laboratory procedures." Making this change simplifies the process and reduces administrative tasks. Making this change would be consistent with recently revised 1VAC30-46. | DCLS agrees with the commenters that a certification statement for the demonstration of capability need not be retained. The documentation to be retained by the laboratory for the demonstration of capability is detailed in the revision to 1VAC30-45-730 G. The reference to the certification statement in 1VAC30-45-730 E 4 has been revised appropriately. |

1. Virginia Association of Municipal Wastewater Agencies (VAMWA): comments received directly
2. Spotsylvania County Laboratory Services Division (SCLSD): comments received directly and on Town Hall (duplicate comments)
3. Augusta County Service Authority (ACSA): comments received on Town Hall
4. Upper Occoquan Service Authority (UOSA): comments received on Town Hall

Other comments

Two other commenters posted comments on Town Hall. Their comments concerning mental health programs are not relevant to this rulemaking.

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

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

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

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

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| | 95 | | Creates 1VAC30-45-95 on suspension of certification. DCLS currently provides for suspension through guidance and is adding these provisions to 1VAC30-45.<br>DCLS can suspend certification prior to withdrawing certification. Suspension is beneficial to laboratories. The process allows the laboratory faced with decertification a chance to correct its deficiencies. Suspension is allowed for five specific reasons listed in subsection B. DCLS will use the procedures set out in subsection C.<br>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.<br>Subsection D sets out the responsibilities for the agency and the laboratory once DCLS suspends a lab. This includes the consequences when a laboratory does not correct its deficiencies within the six-month suspension period. |
| 100 B 2 | | Specifies two of the reasons for decertification | Subdivision 100 B 2 is revised to simplify the language of the requirement. |
| | 100 B 9 and B 10 | 1VAC30-45-100 B lists the reasons why DCLS may withdraw certification from an environmental laboratory. | Adds 1VAC30-45-100 B 9 and B 10. These two reasons are not new and found elsewhere for withdrawing certification. |
| 100 D | | Section title | Revised to use the term "decertification." |
| 100 D 2 | | States that DCLS shall issue an addendum to an certification certificate when it withdraws certification in part. | Revises the provision to state that DCLS shall issue a revised certificate rather than an addendum to the original certificate. This change reflects current DCLS practice. |
| | 100 D 3 | | Adds a provision to state that the environmental laboratory shall not continue to analyze samples or report analyses for the fields of certification for which DCLS has withdrawn certification. This provision is implied by the fact that DCLS has withdrawn certification. The addition of the provision ensures clarity on this point. |
| 100 E | | States that a laboratory that has corrected the reason for certification may reapply for certification. | Adds a phrase to indicate the application would be made under 1VAC30-45-70. |
| 110 | | Sets out the procedures DCLS uses to deny or withdraw certification. | 1. Revises the entire section deleting references and discussion in subsection A and entirely deleting subsections B and C pertaining to informal fact finding and informal discussions prior to an informal fact finding. Adds a new subdivision B that provides a laboratory |

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| | | | may appeal a final decision to deny or withdraw pursuant to the Administrative Process Act (APA).<br>2. Rewrites subsection A, adding subdivisions 2 - 6. This subsection specifies how DCLS will notify a laboratory when the agency determines it has cause to deny or to decertify and what DCLS shall include in its notice. Subsection A also specifies the action a laboratory must take if it believes DCLS is incorrect in its determination.<br>3. DCLS is revising this section to simplify and make clear the actions that must take place when the agency believes it should deny or withdraw certification. The change to the appeals language, deleting the current subsections B and C and adding a new B properly references the APA rather than describing some of its provisions. |
| 130 | | Sets out the provisions on fees. | The fee provisions are revised extensively.<br>1. The fees are charged annually instead of every two years.<br>2. The maximum fee is omitted. The maximum fee is currently quite low and does not reflect the cost of certification.<br>3. The simple test procedure (STP) laboratories will be charged an annual flat fee of $600. This amount is the current maximum fee which most STP labs pay every two years. The fee of $600 has not covered the cost of the on-site assessment of most STP laboratories much less the review and oversight of proficiency testing for these laboratories.<br>4. The fees for general environmental laboratories will still be structured using base fees and test category fees. These fee concepts have been expanded. Base fees as well as the test category fees are now differentiated by the number of test methods for which the laboratory is certified. The base and test category fees are revised to account for the number of field of certification matrices for which the laboratory is certified. These expanded base fees and test category fees are set out in two tables. Using this approach better reflects the true cost of certifying these laboratories. The more testing a laboratory does, the more costly it is to certify the laboratory.<br>5. The minimum and maximum fees for review of a transfer of ownership in subdivision F 2 are deleted. The actual cost of the review will be charged.<br>6. The additional fees described for a request to consider multiple noncontiguous laboratory sites as one site are deleted because the provision in 1VAC30-45-60 B 3 is being deleted (see above). |

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

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| 530 | | Special requirements for aquatic toxicity PTs. | Deletes these requirements. Current noncommercial laboratories do not perform these specialized tests. |
| | 600 C | Requirement for personnel to know the quality system documentation and to implement its policies and procedures | Adds language to clearly require that laboratory personnel be made aware of, understand, and implement the quality system documentation including its policies and procedures in their work. While implied this requirement had not previously been stated in the regulation. |
| 610 B and C | 610 C | The elements of a quality manual are specified. | The list containing the elements of a quality manual is revised and placed into two sections. The first are required items to be included in the manual. The second are items that may either be included in the manual or referenced in the manual. This change is based on relaxed TNI standards. In addition, a new element for the quality manual is added: a policy addressing the use of unique electronic signatures, but only where applicable. |
| 720 E | | Sets out the records that must be kept for each major item of equipment. | Deletes the requirement to keep records of the date received and date placed in service and the requirement to record if available the condition of the equipment when received. This change is based on a relaxed TNI standard. |
| 730 C 2 | | Sets out requirements for laboratory methods manuals. | Deletes references to laboratory methods manuals and substitutes standard operating procedures (SOPs). Makes minor revisions for clarity. This change is based on a relaxed TNI standard. |
| 730 E | | Sets out requirements for demonstration of capability (DOC) | Adds "initial" to subdivision 1 and "ongoing" to subdivision 2 to designate the difference between the two requirements. In subdivision 3, substitutes "at least one year prior to application" for "before July 1999" as the grandfather date when an initial DOC is not required. In subdivision 4, deletes the requirement for a certification statement as set out in 1VAC30-45-730 G and notes that DOCs must be documented as specified in revised subsection G. In subdivision 5, specifies that a change in a test method also means the addition of an analyte to a certified test method (FoC). Deletes the work cell requirements in subdivision 6. |
| 730 G | | Provides the certification statement required for the DOC. | Deletes the requirement for the certification statement and requires the laboratory only to keep the pertinent documentation for the DOC. This revision eliminates the need for the certification statement but retains the previous documentation requirement as specified. |
| 730 J 2 | | Sets out requirements for documentation and labeling of standards and reagents. | The documented procedures required for original containers are revised to label the container with an expiration date only if the date is provided by the manufacturer. This change is based on a relaxed TNI standard. |

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| 740 D 1 d | | Sets out standards for support equipment used in laboratory operations. | Clarifies language condition used for checking support equipment. "On each day the equipment is used" is substituted for "prior to use on each working day." This change is based on a TNI standard that clarifies the requirement. |
| 750 B | | States that 1VAC30-45-760 through 1VAC30-45-829 set out the essential quality control requirements for specific types of testing. | Currently certified noncommercial laboratories do not perform toxicity, radiochemical, or asbestos testing. Those specific sections are deleted in this proposal (see below). The revision here substitutes the 2009 TNI Standards requirements for any noncommercial laboratory that wishes to become certified for these types of testing. |
| 760 A 1 | | Requires labs to follow quality control protocols specified by the lab's method manual. | Substitutes "method SOPs" for "method manual." This change is based on a TNI standard that clarifies the requirement. Laboratories must have methods SOPs for their test methods but these SOPs do not have to be gathered into a methods manual. |
| 770 B 3 b and D 3 b(2) | | Sets out positive controls for chemical testing | Corrects errors. The provisions currently indicate for methods that include 11-20 targets, components should be spiked "at least 10% or 80%, whichever is greater." The provision is corrected to read "at least 10 or 80%, whichever is greater." |
| 771 B 3 | | Sets out limit of detection for chemical testing | Deletes the requirement for established procedures to relate limit of detection with limit of quantitation. This change is based on a relaxed TNI standard. |
| 775 B | | Chemical testing. Requires glassware to be cleaned to meet the sensitivity of the test method. | Deletes the requirement. The requirement is not needed because method blanks verify cleanliness. This change is based on a relaxed TNI standard. |
| 780 through 789 | | Sets out quality control requirements for toxicity testing. | Deletes these requirements because current noncommercial laboratories do not perform this type of testing. If any noncommercial laboratory wants to become certified for toxicity testing, the lab will need to meet the 2009 TNI standards for toxicity testing. See revision to 1VAC30-45-750 B. |
| 791 A 2 | | Sets out sterility checks and balances for the filtration technique for microbiological testing. | Revises procedure to require one beginning and one ending sterility check for each filtration series rather than each laboratory sterilized filtration unit used in the filtration series. This change is based on a relaxed TNI standard. |
| 791 A 4 | | Sets out requirements for sterility checks on sample containers for microbiological testing. | Requires labs to perform sterility checks on sample containers using nonselective growth media. The current provision is not clear with respect to what a lab should use to perform the sterility check for purchased, presterilized containers. |
| 796 F | | Sets out requirements for procedures for media, | Deletes the requirement to document the amount of the media received when the lab purchases it pre-prepared |

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| | | solutions and reagents for microbiological testing. | and ready to use. This change is based on a relaxed TNI standard. |
| 798 B 2 d | | Sets out requirements for autoclave maintenance for microbiological testing. | Relaxes the requirement for annual maintenance of autoclaves if a laboratory can demonstrate regular monitoring of pressure and annual calibration of the maximum registering thermometer. |
| 798 B 6 a | | Sets out requirements for incubators and water baths for microbiological testing. | Revises the provision on temperature distribution in incubators and water baths to require only that the uniformity (and not the stability) of temperature be established. Eliminates need to determine the time required to reestablish equilibrium conditions. This change is based on a relaxed TNI standard. |
| 800 through 808 | | Sets out quality control requirements for radiochemical testing. | Deletes these requirements because current noncommercial laboratories do not perform this type of testing. If any noncommercial laboratory wants to become certified for radiochemical testing, the lab will need to meet the 2009 TNI standards for radiochemical testing. See revision to 1VAC30-45-750 B. |
| 811 B | | Requirements for laboratory control samples for air testing. | Deletes the requirement to notify the client prior to the start of analysis if a calibration solution must be used for the laboratory control sample. This change is based on a relaxed TNI standard. |
| 820 through 829 | | Sets out quality control requirements for asbestos testing. | Deletes these requirements because current noncommercial laboratories do not perform this type of testing. If any noncommercial laboratory wants to become certified for asbestos testing, the lab will need to meet the 2009 TNI standards for asbestos testing. See revision to 1VAC30-45-750 B. |
| 850 3 b | | Sets out thermal preservation requirements for samples. | Revises the requirements. Thermal preservation in the field is not required if the lab receives the sample and either begins the analysis or refrigerates the sample within 15 minutes of collection. This change is based on a relaxed TNI standard. |