



## Final Regulation Agency Background Document

<b>Agency name</b>	Department of General Services Division of Consolidated Laboratory Services
<b>Virginia Administrative Code (VAC) citation</b>	1 VAC 30, Chapters 45 and 46
<b>Regulation title</b>	Certification for Non-Commercial Environmental Laboratories (Chapter 45) and Certification for Commercial Environmental Laboratories (Chapter 46)
<b>Action title</b>	Virginia Environmental Laboratory Certification Program
<b>Document preparation date</b>	January 10, 2005

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 21 (2002) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

### Brief summary

*Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.*

The new regulations establish the certification program required by §2.2-1105 of the *Code of Virginia* for environmental laboratories submitting data to the Department of Environmental Quality (DEQ) under the state's air, water and waste laws. There are two regulations, one for non-commercial environmental laboratories (Chapter 45) and one for commercial environmental laboratories (Chapter 46).

The agency has made changes to the regulations since publication of the proposed regulations. Some of the changes made to the regulations were substantive. The agency therefore provided a second public comment period of thirty days (September 20 – October 20, 2004) after publishing a general notice in the *Virginia Register of Regulations* (Sept. 20, 2004). The substantive changes to the proposed regulations are as follows:

- Addition to Chapter 45 of specific quality control requirements for different types of testing (in lieu of generic requirements).
- Revision to the fees in both regulations.

- In Chapter 45, substitution of matrix, technology/method, and analyte/analyte group in the definition of field of testing for program, method and analyte.
- In Chapter 46, limiting certification to 12 months instead of 24 months.
- In Chapter 46, substitution of the 2003 NELAC standards for the 2002 NELAC standards.
- Addition of one year to the establishment of the program (when laboratories must be certified to submit data to DEQ).

### 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 environmental laboratory certification regulations on March 17, 2005. The regulations are entitled Certification for Non-Commercial Environmental Laboratories (Chapter 45) and Certification for Commercial Environmental Laboratories (Chapter 46).

### Legal basis

*Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter numbers, if applicable, and (2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.*

Section 2.2-1102 A 1 of the *Code of Virginia* (Title 2.2, Chapter 1) authorizes the Department of General Services to promulgate regulations as necessary to perform the duties conferred upon it by law. Section 2.2-1102 A 2 authorizes the Department of General Services to establish and collect fees when general funds are not applicable. Section 2.2-1105 gives the Division of Consolidated Laboratory Services (DCLS) the authority to promulgate regulations establishing a program for the certification of environmental laboratories.

The statutory provisions cited above can be found at the following web addresses:

<http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+2.2-1102>

<http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+2.2-1105>

Section 2.2-1105 A of the *Code of Virginia* (Title 2.2, Chapter 11) requires that DCLS establish by regulation a program to certify laboratories conducting any tests, analyses, measurements, or monitoring required pursuant to the State Air Pollution Control Board (§10.1-1300 *et seq.*), 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 A requires that the program include minimum criteria for the following: (1) laboratory procedures; (2) performance evaluations; (3) supervisory and personnel requirements; (4) facilities and equipment; (5) analytical quality control and quality assurance; (6) certificate issuance and maintenance; (7) recertification and decertification; and (8) granting full and partial exemptions from the program based on compliance and performance. Other

criteria may be included. Section 2.2-1105 A states further that regulations shall be proposed only after national accreditation standards are adopted by the National Environmental Laboratory Accreditation Conference. The last sentence of §2.2-1105 A specifies the purpose of the program: “to ensure that laboratories provide accurate and consistent tests, analyses, measurements and monitoring so that the goals and requirements of [Virginia’s air, waste and water laws] may be met.” Section 2.2-1105 B states that once the certification program is established, laboratory certification is required before any tests, analyses, measurements, or monitoring performed by a laboratory may be used for the purposes of Virginia’s air, waste or water laws. Section 2.2-1105 C requires that a fee system be established to pay for the costs of certifying laboratories under the program. Section 2.2-1105 D requires the program to include procedures for determining the qualifications of out-of-state laboratories to conduct tests, analyses, measurements or monitoring for use in Virginia. Environmental laboratories located outside Virginia that are certified or accredited under a program determined by DCLS to be equivalent to Virginia’s program must be deemed to meet the certification requirements established under §2.2-1105. Section 2.2-1105 E requires that DCLS must deny certification to or decertify laboratories found to be falsifying data or providing false information to support certification. Section 2.2-1105 F allows any laboratory subject to the regulations to petition the Director of DCLS for a reasonable variance from the requirements of the regulations. The director may grant a petition if the petitioner demonstrates to the Director’s satisfaction that the variance will meet the goals and purposes of the statute or the regulations and will not conflict with federal or state law or regulations.

**Purpose**

*Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons it 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.*

The proposed regulations fulfill the mandate of §2.2-1105 of the *Code of Virginia* to establish a program to certify laboratories conducting tests, analyses, measurements, or monitoring required pursuant to the State Air Pollution Control Board (§10.1-1300 *et seq.*), 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 specifies that the purpose of the program is “to ensure that laboratories provide accurate and consistent tests, analyses, measurements and monitoring . . .” required by these laws.

Compliance with the laws of the State Air Pollution Control Board, the State Water Control Law and the Virginia Waste Management Act is determined, to a great extent, by the analysis of samples and other measurements taken of Virginia’s air, water and terrain. Accurate and consistent analysis of these samples is a critical component of the determination of compliance with Virginia’s air and water quality and waste management laws.

Prior to 1997, there were no requirements to certify laboratories conducting tests, analyses, measurements or monitoring required by Virginia’s environmental laws. The Department of Environmental Quality (DEQ) audits a limited population of wastewater laboratories as part of the Virginia Pollutant Discharge Elimination Program (VPDES). These audits are part of the overall inspection program carried out by DEQ’s water staff.

The 1997 General Assembly passed §2.1-429.01, now §2.2-1105, requiring the establishment of an environmental laboratory certification program in response to findings of the January 1997 report by the Joint Legislative Audit and Review Commission (JLARC), Review of the Department of Environmental Quality (House Document No. 67)[the Report]. JLARC in its review of the DEQ's water program on pages 56-61 of the Report, focused on three related problems.

First, JLARC found that source-reported monitoring data were not always accurate. The DEQ determines compliance with water permits mainly through data received in Discharge Monitoring Reports (DMR). Permittees are responsible to provide these data. The DEQ reviews the quality of the DMR data received through use of performance test samples that the permittees must analyze. The JLARC report at page 57 discusses this process:

The EPA-driven Discharge Monitoring Report-Quality Assurance (DMR-QA) program serves as a check on the source-reported DMR data through use of Performance Evaluation (PE) samples sent to the analyzing laboratories (both commercial and source-run) to emulate possible effluent samples from the permitted source. This program is administered to all major sources and a handful of minor sources chosen by DEQ. The samples are analyzed by the laboratories and the results are sent back to EPA for comparison with the actual make-up of the samples. This program has been in existence since 1980 and is conducted on an annual basis. States are examined for their permitted facilities' ability to analyze all parameters correctly (meaning the results of all analyses are within the acceptable confidence interval for the actual make-up of the sample), as well as the overall level of correct analyses among the permitted facilities.

JLARC demonstrated that the ability of Virginia permittees to report data accurately had been diminishing over time. In 1995, the last completed report at the time of the Report, less than 50 percent of Virginia permittees had acceptable results for all parameters.

Second, JLARC discussed problems that DEQ had experienced over time with permittees falsifying DMR data. JLARC indicated DEQ had no systematic way to check for report falsification. While DEQ investigated when their inspectors detected possible falsification and enforced when it was found, the agency was concerned about the time it sometimes took to uncover these problems.

Third, JLARC discussed the need for and benefits of a laboratory certification program in Virginia. Because "there are no minimum requirements for operation of laboratories for VPDES sample analysis . . . this adds to the question of the validity of source-reported effluent data." The DEQ audits laboratories to determine the quality of the laboratories' data. The audits are limited both in the number of laboratories audited and in the frequency of the audits. The laboratories audited are permittee laboratories and commercial laboratories used by permittees. JLARC discussed DEQ's lack of authority to limit permittees' use of commercial laboratories that do not perform well. DEQ can address the problem only through the permittee. The permittee may then use another commercial laboratory. The problematic commercial laboratory is still free, however, to provide analytical services to other permittees who are not aware of the problems at this laboratory.

JLARC listed the benefits of a laboratory certification program on page 60 of the Report:

- direct control over analytical activity by the regulatory agency;
- greater assurance that the reported data are accurate and representative of the discharge;
- minimum standards of quality; and
- improved control of factors influencing the quality of the environment.

JLARC in Recommendation 20 of the Report, stated the following:

The General Assembly may wish to consider studying the adoption of a laboratory certification program for laboratories wishing to conduct sample analyses for environmental permit holders in the Commonwealth. The General Assembly should consider including Virginia laboratories in any national certification or accreditation programs that may be developed if these national programs are determined to be adequate to meet the needs identified for Virginia.

Section 2.2-1105 of the *Code of Virginia* was the ultimate result of this recommendation.

Section 2.2-1105 A specifies that regulations shall be proposed only after national accreditation standards are adopted by the National Environmental Laboratory Accreditation Conference (NELAC). The standards adopted by NELAC provide the minimum standards recommended by JLARC in its report. The purpose of NELAC is “to foster the generation of environmental laboratory data of known and documented quality in a cost-effective manner through the development of nationally accepted standards for environmental laboratory accreditation.” NELAC 2001 Standards, page 1 of Chapter 1, Policy, Program and Structure.

Environmental permittees and regulatory agencies use hundreds of standardized test methods that are required under federal environmental laws to determine compliance with environmental laws and regulations. Environmental laws set limits for pollutants being released into the air, water and soil. Test methods provide a uniform and consistent way of determining whether the sources of pollutants (industrial facilities, wastewater treatment facilities run by local governments, etc.) exceed the limits set in their permits.

The NELAC standards and individual state certification or accreditation programs for environmental laboratories use quality assurance and quality control measures to determine whether environmental laboratories operate uniformly and consistently. Quality assurance is defined by EPA's Quality Assurance Management Group as “an integrated system of activities involving planning, quality control, quality assessment, reporting, and quality improvement to ensure that a product or service meets defined standards of quality with a stated level of confidence.” NELAC 2001 Standards, page 1A-8 of the Glossary, Appendix A, Chapter 1. Quality control is defined as “the overall system of technical activities whose purpose is to measure and control the quality of a product or service so that it meets the needs of users.” NELAC 2001 Standards, *ibid*.

The certification program will provide standards and requirements for all environmental laboratories providing data required by Virginia's environmental laws. The program initiates certification requirements for laboratories that analyze air and waste samples. It enhances laboratory audit and certification programs for water by increasing the frequency of on-site assessments of laboratory facilities for all but major wastewater facilities, and the frequency of proficiency testing for all laboratories analyzing water samples. By requiring environmental laboratories to meet standards to obtain certification, the program will encourage the production of environmental data that are

consistent, accurate and comparable. The program will enhance the quality of all environmental laboratories by assisting and educating laboratories in their continuing development of good laboratory practice. In turn, the public health and environmental quality will be protected because public health and environmental management decisions will be based on data that are of high quality. Basing environmental and public health decisions on sound data is inherently cost efficient and best protects the quality of the Commonwealth’s air, water and terrain.

The frequency of current audit and certification programs will increase. Once a laboratory receives certification under the proposed program, the certification must be renewed every two years. Proficiency testing is limited under current programs. Proficiency tests must be completed successfully twice a year to attain and maintain certification under the proposed program.

Drinking water laboratories are certified by DCLS under federal and state requirements every three years. These laboratories participate in one proficiency test study per year. A proficiency test study determines the ability of laboratory analysts to accurately analyze samples for different substances.

The DEQ audits laboratories at wastewater and water treatment facilities that hold discharge permits from DEQ and commercial laboratories that serve these permit holders. These audits are carried out every year for major sources, every two years for minor sources and every five years for small and low priority sources.

As part of the laboratory audit program for discharge permittees, DEQ requires proficiency test studies to be done once per year for major sources and selected minors. In the most recent study (2004), 139 majors and 97 selected minors participated.

Source size is defined under Virginia’s water law and regulations as follows:

DESIGNATION	DESCRIPTION
Municipal major	≥1 million gallons per day (mgd) flow rate
Municipal minor	≥40,000 gallons per day and <1 mgd
Municipal small	≥1,000 gallons per day and <40,000 gallons per day
Industrial major	chosen on the basis of flow, potential to harm and contaminants
Industrial minor	industrial sources that are not major or small sources
Industrial small	industrial facilities with low environmental impact potential such as discharges of non-contact cooling water, sand and gravel operations, and car washes

As of July 2004, 146 major sources and 1018 minor sources have water program permits. The total number of minor sources does not include those holding general permits. These permittees generally are not required to provide data from laboratory analyses as part of their permits. The proposed laboratory certification program will cover an estimated 773 wastewater permittees. This includes 123 major sources and 650 minor sources. The wastewater permit holders were reviewed to eliminate those sources that perform only field testing or contract out laboratory work. Field tests are not included in the proposed program except when the tests are performed in an environmental laboratory. These numbers have changed since originally provided in 2002; the number of permit holders does fluctuate over time. In 2002, there were 160 major sources and 1198 minor sources holding water program permits. The laboratory

certification program was proposed to cover 915 wastewater permittees. This included all the major sources and 755 minor sources.

The proposed certification program will ensure that laboratories that provide data required by Virginia's air and waste laws and regulations are capable of consistently and accurately carrying out the methods used to analyze samples. The proposed program also will ensure that more laboratories serving wastewater and water treatment plants are assessed either for the first time or on a more frequent basis.

## Substance

*Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the "All changes made in this regulatory action" section.*

A summary of the regulations is set out below.

### 1 VAC 30, Chapter 45

This chapter applies to non-commercial environmental laboratories. A summary of this regulation follows.

1. Part I of the regulation addresses general requirements of the certification program for non-commercial environmental laboratories. The following are some of the general requirements covered by Part I: establishment of the program, applicability of environmental laboratories, definitions, the scope of certification, general requirements, the process to apply and obtain certification, the reasons why certification would be denied, how to maintain certification status, the process to change certification scope or status, the reasons why certification might be withdrawn and the process of withdrawal of certification, appeal procedures, exemptions, fees, and petitioning for a variance.
2. The regulation establishes the certification program on the first day of the 37th month following the regulation's effective date [1 VAC 30-45-20 B]. Non-commercial environmental laboratories must be certified prior to this date. After this date, only data from certified environmental laboratories can be used for the purposes of Virginia's air, waste and water laws. [1 VAC 30-45-20 A].
3. The regulation applies to any owner or operator of a non-commercial environmental laboratory [1 VAC 30-45-30 A].
4. An environmental laboratory is a facility or a defined place within a facility where environmental analysis is performed. Environmental analysis is any test, analysis, measurement or monitoring used for or required by Virginia's air, waste or water laws, regulations, or any permit or order issued under those laws or regulations. Environmental analysis does not include sampling, field testing and measurement, or taxonomic identification of samples. [1 VAC 30-45-40]
5. A non-commercial environmental laboratory is one where environmental analysis is performed solely for the owner. Activities that might be seen as commercial but that are considered to be non-commercial in this regulation are listed in the definition. [1 VAC 30-45-40]

6. Environmental laboratories owned by federal government agencies may be certified either through Chapter 45 or by a federal primary accrediting authority to the standards established by the National Environmental Laboratory Accreditation Conference [1 VAC 30-45-30 B].

7. Environmental laboratories will have to meet the standards in Part II of the regulation to be certified. The components of the standards are personnel qualifications, proficiency testing, on-site assessment, and quality systems. The Division of Consolidated Laboratory Services (DCLS) will grant certification by matrix, technology/method and analyte/analyte group. [1 VAC 30-45-50 and 1 VAC 30-45-60]

8. Owners or operators of non-commercial environmental laboratories must submit applications for certification within eight months after the regulation becomes effective. DCLS may determine more specific application deadlines and notify existing laboratories. Application requirements are listed and include an application fee and certification of compliance. [1 VAC 30-45-70]

9. DCLS will determine if the application package is complete and will notify the applicant laboratory of its determination. DCLS may determine that the application package is complete and the laboratory has satisfied all requirements except on-site assessment. If this occurs and DCLS is unable to schedule the on-site assessment within the next 90 days, the agency will grant the laboratory interim certification. [1 VAC 30-45-70 G and H]

10. DCLS will either grant or deny the application for certification. If certification is granted, a certificate will be issued to the laboratory. If DCLS believes it has grounds to deny certification, the agency will provide a written notice to the laboratory with a detailed explanation of the basis for the notice and of the process to follow. The following are causes for DCLS to deny certification to an applicant laboratory:

- The laboratory is found to be falsifying data or providing false information to support certification.
- The laboratory does not meet the standards in Part II of the regulation.
- The laboratory does not pay the required fees.

[1 VAC 30-45-70 K and L and 1 VAC 30-45-110]

11. Certification expires two years from the issuance date of the certificate. Environmental laboratories retain their certification by maintaining their approved quality system and participating in proficiency test studies on a regularly scheduled basis. Laboratories are also required to keep pertinent records and notify DCLS of changes in key certification criteria. [1 VAC 30-45-70 K, 1 VAC 30-45-80 and 1 VAC 30-45-90]

12. DCLS shall decertify an environmental laboratory if the laboratory is found to be falsifying any data or providing false information to support certification. DCLS may decertify an environmental laboratory when the laboratory fails to maintain the standards and quality system for which it was certified. Decertification may be for all aspects of the certification or part of the certification. DCLS, if it believes it has grounds to decertify a laboratory, will provide a written notice to the environmental laboratory with a detailed explanation of the basis for the notice and of the process to follow. [1 VAC 30-45-100 and -110]

13. A laboratory may apply to DCLS for a partial or full exemption from the certification program requirements. The laboratory must have met all requirements for certification for four years before

DCLS will consider granting an exemption. DCLS will provide a notice in the *Virginia Register* and take comments on the request before deciding to grant or deny the application for an exemption. The exemption shall be limited to 24 months. [1 VAC 30-45-120]

14. The fees address two categories of environmental laboratories: laboratories that perform only simple test procedures and general environmental laboratories. Simple test procedures are defined as the following: (1) “field testing and measurement performed in an environmental laboratory” and (2) specific test procedures such as biochemical oxygen demand, fecal and total coliform, and fecal streptococci. General environmental laboratories perform tests other than simple test procedures although they may perform these tests as well.

15. When applying for initial certification and when renewing certification, owners or operators of environmental laboratories must pay a fee. The fee is computed by adding a base fee to test category fees. If the sum of these fees exceeds a specified maximum fee, the laboratory pays the maximum fee. The base and maximum fee are different depending on whether the laboratory is defined as a simple test procedure laboratory or a general environmental laboratory. Laboratories performing only simple test procedures have a base fee of \$100 and a maximum fee of \$600. General environmental laboratories have a base fee of \$1700 and a maximum fee of \$5200. The test category fees range from \$375 to \$1200. Additional fees pertain to laboratories that apply to modify their scope of accreditation, transfer ownership, or request that multiple noncontiguous laboratory sites be considered as one site. If DCLS cannot provide a timely on-site assessment, the laboratory may request an approved third-party on-site inspection at its expense. DCLS does not anticipate any need to use third-party on-site assessors except during the initial stage of the program; even then these assessors may not be needed. [1 VAC 30-45-130]

16. To be accredited, laboratories must meet the standards specified in Part II of Chapter 45. The standards cover personnel, on-site assessment, proficiency testing and quality systems.

17. Article 1 of Part II covers personnel. Every environmental laboratory must designate a person responsible for the operation of the laboratory. For general environmental laboratories, the regulation requires the laboratory manager to have two years’ experience either managing a laboratory or performing the analyses for which the certification is sought. Full-time employees of wastewater treatment or drinking water facilities qualify as laboratory managers if they hold a valid treatment plant operator’s certificate for the size of the facility in question. For laboratories performing only simple test procedures, the regulation requires the laboratory to designate a laboratory manager. Every environmental laboratory must designate a quality assurance officer who will be responsible for the laboratory’s quality system and for ensuring that the system is working. When laboratory staff is limited, the laboratory manager may be the quality assurance officer or a consultant may be hired as a quality assurance officer. The quality assurance officer must have documented training or experience in quality assurance and quality control procedures. Article 1 sets out laboratory personnel requirements and management responsibilities in addition to those for the laboratory manager and quality control officer.

18. Article 2 of Part II covers on-site assessment. DCLS will perform an on-site assessment as a condition for granting certification. Poor performance on a proficiency testing sample or a change to the laboratory’s operations may cause DCLS to carry out additional on-site assessments. The on-site assessment personnel shall minimize disruption of the laboratory’s work during the assessment. The regulation sets out provisions on what areas of the laboratory’s operation would be assessed, the process to be used during the visit such as records review, the documentation used in on-site assessment, and the follow-up and reporting procedures.

19. Article 3 of Part II covers proficiency testing. The regulation requires environmental laboratories to participate in two single-blind, single-concentration proficiency test (PT) studies per year, if available, for each PT field of testing for which the laboratory wishes to obtain or maintain certification. PT studies are not available for all fields of testing, such as air testing and analysis. The laboratory must obtain PT samples from NIST or other approved providers. Article 3 has provisions on how the study results are reported, on recordkeeping, and on the criteria for certification.

20. Article 4 of Part II covers quality system. The requirements in Article 4 are general requirements on which the quality system of an environmental laboratory must be based. The quality system should be appropriate to the type, range and volume of the testing done by the laboratory. It should be pertinent to the work of the environmental laboratory.

21. The laboratory documents its quality system in a quality manual. The elements of the manual are listed in Article 4. Provisions specifying in more detail many of the elements of the quality manual follow the list of these elements. Other components of management of the quality system include organization, records management and storage, auditing of laboratory operations, corrective actions, subcontracting, services and supplies, and complaints. The technical requirements for the quality system cover topics such as the laboratory physical environment, equipment and reference materials, test methods and standard operating procedures, procedures for demonstration of capability, data verification, documentation of standards and reagents, measurement traceability and calibration, quality control procedures, sample handling, acceptance and receipt, and the laboratory report.

#### 1 VAC 30, Chapter 46

This chapter applies to commercial environmental laboratories. A summary of this regulation follows.

1. Part I of the regulation addresses general requirements of the certification program for commercial environmental laboratories. Many of the sections in Part I of Chapter 46 are essentially the same as sections in Part I of Chapter 45 as follows: the establishment of the program (1 VAC 30-46-20), the general accreditation requirements (1 VAC 30-46-60), provisions on the contents of the application, completeness determination, grant of interim accreditation, and on-site assessment (1 VAC 30-46-70 F through I), denial of accreditation and reapplication following denial of accreditation (1 VAC 30-46-70 L and M), maintaining accreditation (1 VAC 30-46-80 A-C), notifications and changes to accreditation elements and status (1 VAC 30-46-90), withdrawal of accreditation (1 VAC 30-46-100 A-C and E), and procedures to deny or withdraw accreditation and appeals (1 VAC 30-46-110).

2. Chapter 46 uses the term “accreditation” instead of the term “certification.” Unlike Chapter 45, Chapter 46 uses the 2003 National Environmental Laboratory Accreditation Conference (NELAC) standards as the standards to be met by commercial environmental laboratories. The term used by the National Environmental Laboratory Accreditation Program is “accreditation.”

3. The regulation applies to any owner or operator of a commercial environmental laboratory. [1 VAC 30-46-30 A]

4. An environmental laboratory is a facility or a defined place within a facility where environmental analysis is performed. Environmental analysis is any test, analysis, measurement or monitoring used for or required by Virginia's air, waste or water laws, regulations, or any permit or order issued under those laws or regulations. Environmental analysis does not include sampling, field testing and measurement, or taxonomic identification of a sample. [1 VAC 30-46-40]
5. A commercial environmental laboratory is one where environmental analysis is performed for another person. A "person" is an individual, corporation, partnership, association, or other legal entity, including any government. [1 VAC 30-45-40]
6. The owner or operator of any environmental laboratory currently accredited under the NELAC standards who wishes to apply for reciprocal accreditation must apply under Chapter 46. [1 VAC 30-46-30 A]
7. The regulation applies to DCLS. DCLS will meet the requirements of the regulation through review and accreditation by a National Environmental Laboratory Accreditation Program (NELAP)-accredited federal or state accrediting authority. This process will be complete before the program is established. In addition, DCLS will meet the NELAC standards to become the primary accrediting authority for Virginia. This process shall be complete no later than one year after the effective date of the regulation. [1 VAC 30-46-30 B]
8. Any environmental laboratory owner or operator may voluntarily apply for accreditation under Chapter 46. When an environmental laboratory owner or operator must get drinking water certification under Chapter 40 of 1 VAC 30 and environmental laboratory certification under Chapter 45, the owner or operator may apply under Chapter 46 and meet the requirements of both regulations. [1 VAC 30-46-30 C and D]
9. Owners or operators of commercial environmental laboratories must submit applications for accreditation within six months after the regulation becomes effective. DCLS may determine more specific application deadlines and notify existing laboratories. Application requirements are listed and include an application fee and certification of compliance. Owners or operators of NELAC-accredited environmental laboratories must apply for reciprocal accreditation no later than six months after the regulation becomes effective. [1 VAC 30-46-70]
10. Information about accredited laboratories will be provided to the NELAP database. The information to be provided is basic information about the laboratory's certification such as the technical director's name, certification status and fields of testing for which the laboratory is accredited. [1 VAC 30-46-120]
11. The regulation lists requirements for owners or operators of laboratories accredited under Chapter 46 who wish to use the NELAP accreditation status and logo. [1 VAC 30-46-130]
12. DCLS, once it is recognized by NELAP as a primary accrediting authority, may grant reciprocal accreditation to environmental laboratories already accredited by another primary accrediting authority. The regulation describes the process that these laboratories need to use to apply for and receive reciprocal accreditation under the program. [1 VAC 30-46-140]
13. The term of accreditation is one year. Fees are paid at initial accreditation and every two years thereafter. In the interim year, the laboratory retains its accreditation status by maintaining

compliance with Chapter 46 and attesting to that compliance by signing the certificate of compliance, and by reporting acceptable proficiency test values for the laboratory's fields of accreditation. [1 VAC 30-46-70 C]

14. The accreditation fee is computed by adding a base fee to test category fees. If the sum of these fees exceeds a specified maximum fee, the laboratory pays the maximum fee. Chapter 46 laboratories will pay a maximum fee of \$5200. The base fee is \$1700. Test category fees range from \$375 to \$1200. Additional fees pertain to laboratories that apply to modify their scope of accreditation, transfer ownership, or request that multiple noncontiguous laboratory sites be considered as one site. If DCLS cannot provide a timely on-site assessment, the laboratory may request an approved third-party on-site inspection at its expense. DCLS does not anticipate any need to use third-party on-site assessors except during the initial stage of the program; even then these assessors may not be needed. [1 VAC 30-45-130]

15. To be accredited, laboratories must meet the 2003 NELAC standards that are incorporated by reference into Part II of Chapter 46. The standards cover personnel, on-site assessment, proficiency testing and quality systems.

## 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.*

### General public

**Advantages.** The program provides a set of quality assurance and quality control standards that environmental laboratories must meet to be certified. Once the program is established, the certification will be required before these laboratories can provide the data required under Virginia's environmental laws. By requiring environmental laboratories to meet standards to receive and maintain certification, the program will encourage the production of environmental data that are consistent, accurate and comparable. This certification will give the general public increased confidence in the environmental laboratory data provided to the Department of Environmental Quality (DEQ).

**Disadvantages.** The proposed regulatory action presents no disadvantages to the general public.

### Regulated entities

**Advantages.** There are several advantages for regulated entities. First, DEQ and the customers of the commercial laboratories will be assured that the laboratories have been reviewed to standards set by the program. This assurance should enhance the credibility of the data produced by the laboratories. Decisions that must be made using these data will be made with greater confidence. Second, an advantage for all laboratories subject to the proposed regulations and especially for small local government laboratories is the assistance and education that will be provided during the certification process. On-site assessments often provide teaching and learning opportunities for a certifying agency and the laboratory. Third, certification enhances the ability of commercial environmental laboratories to compete within the state and outside Virginia. Once accredited

under Chapter 46, commercial laboratories in Virginia may apply for reciprocal accreditation in any state that has a NELAC program. The certification process under the proposed program will be the same for all commercial environmental laboratories. Each laboratory will have to meet the same general standards and pay the same costs relative to the commercial work done by the laboratory. The certification program enables the commercial laboratories to compete on an equivalent basis.

Disadvantages. The disadvantages are the new or increased costs for environmental laboratories to become certified and to maintain that certification.

#### Agency

Advantages. There are a number of advantages for the agency. First, the Division of Consolidated Laboratory Services (DCLS) will manage a program that will enhance the overall environmental quality programs of the Commonwealth. The program should enable DEQ to accurately assess the quality of the data produced by environmental laboratories and, in turn, the quality of the air, water and terrain in the Commonwealth. Second, the program allows DCLS to provide an additional service to DEQ. Third, DEQ and DCLS will both benefit from increased communication regarding these environmental programs. Fourth, DCLS will become one of a growing number of states which accredit environmental laboratories under a set of national standards.

Disadvantages. DCLS must undergo review by the National Environmental Laboratory Accreditation Conference (NELAC) to become the primary accrediting authority for NELAC standards in Virginia. Because DCLS provides laboratory services for DEQ, DCLS must also undergo a separate review by NELAC to be accredited under the standards incorporated into its own regulation. These reviews will take time and effort, and therefore will be a cost to the agency. This cost is not included in the proposed fees.

#### Other matters - Memorandum of Understanding between DCLS and DEQ

For two reasons, DCLS believed early in the development of the program regulations that a memorandum of understanding (MOU) between DCLS and DEQ would be a critical element of the program. First, the purpose of the program is to certify laboratories that provide data to DEQ. Second, DEQ already audits laboratories under the water permit (VPDES) program. The two agencies needed to resolve this conflict of responsibilities. In addition, laboratories affected by both the VPDES and the new certification program had concerns about the potential duplication of review by the two agencies.

DCLS and DEQ discussed and developed an MOU in meetings during late February and March 2000. Representatives of both agencies signed the MOU in August 2000. The MOU addresses communication and coordination between the two agencies and the conflict of responsibilities mentioned earlier. The two agencies will form a workgroup to communicate on program implementation, certification and data issues. The MOU provides that DCLS will assume DEQ responsibilities for laboratory auditing under the VPDES program. This will be done after an interim transition period during which staff from the two agencies will work together. Prior to this time, DEQ will be responsible for laboratory audits under the VPDES program. After the program is established, DCLS will be responsible for laboratory audits under the VPDES program. These audits will be a part of the certification program's review process. During the interim period, DEQ auditors will train DCLS auditors in all aspects of the requirements under VPDES. The certification program regulation, as proposed, does not include field testing; lab audits under VPDES cover field testing. To avoid duplication of tasks by the two agencies, DCLS will take over the audit of field testing at large minor and major sources.

As proposed in February 2004, the certification program would be established at the beginning of the 25th month following the effective date of the regulation. The final regulation adds an additional year to this transition period, changing the date the program would be established to the beginning of the 37<sup>th</sup> month following the effective date of the regulation. DCLS and DEQ will be revising the MOU signed in 2000 to bring it up to date. As part of this process, DCLS and DEQ will discuss the effect the year added to the transition period will have on the agencies' responsibilities. With regard to this issue, DCLS and DEQ have tentatively discussed and agreed to retain the same schedule as that agreed to in August 2000 for DCLS taking over DEQ's audit responsibilities.

**Changes made since the proposed stage**

*Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar's office, please put an asterisk next to any substantive changes.*

Section number	Requirement at proposed stage	What has changed	Rationale for change
<b>1VAC 30-45-</b>			
10 (also 1 VAC 30-46-10)	Purpose	Replaced "by" with "pursuant to." This change is made throughout where the phrase "required by the" regulations or the environmental statutes is used.	Change better reflects meaning of environmental laboratory certification statute.
"(also 1 VAC 30-46-10)		Deleted "or operators". This change has been made throughout.	The definition of "owner" already includes an operator.
"		Replaced NELAC with NELAP	The use of NELAC is incorrect when referring to labs or states accredited under the NELAC standards. Their accreditation is under the program, or NELAP.
"		Replaced environmental laboratories "located outside Virginia" with those "seeking reciprocal accreditation in Virginia"	Better reflects intent of legislation.
20 B (also 1 VAC 30-46-20 B)	Establishment of certification program	* Requires the program to be established after three years rather than after two years.	Provides additional needed time for agency to certify laboratories.
30 B	Applicability	Adds "By" to the beginning of subdivisions 1 and 2	Provides clarity
40 (also 1 VAC 30-46-40)	Definitions - General	Adds language that the terms in this section on definitions have no other meaning even if these terms are defined differently in the <i>Code of Virginia</i> or in other regulations.	Limits confusion over terms that may appear in environmental regulations other than this regulation
40	Definitions	Definition of aliquot revised	Revises to give the word its meaning in chemistry rather than its meaning in math.
"		Definition of analytical batch moved under definition of batch	Definitions of different types of batch are clearer when placed together
"		Definition of batch (see above) enlarged with sub-definitions including definition of preparation batch	See above
"		Definition of blank expanded to include two examples of blanks	Definition is clearer with different types of blanks included as part of the general definition
" (also 1		Definition of environmental analysis. Adds	Clarifies the language of the definition

Section number	Requirement at proposed stage	What has changed	Rationale for change
VAC 30-46-40)		soil and sediments to list of media in the exceptions for sampling and field testing.	
“(also 1 VAC 30-46-40)		Definition of environmental laboratory. Adds provision stating that a field shelter is not a laboratory.	Clarifies an issue of concern to many laboratories.
“		* Definition of field of testing. “Testing” is now “certification.” Revises the definition to substitute matrix for program, to add technology to method and to add analyte group to analyte. Changes made throughout regulation to reflect this change.	DEQ commented on the problems raised when certification is based on program and not on matrix. The other changes are made based on DEQ comments and for similar reasons.
“		* Definition of matrix expanded due to change in definition of field of testing. Adds sub-definitions of “field of certification matrix” and “quality system matrix.”	Necessary change to match the changes made to field of testing.
“		Definition of National Institute of Standards and Technology. Deletes phrase “to those laboratories testing drinking water and wastewater.”	NIST-certified PT samples are no longer limited to drinking water and wastewater.
“(also 1 VAC 30-46-40)		Definition of noncommercial environmental laboratory. Substitutes “wastewater” for “sewage” and “system” for “plant” in subdivisions a and b. Changes subdivision c to expand meaning of exception.	Changes in subdivisions a and b reflect more common language usage. Changes in subdivision c are the result of comments from affected industry.
“(also 1 VAC 30-46-40)		Definition of owner or operator. Deletes “operator” from the term being defined. Expands definition to include “leases or controls.”	Owner as defined includes operator. As proposed, the use of operator led to confusion.
“		Definition of PT field of testing. Modified to reflect change from program approach to matrix, technology/method, and analyte/analyte group/	Reason is the same as that for field of testing definition change.
“(also 1 VAC 30-46-40)		Definition of PT sample. Modifies the definition to match the certification requirements for proficiency testing.	Clarifies that to be certified laboratories must perform PTs that have compositions unknown to both the laboratory and the analyst. Comments indicated confusion on this point.
“		Definition of program. Deletes the reference to field of testing.	Reason is the same as that for field of testing definition change.
“		Definition of simple test procedure modified to include E. coli and Enterococci.	Standard water requirements now include these tests, which are simple. DEQ and others provided comments.
“		Adds definition of system laboratory.	Changes in other provisions require this definition.
“(also 1 VAC 30-46-40)		All definitions (3) of test, analysis, measurement or monitoring under the air, waste, and water laws. Modified definitions to eliminate references to methods adopted by specific regulations. Kept reference to VAC Title and Agency only.	References to specific regulations are unnecessary. Using a reference to the VAC title and agency is sufficient.
“(also 1 VAC 30-46-40)		Definition of test method modified.	Clarifies meaning.
“(also 1 VAC 30-46-40)		Definition of wastewater added.	Needed because of change to definition of noncommercial laboratory.
50 C (also	Scope of	Revised to reflect change to approach to	See rationale for change to definition

Section number	Requirement at proposed stage	What has changed	Rationale for change
1 VAC 30-46-50 C)	certification.	certifying laboratories. Matrix is used rather than program. Certification granted for field of certification rather than field of testing.	of field of testing.
60 B 3 (also 1 VAC 30-46-60 B 3)	Timely initial applications.	Adds provision that allows laboratories owned by the same person located at separate sites to apply for certification for all the labs with one application, if the labs meet certain conditions.	Comments received from owners of multiple labs at noncontiguous sites. Change provides potential benefit for these labs under reasonable conditions.
70 D (also 1 VAC 30-46-70 D)	Responsibilities of owner and operator.	Modifies title.	Clarifies meaning.
70 F 1 j (also 1 VAC 30-46-70 F 1 j)	Contents of application.	Contents of application. Adds title to information required on laboratory contact person	All other information on people at the lab already includes title except for this person.
70 F 1 k	“	Modifies laboratory type to recognize that some laboratories are both public water and public wastewater labs.	Clarifies meaning.
70 G 1 (also 1 VAC 30-46-70 G 1)	Completeness determination	Expands provision to include time period for renewal application.	This information, not previously provided, was needed.
70 H 1 c (also 1 VAC 30-46-70 H 1 c)	Timely renewal applications.	Adds provision that gives interim certification status to laboratories applying for renewal of certification if the application is on time and is determined to be complete.	Renewal applications are due 90 days prior to expiration of certification. Determination of completeness could take 60 days. Certification could expire before the on-site assessment is completed. Subsection H allows interim certification if an application is complete and DCLS cannot do an on-site assessment during the next 90 days. A provision to give renewing applicants interim certification was needed under this scenario.
70 H 2 (also 1 VAC 30-46-70 H 2)	Grant of interim certification.	Adds the word “status” to the phrase “interim certification.”	Clarifies meaning.
70 H 3 (also 1 VAC 30-46-70 H 3)	Grant of interim certification.	* Limits interim certification status to twelve months instead of allowing this status to remain until the agency makes a final determination on certification.	Based on DEQ comments. DEQ is concerned that there be some limit to the time allowed for interim certification status. DEQ recommends the limit set out in the NELAC standards. Also see rationale for 70 J 2 below.
70 I 2 (also 1 VAC 30-46-70 I 2)	Third-party on-site assessors.	Deletes provision in 1 VAC 30-45-130 G (Fees) and adds expanded provisions to 1 VAC 30-45-70 I for clarity.	Proposed provision on third-party, on-site assessors raised questions and comments. The provisions, proposed in the section on fees, more properly belong in the provisions on applying for certification. The revised provisions should answer the questions raised by the commenters.
70 J 2 (also 1 VAC 30-46-70 J 2)	Final determination on certification.	Modified to require DCLS to complete action within nine months from the time the completed application is received rather than within nine months from the time application is determined to be complete.	Based on DEQ comment. DEQ bases their comment on the NELAC program requirements which are used in 1 VC 30-46. For consistency the same change was made to 1 VAC

Section number	Requirement at proposed stage	What has changed	Rationale for change
			30-45.
70 K 2 (also 1 VAC 30-46-70 K 2)	Grant of certification.	Various modifications.	For clarity and as discussed above.
70 L 2 c (also 1 VAC 30-446-70 L 2 c)	Denial of certification.	Modified for clarity.	Based on comments received.
70 L 3, 100 C, and 110 (also 1 VAC 30-46-70 L 3, 100 C, and 110)	Appeal provisions and cross-references, including notifications and rights.	* Modifications made to provisions in 70 L 3 and 100 C that now only reference the expanded provisions in 110. Section 110 revised to explain the process available to laboratories if they want to discuss problems with the agency informally. Modifications also more explicitly set out the formal appeals available to laboratories.	Considerable comments received on the limited language provided explaining the appeals process in the proposed regulations.
90 Title (also 1 VAC 30-46-90)	“Changing certification status.”	“Notifications and changes to certification elements and status.”	Made for clarity.
90 A (also 1 VAC 30-46-90 A)	Changes to key certification criteria.	Deletes proposed subdivisions A 2 and A 3. Provisions now state that changes in key certification criteria must be made in writing to the agency within 30 calendar days of the change. Limits key certification criteria to laboratory ownership, location, key personnel, and major instrumentation.	Extensive comments received. As proposed, key certification criteria included test methods and analytes. These provisions on how labs could get approval for changes to their certified test methods and analytes were unclear. The change solves the problem.
90 B (also 1 VAC 30-46-90 B)	Changes to scope of certification.	Clarifies language. Adds provision providing deadline for DCLS to act on applications for changes to scope of certification.	Extensive comments received. Provisions needed to be made clearer.
90 C (also 1 VAC 30-46-90 C)	Change of ownership or location of laboratory.	Adds language that limits the requirements to fixed-base labs. Added provisions indicating that recertification, reapplication or an on-site assessment might be required under certain circumstances. In subdivision 5 (new 6), changed the requirements for recordkeeping from five to three years. Clarified provisions.	Extensive comments received. Provisions needed to be made clearer.
130 A (also 1 VAC 30-46-150 A)	Fees	Modified the provision stating when fees are to be submitted to include reapplications and all renewal applications.	Provision needed to be made clearer. Comment received.
130 C	“	* Maximum fee for simple test procedure laboratories was increased from \$400 to \$600.	Extensive comments received on equity of fees. Part of general rethinking of fees charged.
130 D	“	* Maximum fee for general environmental laboratories was increased from \$3800 to \$5200.	Extensive comments received on equity of fees. Part of general rethinking of fees charged.
130 E 3 (also 1 VAC 30-46-150 E 3)	“	* All test category fees increased. Chemistry metal categories: modified number of methods per category. Whole effluent toxicity changed to aquatic toxicity. Benthic assessment added.	Extensive comments received on equity of fees. Part of general rethinking of fees charged. Name changes reflect changes to 40 CFR 136 which lists test methods.
130 F (also 1 VAC 30-46-150 F)	“	* Specifies when additional fees will be charged. Removed references throughout regulation. In subdivision F 4 and F 5, provisions added to reflect changes to other parts of the regulation where fees should be	Extensive comments received on equity of fees. Part of general rethinking of fees charged.

Section number	Requirement at proposed stage	What has changed	Rationale for change
		charged because of the additional work that the agency would have to do.	
130 H (also 1 VAC 30-46-150 H)	“	* Added new provision on travel costs for assessing out-of-state laboratories.	Comments received on this issue. Part of general rethinking of fees charged.
130 I (also 1 VAC 30-46-150 I)	“	* Added new provision describing how the agency would derive the travel costs it charges.	Comments received on this issue. Part of general rethinking of fees charged.
140 A (also 1 VAC 30-46-160 A)	Petitioning for a variance.	Replaced “must” with “shall.”	Technical error.
140 C 2 (also 1 VAC 30-46-160 C 2)	“	Replaced the phrase “If the director continues to believe” with “If the director finds.”	Change was made to reflect more accurately the decision-making process.
140 F (also 1 VAC 30-46-160 F)	“	Added the phrase “in whole or in part, or to modify or terminate a variance” following “Decisions to grant or deny a petition.”	Revision more fully explains the decision to be taken.
200 A 3	Laboratory manager.	New provision stating that a laboratory may appoint one or several technical directors.	While regulation did not prevent labs from making such appointments, the additional language provides more flexibility.
230	Absence of laboratory manager.	Revised the provisions on the absence of a laboratory manager. Limits the requirements to absences beyond 15 consecutive calendar days. Provides that another staff member may substitute for the manager.	Comment received. Sets a standard for lab manager absences. Proposed language was ambiguous.
300 A	Frequency of on-site assessment.	Specifies in more detail when comprehensive on-site assessments are performed.	Comment received. Provides specificity.
300 B	Other on-site assessments	Revised completely the provisions on when other on-site assessments might take place.	The provisions were revised for clarity.
330	Areas to be assessed.	Adds sentence explaining in general what standards would be used to assess labs during the on-site assessment. Adds recordkeeping to the list of items to be reviewed.	Provides a clear introductory requirement.
350 A and 390 F		Replaced “supervisor” with “manager” and “technical director” with “manager.”	Technical errors.
400 C	Release of report.	Modified provisions to show sequence of the release of an on-site assessment report. Included the role of the VA FOIA.	The provisions were revised for clarity.
500 A	Lab enrollment in PT program.	* Modifications to subdivisions 1 and 3 reflect specific requirements for environmental toxicology. Modifications to subdivision 2 include references to PT providers approved under NELAC PT provider standards.	Comment received asking that NELAC PT provider requirements be included in the regulations. Concern relates to the qualifications of the providers that DCLS may approve. Specific provisions relating to environmental toxicology provide flexibility for labs performing these tests.
500 C 3	Reporting results.	Deletes provision.	The provision conflicted with other PT requirements.
510 A	Requirements for lab testing of PT study samples.	Provision added pertaining to environmental toxicology.	See rationale for 500 A.
510 B	“	The phrase “and frequency of analysis” was deleted. Provision added describing how laboratory should analyze a PT sample.	“Frequency of analysis” not pertinent to the provision from which is was deleted. Additional language further

Section number	Requirement at proposed stage	What has changed	Rationale for change
			expands the meaning of the first sentence in this subsection.
510 D	Maintenance of records.	Labs are to maintain records for three instead of five years.	Revision keeps the requirement consistent throughout the regulation.
520 B 4 and C 2	PT criteria for lab certification.	Modified provisions to allow participation in PT studies at least 15 days instead of 30 days apart. More fully describes the start and end point for the 15 days.	Change meets current NELAC requirements rather than older requirements on which the provisions were based.
520 E 2	Second failed study.	Revises provision to reflect that the term "program" is no longer part of the PT field of testing.	Change due to revised approach to certifying labs.
520 F	Scheduling of PT studies.	Deletes provision that agency would schedule PT studies. Allows labs to schedule their own.	Provisions as proposed allowed but did not require DCLS to set the PT study schedule. Labs want to set their own schedule.
530		* Adds provisions concerning whole effluent toxicity.	Labs performing whole effluent toxicity testing have special PT requirements that have become available recently.
600 B	Quality system	Language indicating that not all the requirements of Article 4 on Quality System will apply to all laboratories because not all laboratories perform the same tests has been deleted.	The language caused confusion and is not necessary.
600 C (also 1 VAC 30-46-210 D 2 d)	"	Modified the provision to ensure that either standard or requirements could be more stringent in regulation than in the quality system provisions of Article 4.	Change makes provision clearer.
610 B	Quality manual elements.	Reorganized the list of elements to be included in a quality manual. Clarified the language in subdivision 3.	The revision reflects the progression of provisions in Article 4. All proposed material was included in revisions, just reorganized.
610 C	Review and approval of quality manual.	Replaced phrase "may significantly affect" with "affects."	Revision eliminates the ambiguity from the requirement.
640 B	Recordkeeping system and design.	Adds sample preservation as well as the phrase "all documentation sent by the person transmitting the sample, . . ." to the provision concerning what sampling records should include.	The sampling information needed to be included in the provision.
660 A	Records of sampling handling.	Adds language on the additional records of sampling information that needs to be kept.	The sampling information needed to be included in the provision.
660 D 2	Administrative records.	Includes work cells in the requirement to keep records of demonstration of capability.	Comment received on labs' use of work cells or groups and the need to include pertinent language.
670 A 4	Internal audits.	Revises provision to include all laboratories, not just small laboratories, when stating that an outside source may audit a lab's operations.	Clearly any laboratory may utilize this opportunity.
670 D	Performance audits.	These quality control measures were deleted from 670 and added to 750 A on quality assurance in general.	Change makes the regulation better organized.
690	Outside support services and supplies.	The provisions of this section were revised significantly. Specific requirements are added to indicate what should be included in a lab's procedures for obtaining services and supplies.	The provisions were ambiguous and needed more specificity.

Section number	Requirement at proposed stage	What has changed	Rationale for change
710	Environment and work areas.	Replaced “may” with “shall.”	The use of “may” was inappropriate.
710 4	“	Provision rewritten.	The provisions were ambiguous and needed more specificity.
720 C	Equipment and reference materials	Revision made to make clear that mishandled or defective equipment must be taken out of service immediately.	Once equipment becomes defective, it should not be used.
720 E	“ - Records	Replaced “may” with “shall.”	The use of “may” was inappropriate.
730 B 2	Standard operating procedures	Replaced “approving authority” with “responsible laboratory manager or managers”	Phrase “approving authority” had no specific meaning.
730 E 1	Demonstration of capability	Replaced “matrix” with “quality system matrix sample” in describing the matrix used to demonstrate capability. Changed “water” to “drinking water” in the list of examples of a quality system matrix sample.	Change related to the redefinition of “field of certification” and “matrix” and makes the requirements compatible with the revised approach to certifying laboratories.
730 E 6	“	Adds provision related to specialized work cells.	Comment received requesting that requirements for work cells be included as well as for single analysts.
730 F 1	Procedure for demonstration of capability	Revised to expand the types of tests for which demonstration of capability is done.	The proposed language was limited and needed further explanation.
730 F 1 a	“	Revised to allow the quality control sample to be purchased or made by the laboratory.	The change provides flexibility and clarity.
730 F 1 b	“	The phrase “quality system” was added to “matrix.” Revised concentration to “1-4 times the limit of quantitation” from “approximately 10 times” the method or detection limit.	Revision made to conform procedure to 2003 NELAC standards from which procedure was derived.
730 F 1 d and f	“	Replaced “must” with “shall.”	Technical error.
730 G	Demonstration of capability certification statement	Changed examples of method and number to “6010 B” and “8021 B” from “6010” and “8021.”	40 CFR 136 currently includes the methods 6010 and 8021 as 6010 B and 8021 B.
730 J 1	Documentation and labeling of standards and reagents	Adds records for reference materials to list of documents that must be retained. Replaces “supplied” with “available” for the manufacturer’s Certificate of Analysis or purity.	Reference materials may be used for calibration or calibration verification. Some manufacturers don’t supply certificates although they may be available.
730 K 1	Computers and electronic data related requirements	Deletes sentence stating that “all requirements of this article are to be complied with.”	Sentence is unnecessary.
730 K 2	“	Revises provision on computer software to specifically discuss software developed by the user, or laboratory.	Provision needed clarification.
740 A, B & C	Measurement traceability and calibration.	* Rewritten for technical clarity.	The basis for these provisions was the 1999 NELAC standards. NELAC has made considerable changes to subsequent versions of these standards that contribute to better understanding. These revisions conform to the 2003 NELAC standards.
740 C 3	Measurement traceability and calibration.	Specifies that reference materials shall be traceable to appropriate measurement standards.	Requirement was incomplete as originally proposed.

Section number	Requirement at proposed stage	What has changed	Rationale for change
	Reference standards.		
740 D 2 b (3)	“. Initial instrument calibrations.	Revises the provision to allow continuing instrument calibration verification when required by regulation, method, or program.	As proposed, provision was too limiting. The 2003 NELAC standards allow the exception provided here.
740 D 2 b (5)	“	Specifies either the calibration coefficient at 0.995 or greater or the criterion in the method.	Change conforms to guidance issued by DEQ Water.
740 D 2 c (2) (b)	“. Continuing instrument calibrations.	Adds provision to require all concentrations of calibration standards to be used for verification over time. Revises language on the use of internal standard for clarity.	DEQ states that this change is needed to ensure that the calibration range is appropriate for the lab's system of analysis.
740 D 2 c (2) (d)	“	Adds phrase “percent recovery” to example of criteria for acceptance of a continuing instrument calibration verification.	The additional phrase is used more frequently by labs than the phrase used in the proposed regulation.
750	Quality assurance	* Title changed from “Essential quality control procedures.” Material from 670 D added to 1 VAC 30-45-750 A. Material proposed initially in this section now in subsection B, entitled “Essential quality control procedures.” Proposed subsections C through E deleted from 750 because their requirements appear in a new 760. Subsection B directs the reader to new sections 760 through 829. These new sections specify quality control requirements in general and for specific test types.	DEQ believes that proposed quality control language is inadequate. Many test methods do not include quality control requirements. NELAC, Chapter 5, Appendix D specifies appropriate quality controls. DEQ asks that these requirements be included in Chapter 45.
760-new		* Adds general quality control (QC) requirements. These standards if appropriate to the test methods performed by a laboratory must be included in method manuals or quality manuals (depending on organization used by the laboratory).	“
770 through 779 - new		* Adds specific QC requirements for chemistry testing.	“
780 through 789 - new		* Adds specific QC requirements for toxicity testing.	“
790 through 799		* Adds specific QC requirements for microbiology testing.	“
800 through 809		* Adds specific QC requirements for radiochemical testing.	“
810 through 819		* Adds specific QC requirements for air testing.	“
820 through 849		* Adds specific QC requirements for asbestos testing.	“
850 1	Sample handling, sample acceptance policy and sample receipt. Sample tracking.	Adds requirements pertaining to system laboratories and the tracking of samples.	Comment received on the need for the provision. In addition, some laboratories serve multiple facilities and smaller labs. These system labs commented on the need to include provisions for such organizations.
850 2	“. Sample acceptance policy.	Adds provision requiring that samples should come into labs with appropriate sampling	The sampling records need to be included with the sample when it

Section number	Requirement at proposed stage	What has changed	Rationale for change
		records. Cross-reference made to where the regulation defines what should be included in those records.	enters the lab.
850 3 b	“. Sample receipt protocols.	Criteria specified on thermal preservation may not be met by samples delivered immediately after collection. Adds that samples delivered on the same day may also not meet the criteria.	Proposed language limited the meaning intended and needed to be revised.
<b>1 VAC 30-46 (changes other than those also made to 1 VAC 30-45)</b>			
10	Purpose	Replaces 2002 NELAC standards with 2003 NELAC standards. (see 200 A & B, below)	The 2003 standards will become effective July 2005 and will be the current standards at the time the program regulation is expected to be effective.
30 A	General applicability	Revises provision 2 to include all laboratories holding NELAP accreditation, not just those outside Virginia.	Allows NELAP-accredited labs in Virginia as well as those outside Virginia to get secondary accreditation from VA.
40	Definitions	Definition of “accreditation” revised to include general definition.	Provides meaning of the term as well as a statement that accreditation is a substitute for the term “certification” in this chapter.
“	“	Definition of “accrediting authority” revised to delete last two words: “under NELAC.”	This definition is derived from the glossary in the NELAC standards. The proposed regulation added “under NELAC.” The phrase is unnecessary because the standards that labs will have to meet to be accredited under this chapter are the NELAC standards.
“	“	Definition of “field of proficiency testing” revised to include “method” with “technology.”	Proposed definition inadvertently left out the word “method.”
“	“	Definition of “quality system matrix,” subcategories: biological tissue and solids. Under biological tissue, deleted “i.e., by species.” Under solids, revised to read “more” rather than “less” than 15% settleable solids.	Revised to correct inconsistencies with current NELAC definitions.
70 A and B 3	Process to apply and obtain accreditation. Duty to apply.	Changed “NELAC” to “NELAP.” Deleted phrase “located outside Virginia” which modified NELAP-accredited laboratories.	NELAP is the correct term, not NELAC. The provision as proposed restricted NELAP-accredited laboratories to those outside Virginia. This restriction was unintentional.
70 C	“. Timely renewal applications.	* Revised completely to require renewal of accreditation every year. Every two years, a complete application package including fees will be due. In the alternate years, DCLS will renew accreditation if the lab maintains compliance with the regulation, attests to their compliance by signing a Certificate of Compliance, and reports acceptable PTs for the labs’ field(s) of accreditation. The lab must submit an abbreviate application. Fees are not required during alternate years. Alternate year applications are due 14 days prior to expiration of accreditation.	The NELAC standards require annual renewal. The change was made to conform to these standards.
70 J 5	Final determination on accreditation	Release of on-site assessment reports. Deletes sentence pertaining to comments and recommendations in these reports.	Comments received on the value of the provision. Deleted because the sentence is not necessary.

Section number	Requirement at proposed stage	What has changed	Rationale for change
70 K 6	Grant of accreditation	* Revises term of accreditation from two years to one year.	NELAC standards specify a review of accreditation on a yearly basis.
140 A	Reciprocal accreditation	Deletes phrase "located outside Virginia" as it modifies laboratories holding NELAP accreditation.	Proposed language wrongly limits NELAP-accredited laboratories that may apply under this chapter.
150 C	Base fee	* Drops the base fee to \$1700 from \$2100.	Extensive comments received on equity of fees. This change is part of the general rethinking about the fees charged.
150 D	Maximum fee	* The maximum fee has been raised from \$4200 to \$5200.	"
200 A and B	Incorporation of NELAC standards	* Revises the date of the NELAC standards incorporated by reference from 2002 to 2003.	The proposed regulations were under review from Sept. 2002 until Apr. 2004. The revision reflects the standards that will be in effect on July 1, 2005, when the program regulations should be in effect.
200 C	"	* Provisions added to specify how the requirements of Chapter 4 of the NELAC standards are incorporated by reference into Chapter 46.	Comments received on various aspects of NELAC Chapter 4. This new language should make it clear that Chapter 4's provisions are incorporated by reference where not superseded by Virginia law.
210 A through D	"	* The provisions incorporated by reference have been updated by reviewing the 2003 NELAC standards and ensuring that all appropriate material is incorporated into Chapter 46.	Comments received on whether the NELAC standards have been sufficiently incorporated by reference.

**Changes made since the second proposed stage**

*Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar's office, please put an asterisk next to any substantive changes.*

Section number	Requirement at second proposed stage	What has changed	Rationale for change
1 VAC 30-45-40 and 1 VAC 30-46-40		Language added to definitions explaining that terms not defined in the regulation shall have the meaning commonly given them by recognized authorities, i.e., dictionaries.	A comment suggesting a definition for a commonly used term indicated a need for the additional language.
1 VAC 30-45-40	Definition of aliquot. "Aliquot" means a measured portion of a sample taken for analysis.	"Aliquot" means a portion of a sample taken for analysis.	The quantity of the subsample is not known exactly. Deleting the word "measured" eliminates this impression.
1 VAC 30-45-40 and 1 VAC 30-46-40	Definition of environmental analysis	The definition indicates what the term shall not include. The media air, water, soil, sediments, and waste were listed. These were revised so that they are the same as the field of certification matrices.	The change was made to ensure compatibility of terms.
1 VAC 30-	Definition of environmental	An additional category was added to the	There is no agreed upon

Section number	Requirement at second proposed stage	What has changed	Rationale for change
45-40 and 1 VAC 30-46-40	analysis	list of what environmental analysis does not include. This category is taxonomic identification of samples for which there is no national accreditation standard; examples were given. Definitions were provided for the examples, e.g., algae, benthic macroinvertebrates, macrophytes, vertebrates, and zooplankton.	national accreditation or certification standards for taxonomic identification. Some states have quality assurance and quality control standards for such identification. However among those who do, there is no agreement as to how this QA/QC should be done.
1 VAC 30-45-40		The following definitions were added: certified reference material, International System of Units (SI), LCS, LOD, LOQ, matrix spike, matrix spike duplicate, reference standard, and standardized reference material.	These definitions were added to enhance understanding of the quality control requirements that had been added to the regulations previously.
1 VAC 30-45-40	Definition of “quality assurance officer”	Replaced the term “technical director” with the term “laboratory manager.”	The term “technical director” is a term not in use in 1 VAC 30-45.
1 VAC 30-45-70 G and 1 VAC 30-46-70 G	There was no time limit for DGS-DCLS to carry out a completeness determination during the initial certification period.	DGS-DCLS now has 90 calendar days to carry out a completeness determination during the initial certification period.	DGS-DCLS did not establish a deadline for itself for the completeness determination during the initial certification period. Although the agency intended to carry out the determination in a reasonable time, it did not want to set a deadline. Based on comments, DGS-DCLS now has a self-imposed deadline that it believes is reasonable for all concerned.
1 VAC 30-45-70 H 3	Interim certification status would not exceed 12 months.	The language reverted to that originally proposed as follows: “Interim certification status expires when DGS-DCLS issues a final determination on certification.”	DGS-DCLS, in responding to a DEQ comment on the original proposed language, limited interim certification status to 12 months. During the second round of public comment, commenters stated that this approach penalizes applicants when DGS-DCLS has failed to complete the on-site assessment. DGS-DCLS does not anticipate taking 12 months to complete an on-site assessment. However the comments are understandable and the change back to the original language was made.
1 VAC 30-45-70 I 2 a	The third-party on-site assessors are on a DGS-DCLS-approved list of NELAC-trained on-site assessors.	The third-party on-site assessors are on a DGS-DCLS-approved list of on-site assessors.	The phrase “NELAC-trained” is not necessary in the context of 1 VAC 30-45.
1 VAC 30-45-70 L	The provisions concerning denial of certification or	The provisions concerning denial of certification or accreditation are	This change of terminology was made to ensure that the

Section number	Requirement at second proposed stage	What has changed	Rationale for change
and 1 VAC 30-46-70 L	accreditation use the phrase "laboratory owner or employee" when describing causes for denial.	modified to use only the term "laboratory" when describing causes for denial.	regulatory language is the same as that used in the statute with regard to denial of certification or accreditation.
1 VAC 30-45-90 C 6	The requirement for a new owner to keep records and analyses performed by the previous owner is three years.	The requirement is still three years, unless other regulations require the records and analyses to be kept for a longer period.	DEQ regulations would in some cases require the records and analyses to be kept for a longer period, generally five years.
1 VAC 30-45-100 and 1 VAC 30-46-100	The provisions concerning decertification or withdrawal of accreditation use the phrase "laboratory owner or employee" when describing causes for decertification or withdrawal of accreditation. Subsection A specifies specific instances of falsification.	The provisions concerning decertification or withdrawal of accreditation are modified to use only the term "laboratory" when describing causes for decertification or withdrawal of accreditation. The statutory language concerning falsification is used instead of that originally proposed which was more detailed.	This change of terminology was made to ensure that the regulatory language is the same as that used in the statute with regard to decertification or withdrawal of accreditation.
1 VAC 30-45-110 and 1 VAC 30-46-110	Appeal procedures were revised extensively adding more details about the process, especially about notification and any request for an informal fact finding proceeding.	Appeal procedures were rewritten to clearly communicate the fact that an application cannot be denied or a laboratory decertified (have its accreditation withdrawn) before the laboratory has the opportunity to put its own argument before DGS-DCLS. Other related changes to 1 VAC 30-45 and 1 VAC 30-46 (-70 L and -100) were made to ensure that the regulatory and statutory language are identical with regard to falsification.	From the comments, it was clear that the proposed language inadequately communicated the process inherent in denying certification or accreditation and in decertification and withdrawal of accreditation. DGS-DCLS believes the additional changes provide a clearer explanation of the process.
1 VAC 30-45-130 E 3 and 1 VAC 30-46-150 E 3	DGS-DCLS added a test category, benthic assessment, to the table of test category fees.	DGS-DCLS removed the test category of benthic assessment from the table of test category fees.	Under the definition of environmental analysis, taxonomic identification was listed as not included in the regulation. Benthic assessment is taxonomic identification.
1 VAC 30-45-200 B	Laboratory manager - qualifications	DGS-DCLS added a provision allowing a full-time employee of a drinking water or wastewater treatment facility who holds a valid treatment plant operator's certificate to qualify as a laboratory manager. DCLS also added a provision allowing a full-time employee of an industrial waste treatment facility with one year's experience in environmental analysis to qualify as a laboratory manager.	DEQ suggested these additional provisions from the NELAC standards. These are provisions beneficial to the municipal wastewater community especially. While most of the requirements for the laboratory manager are less stringent than the requirements under 1 VAC 30-46, these additional provisions provide more flexibility in 1 VAC 30-45 and are equivalent to provisions in 1 VAC 30-46 (as incorporated by reference).
1 VAC 30-45-230	If a laboratory manager will be absent for more than 15 consecutive calendar days,	DGS-DCLS revised the requirement to eliminate the requirement that the staff member substituting for the lab	This change allows the laboratory more flexibility to put someone in temporarily

Section number	Requirement at second proposed stage	What has changed	Rationale for change
	the laboratory must designate another full-time staff member to perform the manager's function.	manager would be full-time as long as that person is qualified to be a lab manager.	who might not be an employee of the lab or who might work part-time.
1 VAC 30-45-300 B 2	DGS-DCLS lists changes at a laboratory that would trigger an on-site assessment. Also provided is a general statement about other changes that might trigger an on-site assessment. This general statement characterizes these changes as "major."	The adjective "major" is deleted from the general statement. The statement now reads as follows: "Any other change occurring in a laboratory's operations that might reasonably be expected to alter or impair analytical capability and quality may trigger an on-site assessment."	The adjective "major" was unnecessary and misleading. The sentence indicates an on-site assessment might be triggered by a change that reasonably might "alter or impair analytical capability and quality."
1 VAC 30-45-390 F		Substituted the term "manager" for the term "technical director."	Technical error
1 VAC 30-45-500 A and 1 VAC 30-45-530		The term "whole effluent toxicity" has been deleted and replaced by the term "aquatic toxicity."	Technical error
1 VAC 30-45-530 C		For aquatic toxicity testing, DGS-DCLS added the following requirement: "When the DMR-QA whole effluent toxicity portion does not include all test procedures required for a permit, the laboratory shall perform a proficiency test for aquatic toxicity testing."	The regulation allows laboratories performing aquatic toxicity testing to use the whole effluent toxicity portion of the DMR-QA as a substitute for a proficiency test. However this substitute does not always reflect the data requirements in a DEQ permit. When this circumstance occurs, the laboratory needs to provide a proficiency test instead of the substitute. It is important that the laboratory demonstrate proficiency in a manner that closely reflects the testing it carries out.
1 VAC 30-45-640 H		This provision concerning computer and electronic data record requirements was expanded to include references to all pertinent requirements in 1 VAC 30-45.	The provision was missing some pertinent references.
1 VAC 30-45-680 A	In this provision concerning subcontracting analytical samples, the subcontractor laboratory must be certified under 1 VAC 30-46 or an another State's equivalent program.	The provision now allows only subcontractor laboratories that have been certified under 1 VAC 30-46.	Without the change, subcontractor laboratories would not have been required to obtain reciprocal accreditation in Virginia. Under the statute, laboratories providing air, waste and water data in Virginia must be certified by the Virginia program.
1 VAC 30-45-710 4	There shall be effective separation between neighboring areas in which there are incompatible activities . . . Measures should be taken to prevent cross-contamination.	The last sentence was revised to read as follows: The laboratory shall take measures to prevent cross-contamination.	Edited to provide a direct requirement.

Section number	Requirement at second proposed stage	What has changed	Rationale for change
1 VAC 30-45-730 E and F	Provisions concerning demonstration of capability and the procedure for this demonstration	Revised to clarify the requirements.	The requirements did not make technical sense.
1 VAC 30-45-730 G	Certification statement for the demonstration of capability	Added an explanation of the meaning of the following terms: true, accurate, complete, and self-explanatory.	This explanation was inadvertently omitted in the previous proposal.
1 VAC 30-45-730 J 3	“Records shall be maintained on reagent and standard preparation.”	“Records shall be maintained on standard and reference material preparation.”	The substitution of reference material for reagent preparation records eliminates a burdensome requirement that did not greatly improve lab quality.
1 VAC 30-45-740 D 2 c (2) (b), (c) and (f)	Continuing instrument calibrations	Deleted provisions on checking verification at multiple concentration levels. Substituted language on this topic from the 2003 NELAC standards that had replaced the earlier language used in this regulation.	Comments on this topic resulted in a review of the basis for the original provisions. The use of the changes made to the 2003 NELAC standards should satisfy those who submitted these comments.
1 VAC 30-45-760 A 1	Quality control requirements - general	Added language to indicate that the essential quality control standards outlined in 1 VAC 30-45-760 through 1 VAC 30-45-829 (where appropriate) or the quality controls in the mandated methods or regulations, whichever are more stringent, must be incorporated into the laboratories’ method manuals. If it is not apparent which is more stringent, then the requirements from the mandated methods or regulations are to be followed.	Although the condition added to section 760 is to be found elsewhere, it is important to place the information at the beginning of the provisions on quality control.
1 VAC 30-45-780		Replaced “whole effluent toxicity” with “aquatic toxicity.”	Technical error
1 VAC 30-45-781 A 1 a		Replaced reference to “Appendix C” with “1 VAC 30-45-730 F.”	Technical error
1 VAC 30-45-781 A 1 b		Edited punctuation in last sentence.	The revision provides clarity.
1 VAC 30-45-781 A 4		In the first sentence, deleted the phrase “state or”.	The phrase was repetitive and if left in would lead to confusion.
1 VAC 30-45-791 B 2	Microbiology testing – positive controls	Deleted a requirement for the use of pure culture.	It is inappropriate for wastewater treatment plants to maintain pure cultures of bacteria.
1 VAC 30-45-791 C	Microbiology testing – negative controls	Added condition as follows: “The provisions of this subsection shall not apply to wastewater treatment plants.”	The media used in approved wastewater methods have been tested extensively to select for the target organism. The required positive controls are sufficient.
1 VAC 30-45-812	“The selected sample(s) shall be rotated among client samples so that various sample matrix problems may	“The selected sample(s) shall be rotated among sampling points or sampling locations so that various sample matrix problems may be noted	Because the laboratory is not providing laboratory services for outside clients, rotating samples among

Section number	Requirement at second proposed stage	What has changed	Rationale for change
	be noted and/or addressed.”	and/or addressed.”	sampling points or locations was substituted for rotating among client samples. This change makes sense for the laboratories affected by the requirement.
1 VAC 30-45-822 A 2 d.	“The frequency of interlaboratory verified analysis shall correspond to a minimum of 1 per 200 grid square analyses for clients.”	“The frequency of interlaboratory verified analysis shall correspond to a minimum of 1 per 200 grid square analyses.”	Because the laboratory is not providing laboratory services for outside clients, the phrase “for clients” was deleted. There are other instances in 1 VAC 30-45 where the word “client” is used and no changes were made. In these other cases, “client” means the internal client that the laboratory is serving such as a wastewater treatment plant or a manufacturing facility.
1 VAC 30-45-827 A, B and C	Asbestos testing data reduction	Edited and corrected references	Technical errors

**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.*

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See the Summary and Analysis of Public Testimony which follows at the end of this document.

**All changes made in this regulatory action**

*Please detail all changes that are being proposed and the consequences of the proposed changes. Detail new provisions and/or all changes to existing sections.*

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See section on Substance, above. These regulations are new regulations. The section on Substance provides a narrative summary of the final regulations.

**Family impact**

*Please assess the impact of the proposed regulatory action on the institution of the family and family stability.*

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It is not anticipated that these regulations will have a direct impact on families. However, there will be a positive indirect impact. The regulations will ensure that data used to comply with the Commonwealth’s environmental laws and regulations have been derived in an accurate, precise

and consistent fashion. As a result, the environmental health and welfare of the Commonwealth, including its families, will be protected.

**SUMMARY AND ANALYSIS OF PUBLIC TESTIMONY  
ON PROPOSED REGULATIONS CONCERNING**

**ENVIRONMENTAL LABORATORY CERTIFICATION PROGRAM  
(1 VAC 30, Chapters 45 and 46)**

**INTRODUCTION TO COMMENTS RECEIVED**

On December 30, 2003, the Governor's Policy Office approved the following proposed regulations to be promulgated for public comment:

1 VAC 30, Chapter 45. *Certification for Noncommercial Environmental Laboratories.*

1 VAC 30, Chapter 46. *Certification for Commercial Environmental Laboratories.*

The proposal package, including the notice of public hearing, was printed in the *Virginia Register of Regulations* on February 9, 2004. Public hearings were held throughout the state on March 23-24, 30-31, and April 1. The public comment period closed April 9, 2004.

Following the review of the comments received during the comment period that ended April 9, the Division of Consolidated Laboratory Services (the Division) made substantive changes to the regulations. As a consequence, the Division provided an opportunity for additional public comment. This 30-day public comment period began September 20, 2004 and closed October 20, 2004.

**Analysis of Testimony**

Below are each organization's or person's testimony and the accompanying analysis. Included is a brief statement of the subject, the identification of the commenter, the text or a summary of the comment and the agency response (analysis and action taken). Each issue is discussed in light of all of the comments received that affect that issue. The Division has reviewed the comments and developed a specific response based on its evaluation of the issues raised. The Division's action is based on consideration of the overall goals and objectives and the intended purpose of the regulation.

Comments on provisions where the language is identical in 1 VAC 30-45 and 1 VAC 30-46 appear under the comments for 1 VAC 30-45. These comments are identified as such; a bracketed reference to the provision in 1 VAC 30-46 follows at the end of the subject line. Comments concerning fees are to be found in the section on 1 VAC 30-46; the fee comments were directed at the Chapter 46 fees. However the changes affect both regulations.

The first main section of the analysis of testimony concerns the testimony received from February 9 through April 9, 2004. The second section of the analysis of testimony concerns the testimony received from September 20 through October 20, 2004.

**PUBLIC TESTIMONY RECEIVED, FEBRUARY 9 THROUGH APRIL 9, 2004**

**GENERAL COMMENTS**

1. **Subject:** Positive Effect of Environmental Laboratory Certification Program

**Commenter:** Virginia Department of Environmental Quality (DEQ)

**Text:** The proposed regulation should have a positive impact on the quality of data being reported to DEQ. The program will require laboratories to conduct biannual proficiency tests; include quality control measures currently lacking in many acceptable EPA methods; perform internal audits of laboratory procedures; and include inspections of labs performing analyses for Virginia's Air and Waste programs. DEQ supports this regulation.

**Response:** The Division of Consolidated Laboratory Services (DCLS) appreciates DEQ's support of the proposed program regulations.

2. **Subject:** Major Issues

**Commenter:** DEQ

**Text:** DEQ requests modifications to the proposed regulations on the following major points:

Certification scheme for non-commercial labs should be the same as for commercial labs, which is Matrix, Method/Technology, Analyte/Analyte Group.

The essential quality control procedures given in Chapter 45 lack sufficient detail to be audited in a consistent manner. DEQ believes the requirements of Appendix D of NELAC's Chapter 5 Quality Systems should be included.

Interim accreditation status should expire after a given period rather than allowed to exist indefinitely. Records of sampling information should be required. While sampling procedures are not covered in the certification program, the information concerning where and when the sample was collected and preserved and by whom, is critical for compliance monitoring.

**Response:** Detailed comments from DEQ on these four issues appear in the "Specific Comments" for the two proposed regulations. The responses to these comments appear in the "Specific Comments" section.

3. **Subject:** Sampling and field measurements

**Commenter:** DEQ

**Text:** DEQ would like to have sampling and field measurements (i.e. stack testing, total residual chlorine, pH, flow, temperature, dissolved oxygen) included in the certification program as soon as practicable. Data from field measurements are critical in determining permit compliance and calculating pollutant loads in Virginia's air and water. The elimination of field measurement arguably excludes a data set that is prescribed by law. As for sampling, the quality of the data can only be as good as the validity of the procedures used to collect the sample.

**Commenter:** Hampton Roads Sanitation District (HRSD)

**Text:** The quality of environmental analysis begins with a representative, quality sample collection. The importance of proper sampling protocols cannot be over emphasized. Even the best quality analytical data could be totally meaningless or even erroneous if an improper sample collection method compromised the result. Organizations and groups that collect samples and perform field measurement need to understand the importance of their role and comply with appropriate sampling techniques and protocols. Exempting these activities from the certification process would seriously undermine the purpose of this regulation.

**Response:** The National Environmental Laboratory Accreditation Conference (NELAC) only recently began development of national quality assurance and quality control standards for sampling and field measurements. DCLS agrees that sampling and field measurements are important components of a strong certification program. When mature standards for sampling and field measurements have been

developed by NELAC, DCLS will consider adding these standards to those the agency is proposing at present. No change has been made to the regulations based on these comments.

4. **Subject:** Single versus Dual Standards For All Environmental Laboratories

**Commenter:** Laboratory Association of Virginia (LAVA)<sup>1</sup> and Environmental Systems Services, Ltd. (ESS)

**Text:** Commercial laboratories have been involved in the discussions concerning laboratory regulations since the first public comment sessions and the initiation of the Ad-Hoc Committee. LAVA grew out of need to engage in the debate collectively and help develop a regulation that met the intent of the original statute. Throughout this difficult process, LAVA has negotiated and compromised in good faith with the various stakeholders, therefore we are willing to stand behind the commitments we made and support the current proposed regulation with the compromises agreed to by the parties involved.

Although LAVA believes philosophically that a single standard would be a fair approach, many groups have presented arguments that would make a single standard untenable. This regulation has been debated among the stakeholders and LAVA fears that advocating one program for all laboratories would cause irreconcilable differences amongst the stakeholders and cause this regulation to be completely rewritten thereby delaying the implementation of the regulation. Seven years is a long time to develop and implement an accreditation program. It is not in anyone's best interest to prolong the implementation of this regulation on a philosophical basis alone. The original intent of the statute as described by the JLARC report was to have "direct control over analytical data activity by the regulatory agency; greater assurance that the data are accurate and representative of the discharge; minimum standards of quality; and improved control factors influencing the quality of the environment." LAVA contends that the standards adopted by NELAC provide the minimum standards recommended by JLARC and we are willing to participate in this program. Chapter 45 participants have a program based on NELAC standards, which also meet the minimum standards recommended by JLARC.

**Commenter:** Aquatech Environmental Services, Inc.

**Text:** Aquatech Environmental Services, Inc. (AES) is a NELAP-accredited laboratory for the services of Toxicology Testing in both Aquatic and Sediment Toxicology, as well as, Hazardous Materials WET testing. Our accreditation was initiated at the inception of the NELAP program through the state of California with secondary accreditation through Florida. AES is a small laboratory (only 5 employees). This laboratory as a matter of principal has endured the burden and expense of this program. We believe strongly in what this program is trying to achieve. AES has participated in this program for the last 5 years and provided services across the country as a result of such participation.

**Response:** The commercial environmental laboratory community has participated fully in the development of the program's regulations. DCLS appreciates the willingness of the commercial environmental laboratory community to compromise on the structure of the program's requirements.

5. **Subject:** Dual Program and Commercial Laboratories

**Commenter:** ESS

**Text:** ESS is a company that has been in existence for 31 years now. It began as a company that provides contract operations of wastewater treatment facilities, both municipal and industrial. Obviously, a company involved in that needs to have data, test numbers, laboratory test numbers in order to assess how a treatment plant is operating, assess how changes in that treatment plant design are affecting the effluent that is being discharged, and of course the testing that is required by a permit. That is still a large part of what ESS does. Shortly after the company began though, it was a natural growth for the

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<sup>1</sup> Environmental Systems Services Ltd. supports this and all other LAVA comments.

laboratory to develop in-house. And again, 31 years later, that is still a significant aspect of our business. The laboratory is one in which we are providing numbers both to this group in ESS as well as to other permittees. To give you some quick numbers in 2003 the last year I have figures we did some amount of testing for some 100 permittees in Virginia. Nearly 20-25 of these are permittees for whom ESS does turnkey operations, if you will, of treatment plants. We operate the treatment plant. We provide the test numbers. We fill the DMR each month. We meet with the DEQ when there are problem issues. All aspects of their permit are handled by ESS. Some 75 other permittees are ones for whom I as the lab manager have the responsibility to provide good test numbers and in the case of these permittees they take their test numbers (they operate their own plant) to complete their DMR or additional testing for process control. So while what we are doing is not a true 45-46 split, it does seem to enter a little bit of a gray area here. I'm providing numbers as a commercial lab manager certainly for permittees on a fee basis. But I'm also providing numbers indirectly to other permittees directly through another branch of our company. And so, again, while this doesn't meet the definition of a chapter – the many definitions that had to be developed for a noncommercial, i.e. Chapter 45 lab, we do come close in being into a little bit of a gray area. Whether we are unique in Virginia in that regard, I am not sure. But it is a foundation of what ESS does and has done for over 30 years. So with that in mind and with just the aspect of good science being involved, this would seem to underscore the need for one certification/accreditation program, whether this would be NELAC or not.

**Response:** DCLS appreciates that ESS provides commercial environmental laboratory services and also acts as the operator for individual wastewater treatment plants. DCLS agrees that there is merit to having one certification program in Virginia. DCLS would prefer to use the national standards developed by NELAC for all laboratories. However a consensus for this choice could not be built. The JLARC report that precipitated in great part the passage of the certification program's statute strongly suggested the use of national standards. The writers of the JLARC report were particularly concerned with DEQ's legal limits on the review of the quality of commercial environmental laboratories. DCLS, with the assistance of an *ad hoc* advisory group, developed a compromise that requires the full NELAC standards for commercial environmental laboratories and a set of Virginia standards, based on the NELAC standards, for noncommercial laboratories. DCLS believes this compromise is the best approach to take in setting quality assurance and quality control standards for environmental laboratories in Virginia. No change has been made to the regulations based on these comments.

6. **Subject:** Need for a Lesser NELAC-based Program for the Wastewater Laboratories

**Commenter:** Mark S. Hollyfield, Coeburn-Norton-Wise Regional Wastewater Authority, the Town of Big Stone Gap, and Rural Water Authority

**Text:** I've had concerns all along that we would base the Virginia regulations on the NELAC standards. I have numerous problems with the NELAC standards in general. Specifically I want to applaud DCLS for coming up with a non NELAC-based or a lesser NELAC-based program for the wastewater laboratories. I would like to see whatever final regulation that is published by DCLS to ensure that the small wastewater laboratories do not have to be NELAC-certified. That is very important to the small wastewater laboratories because we don't have to work in the other states. Reciprocity is not an issue for us and there are so many things in NELAC that are reciprocity-driven. Since we only do work in the Commonwealth of Virginia, we only need to meet a standard that is issued and effective for the Commonwealth of Virginia.

**Response:** DCLS appreciates the comments provided by Mr. Hollyfield. See also the response to issue 5.

7. **Subject:** If DCLS Revises Its Proposal to Establish a Single Program for "Commercial" and "Noncommercial" Laboratories, the Program Should Be Based on Proposed Chapter 45

**Commenters:**

Virginia Association of Municipal Wastewater Agencies (VAMWA)<sup>2</sup>; Amherst County Service Authority; Chesterfield County Utilities Department; City of Danville Utilities Department; City of Fredericksburg; County of Henrico Department of Public Utilities; Town of Onancock; Rivanna Water & Sewer Authority; City of Roanoke Public Utilities; and County of Spotsylvania Utilities Department. Virginia Section of the American Water Works Association/Virginia Water Environment Association Laboratory Practice Committee (VA AWWA/WWEA LPC); Augusta County Service Authority; Fairfax County Water Authority, Water Quality Laboratory; HRSD; Hanover County Department of Public Utilities; Town of Round Hill Utility Department; and the Upper Occoquan Sewage Authority.

**Text:** The Department of Planning and Budget (“DPB”) has raised substantial questions regarding the implementation of two programs, one for “commercial” and the other for “noncommercial” laboratories. DPB found that this distinction lacks a “rational basis in either economics or policy.”

The dual program approach that DCLS has proposed is certainly preferable to a single, National Environmental Laboratory Accreditation Conference (NELAC)-based program, which we could not support. VAMWA has long expressed concerns with the option (once considered, but later rejected) of subjecting municipal laboratories to a mandatory NELAC-based program. NELAC is a very prescriptive program that would eliminate the flexibility needed for efficient and effective operation of laboratories and treatment operations. Furthermore, the future of NELAC as a national standard remains questionable due to stagnant levels of state participation and other problems. Accordingly, we continue to believe that the conversion of NELAC standards from voluntary standards to state regulations is inappropriate.

DPB has recommended establishing a single program rather than two. It should be noted that Virginia laboratories will be regulated not by two but three different sets of regulations taking into account the Safe Drinking Water Act program. This is confusing for the regulated community and presumably more so for the public. DPB’s recommendation of a single unified program appears to have merit. If it is implemented, VAMWA strongly recommends that the single program be based on the Chapter 45 proposal rather than the Chapter 46 NELAC-based program. In that case, DCLS could still recognize NELAC accreditation (e.g., for interstate laboratories interested in acquiring and marketing their NELAC status) as a voluntary option for meeting state certification requirements. This approach is used successfully in other states.

**Commenter:** Addison-Evans Water Production & Laboratory Facility, Chesterfield County

**Text in Addition to Comments Above:** The reason for creation of NELAC was to standardize environmental test data across the nation. The preparation of 1 VAC 30-45 was intended to provide a version of NELAC that could be applied in Virginia. The standardization of test data across the nation would appear to be best served by consolidation of existing laboratory standards and not creation of new ones. The State of Virginia should take a reductionist philosophy in administering laboratory regulations and possibly reconsider the need for 1 VAC 30-45.

**Response:** DCLS agrees that there is merit to having one certification program in Virginia. DCLS would prefer to use the national standards developed by NELAC for all laboratories. However a consensus for this choice could not be built. The JLARC report that precipitated in great part the passage of the certification program’s statute strongly suggested the use of national standards. The writers of the JLARC report were particularly concerned with DEQ’s legal limits on the review of the quality of commercial environmental laboratories. DCLS, with the assistance of an *ad hoc* advisory group, developed a compromise that requires the full NELAC standards for commercial environmental laboratories and a set of Virginia standards, based on the NELAC standards, for noncommercial laboratories. DCLS believes this compromise is the best approach to take in setting quality assurance

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<sup>2</sup> VAMWA’s comments are provided *verbatim*. The other commenters listed in group A support VAMWA’s comments and emphasized their concern about this issue in brief paragraphs on the subject. All of VAMWA’s comments are supported by these listed commenters. The commenters in Group B submitted essentially the same comments on this issue as the VAMWA comments.

and quality control standards for environmental laboratories in Virginia. In developing this compromise, many of the noncommercial laboratories represented on the *ad hoc* advisory group thought that commercial laboratories should meet the NELAC standards.

The Department of Planning and Budget (DPB) suggested in its review of the proposed regulations that DCLS use only one set of standards for all environmental laboratories covered by the certification program. DPB further stated that the set of standards should be those specified for noncommercial laboratories. DPB then stated that DCLS could also provide a voluntary NELAC program for commercial environmental laboratories. The result would be two programs: one required program for all environmental laboratories and a voluntary NELAC program for commercial environmental laboratories. Not only would there be two programs but commercial laboratories could choose whether to meet the NELAC or the Virginia standards. The Virginia standards do not include standards for subcontracting and other provisions related to the commercial provision of laboratory services. DCLS sees no advantage in taking the course suggested by DPB.

Virginia does require drinking water certification under its laws and regulations. DCLS has the authority and responsibility to carry out the certification program. Some environmental laboratories perform a dual role for their owner utilities; they provide laboratory services for the drinking water as well as the wastewater treatment facility. There are considerably fewer drinking water laboratories than there are environmental laboratories performing wastewater analysis. These drinking water laboratories are both commercial and municipal laboratories. Drinking water laboratories that are also covered under the environmental laboratory certification program are able under the proposed regulations to get one certification, if they choose to be certified under the commercial, or NELAC, standards. The national drinking water program standards are changing. DCLS recently had its program and lab audited by the national drinking water program at EPA. Its review was a NELAC review.

No change has been made to the regulations based on these comments.

8. **Subject:** Assessor Training

**Commenters:** VAMWA, Amherst County Service Authority; Chesterfield County Utilities Department; City of Danville Utilities Department; City of Fredericksburg; HRSD; County of Henrico Department of Public Utilities; Town of Onancock; Rivanna Water & Sewer Authority; City of Roanoke Public Utilities; County of Spotsylvania Utilities Department; VA AWWA/VWEA LPC; Augusta County Service Authority; Fairfax County Water Authority, Water Quality Laboratory; Hanover County Department of Public Utilities; Town of Round Hill Utility Department; and the Upper Occoquan Sewage Authority; and Addison-Evans Water Production & Laboratory Facility, Chesterfield County.

**Text:** The state and the regulated community alike have a mutual interest in having well-trained assessors. Chapter 46 selectively omits the assessor training provisions of NELAC (Appendices A and B regarding On-Site Assessment). These appendices are integral elements of NELAC that must be included with the other elements. Also, DCLS must include provisions ensuring sufficient training for assessors for Chapter 45 facilities that are similar in quality and quantity to standards set by NELAC.

**Response:** As revised, 1 VAC 30-46 now incorporates all the NELAC on-site assessment standards (2003). DGS-DCLS will use the same assessors for both the noncommercial and commercial programs. These assessors will be trained as required by the NELAC standards (2003).

9. **Subject:** Technical Advisory Committee

**Commenters:** VAMWA, VA AWWA/VWEA LPC; Augusta County Service Authority; Fairfax County Water Authority, Water Quality Laboratory; HRSD; Hanover County Department of Public Utilities; Town of Round Hill Utility Department; the Upper Occoquan Sewage Authority; and Addison-Evans Water Production & Laboratory Facility, Chesterfield County.

**Text:** In sharp contrast to the environmental laws that the new regulations are intended to support, the proposed regulations lack a citizen board independent of DCLS and the laboratories, to handle contested permits/certification decisions and enforcement of the program. We believe that the citizen boards (e.g., Air, Water and Waste Boards to which DEQ is staff) play an important role in environmental protection in Virginia and that a similar process is appropriate here.

At a minimum and especially in the absence of a citizen board, DCLS must establish a standing Technical Advisory Committee (TAC) to ensure continued public input into the operation and effective implementation of this new program. It is recommended that the TAC include regulators, academicians and permittees. We believe such a committee would be particularly beneficial in the first few years of the program. This need has been recognized in the national NELAC program, which has its Environmental Laboratory Advisory Board as well as in several states that have formed similar committees such as:

California (Environmental Laboratory Technical Advisory Committee)  
 Pennsylvania Laboratory Accreditation Advisory Committee)  
 New Jersey (Environmental Laboratory Advisory Committee)

We urge DCLS to adopt a similar committee role here.

**Response:** A policy board, like that of DEQ's air, waste and water boards, requires legislation to implement. The legislation sets the purpose and the size of a board. It tells how many of the members can be from organizations affected by the Board's decisions, if any.

There are technical advisory committees in some NELAP-accredited states, and DEQ's air program has had an advisory committee for decades. These committees serve useful purposes but also add to the work of the agency. There are costs involved as a result. This program is funded through fees. The proposed fees would have to be increased for DGS-DCLS to add a technical advisory committee to the program and to manage its activities. In contrast, the agency may ask for volunteers to work on an *ad hoc* committee when the need arises.

No change has been made to the regulations based on these comments.

#### 10. **Subject:** Start-Up

**Commenters:** VAMWA, VA AWWA/VWEA LPC; Augusta County Service Authority; Fairfax County Water Authority, Water Quality Laboratory; HRSD; Hanover County Department of Public Utilities; Town of Round Hill Utility Department; the Upper Occoquan Sewage Authority; and Addison-Evans Water Production & Laboratory Facility, Chesterfield County.

**Text:** The preamble states that this program will affect 915 laboratories. Given our experience with VPDES permitting and on-site audits, we question the feasibility of successfully certifying all 915 laboratories within 24 months. While interim certification addresses our compliance concerns it is strongly recommended that DCLS consider a phased implementation approach. One benefit of this recommendation is that it would provide DCLS with the time to adequately review applications, conduct site assessments, and provide a more effective implementation of this program. Initial phasing will also space out the flow of renewal applications in subsequent years and generally help balance the agency's workload over time. The VPDES permit program, with its high variability in the number of permit renewals during any given year over the 5-year permit life cycle, is a clear and timely example where the budgeting and implementation difficulties arise absent a phased approach.

**Response:** DGS-DCLS recently revised the estimated number of potential laboratories covered by the program (now 830). The number of VPDES permittees has dropped since the first laboratory estimate was made. DGS-DCLS in planning program start-up determined that the agency will have all program staff hired by the end of the fifth month after the effective date of the program regulations. The applications for the laboratories under 1 VAC 30-46 are due within the following month. This shortens the

available time to train and have staff ready to review applications. It also shortens the time available to carry out the certification process for the applicant laboratories to 1.5 years. To provide sufficient time to certify these laboratories, DGS-DCLS has decided to change the establishment date from two to three years.

11. **Subject:** Memorandum of Understanding between DCLS and DEQ

**Commenter:** LAVA

**Text:** The Memorandum of Understanding is an essential part of this regulation. We feel strongly that this document have both a formal standing amongst the agencies affected and input from the regulated community. This regulation will be overly burdensome if after all is said and done, we continue with multiple inspections for numerous agencies.

This is imperative that this is done with the intent of maintaining a program that does not contain duplicative inspections between the two agencies. All the stakeholders have made this point.

**Commenter:** Mark S. Hollyfield, Coeburn-Norton-Wise Regional Wastewater Authority, the Town of Big Stone Gap, and Rural Water Authority

**Text:** The other thing that I am still concerned about - and I appreciate all the effort that has gone into the Memorandum of Understanding and future negotiations between DCLS and DEQ - as everyone knows my concern all along is I didn't want to see duplicate inspections. I want to stress that I hope that we do not come to the point where the state has duplicate inspections on the small laboratories, particularly the ones at the wastewater facilities.

**Response:** From the beginning of the process to develop these regulations, all of the stakeholders have clearly stated how important it is to have only one agency auditing laboratories. DCLS and DEQ agreed in 2000 to let DCLS perform the lab audits required by the VPDES program once the program was established. This agreement is still in force and will continue to be even when the MOU is updated, which is should be in the near future. The stakeholders should understand that DEQ will still inspect the wastewater facilities that it currently inspects. Those inspections will not change. And, DEQ has the right to look at the raw data and the data produced by the laboratory at any time. Ultimately, DCLS will perform the VPDES lab audits along with the on-site assessments required by the certification program. No change has been made to the regulations based on these comments.

12. **Subject:** Commercial Environmental Laboratories and Costs

**Commenter:** Summit Engineering

**Text:** We have a commercial laboratory. We have a good quality assurance manual specific to our facilities and the equipment that we use. We have a high level of quality in our lab right now but we are not at the level that NELAP is. It is going to be a significant cost to be accredited by NELAP. The fees that they have come up are only a small, small portion of what it is really going to cost. We are going to have to pass that cost on along to our clients which would be the mining industry. What I would like to see is DCLS to help us achieve this accreditation and to provide any assistance that they can in order to keep our costs lower so the mining industry will not ultimately have to pay the price.

Also NELAP evidently has some problems of their own. I don't know if that's the best way to go. When this thing first started several states signed up, participated, and several of those states have now dropped out. I don't know why. I think it would be important for DCLS to investigate why states have quit participating in this program. That's a concern for me. I have dealt personally with two labs are NELAP-accredited and have talked to them and both have told me it is very expensive. Just some things are above and beyond what they really need in order to provide good quality analysis to the clients.

**Response:** Section 2.2-1105 of the *Code of Virginia* requires laboratories that provide data to the Department of Environmental Quality be certified under a set of quality assurance and quality control standards. The NELAC standards are those developed at the national level by state and federal agencies, along with commercial laboratories, with the input from the entire laboratory community. The standards are quite detailed; they cover all types of environmental testing. A commercial laboratory may need to upgrade its recordkeeping or change its operation in some way to meet the standards. However if the laboratory faithfully performs the methods it uses, including the quality controls, the laboratory should be able to meet the NELAC standards. Part of the agency's task is to help laboratories understand the program and what is needed. No change has been made to the regulations based on this comment.

13. **Subject:** Costs to Ratepayers

**Commenter:** Mark S. Hollyfield, Coeburn-Norton-Wise Regional Wastewater Authority, the Town of Big Stone Gap, and Rural Water Authority

**Text:** Another concern that we have is the cost of the program. Since all costs will be passed on to the entities that are certified, I would like DCLS to come up with a program that has the least possible cost because ultimately these are paid by the ratepayers of the Commonwealth of Virginia. Of course, we have some very wealthy people in Virginia but most of the people that we deal with particularly in southwest Virginia have very limited incomes and every dollar makes a difference. We want to keep our rates for our ratepayers as small as possible.

**Commenters:** VAMWA, VA AWWA/VWEA LPC; Augusta County Service Authority; Addison-Evans Water Production & Laboratory Facility, Chesterfield County; HRSD; Hanover County Department of Public Utilities; Town of Round Hill Utility Department; and Upper Occoquan Sewage Authority (UOSA)

**Text:** DCLS states in the preamble that the program presents no disadvantages to the general public. This statement overlooks the fact that local government laboratories will necessarily pass the added costs for implementing these new regulatory obligations on to the general public through some combination of higher taxes, rates or fees.

UOSA adds: "We request that DCLS does not ignore these costs and forges a cost effective Laboratory Certification Program to prevent increased sewer costs to the general public."

**Response:** DGS-DCLS realizes that costs of this program may be passed on to the public. The program provides a positive public good. The public should have increased faith in the data going to the Department of Environmental Quality (DEQ). These data are the basis for many decisions may by DEQ. Improved water and air quality and waste management may be the outcome of this certification program. DGS-DCLS continues to be mindful of the costs of the program both with regard to fees charged and the costs of proficiency tests and of meeting the program's requirements. No changes have been made to the regulation based on these comments.

14. **Subject:** Nutrient management program

**Commenter:** A & L Eastern Agriculture Laboratory

**Text:** My name is Paul Chu. I am with A&L, Eastern Agriculture Laboratory. A & L is kind of a unique laboratory. We serve the farmer. Our main business is testing soil in terms of fertility. There are only two labs in the state of Virginia, A&L and Virginia Tech working on soil testing. Those of us at these two labs have come to a conclusion that our laboratories in terms of soil fertility tests should not be included in this regulation. The simple fact is that both laboratories are unique. We test soils as a service for the farmer. Soil fertility testing has a long history. The methodology, the research behind that, they're all very unique and serve the purpose to provide the farmer a reasonably priced test. For instance we're running 1500 samples today. So for the QA/QC we have our own unique QA/QC that shouldn't be like every 10% that

we put in a calibration again. That would increase costs tremendously. I read a little bit in the regulation. It says that for the public the advantage is such that there is no disadvantage. I totally disagree because any regulation will tremendously cost the general public. Once you put on a regulation that means the preparation, procedures, everything going to increase the cost. Who is going to bear the cost: of course, the farmers. So I would request that our two labs in terms of that kind of test be excluded from this regulation.

**Commenter:** Department of Conservation and Recreation, Division of Soil and Water Conservation and the Virginia Farm Bureau Federation<sup>3</sup>

**Text:** The Department of Conservation and Recreation (DCR) operates the Nutrient Management Program which works with farmers and other nutrient users to encourage the appropriate and efficient use of fertilizer and manure in ways that reduce nutrient losses to ground and surface waters. DCR is required to review and approve nutrient management plans required by the Department of Environmental Quality's (DEQ) Virginia Pollution Abatement (VPA) permits for confined animal and poultry feeding operations. There are currently 1251 DCR-approved nutrient management plans for use in these VPA permits. Although there are no permit limits for nutrients in soils or manure in the VPA animal or poultry waste regulations, soil and manure sampling and analysis are required in these permits for use in developing and implementing nutrient management plans. Therefore, the new regulations will impact 1251 farming operations.

Most of the nutrient management plans DCR has approved utilize Virginia Tech's soil testing laboratory for soil analysis and Clemson University's agricultural service laboratory for manure analysis. Through grants, DCR has funded some research and software improvements used by the Virginia Tech laboratory and presently funds manure sampling for Virginia farmers through a grant with Clemson University. DCR has funded these activities because they are essential to the nutrient management program and because of the programmatic and water quality benefits that are derived through the analysis of collected aggregate data. DCR derives a significant benefit from the funding of manure sampling: the ability to track the progress by various poultry companies in reducing the phosphorus content of feeds and subsequently in excreted manure. To date, a 21% reduction in poultry manure phosphorus has been achieved through this approach. DCR's goal is to achieve and maintain at least a 30% reduction in this phosphorus. This effort is critical in the Commonwealth's efforts to reduce nutrient loads to the Chesapeake Bay and its tributaries.

The proposed environmental laboratory certification program will increase costs for the labs performing the analysis of the soil and manure samples. These labs will have to meet the commercial laboratory standards in proposed Chapter 46. DCR is concerned that fewer labs will be willing to comply with the proposed regulations, and this will have a drastic impact on analysis costs for permittees and create unnecessary difficulties for DEQ in enforcing VPA permit requirements with 1251 farmers.

In recognition of these concerns, DCR makes the following specific recommendations:

DCLS should adopt the baseline standards in Chapter 45 for all laboratories, including commercial laboratories. DCLS could provide NELAC accreditation for laboratories on a voluntary basis.

If DCLS chooses to continue with the regulation scheme as proposed, DCR requests a modification to the definition of "noncommercial environmental laboratory" to add an additional category to subdivision 2 of the definition. The language DCR proposes is as follows:

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<sup>3</sup> The Virginia Farm Bureau Federation submitted an e-mail stating that they support the comments provided by Virginia Tech and the Department of Conservation and Recreation. This organization also states the following: "[F]armers across the Commonwealth, regulated and unregulated, depend on timely results from these types of laboratories. We are concerned that the proposed regulations will slow the process or eliminate services from some labs."

2.g. Environmental analysis performed by a laboratory operated by a state land grant university and operated on a not-for-profit basis for the purpose of the determination of plant nutrients and pH in soil or animal manure.

DCLS should limit the requirement for proficiency testing to once per year. This is sufficient for laboratory performance and will reduce the cost of compliance.

DCLS should modify the regulations to accept proficiency testing for soils and animal manure for plant nutrient content to allow the use of blind samples obtained through programs such as North America Proficiency Testing (NAPT) for soil, plant, and water analysis laboratories and the Manure Analysis Proficiency (MAP) program, both of which are associated with the Soil Science Society of America.

**Commenter:** Virginia Tech Soil Testing Laboratory

**Text:** The primary objective of soil testing has been to identify optimum levels of soil nutrients required for plant growth. Once the optimum level was estimated for a nutrient, the need for additional fertilization or manuring and the economic returns on an investment in fertilizer could be predicted. Routine soil testing has a long and proven history and the overall purpose of routine soil testing is to estimate, based on the amount of a nutrient extracted from a soil, the likelihood that crop yield or quality will be sufficiently improved by the application of fertilizer nutrients to justify the costs involved. However with the growing concern over the potential environmental impacts associated with the land application of organic nutrient sources, routine soil testing procedures, originally designed to estimate the status of plant available nutrients in soils, are being looked at as a means to assess environmental impacts and the probability of environmental degradation resulting from nutrient use, especially organic nutrient sources.

Routine soil testing for the determination of fertilizer needs has been conducted in Virginia since the late 1930s. The Virginia Tech Soil Testing Laboratory and commercial soil testing laboratories use soil extractants that have been proven scientifically (through extensive field testing and calibration against plant response) and accepted by soil scientists as reliable methods of estimating plant available nutrients in Virginia soils. There is a precedence in Virginia for accepting routine soil test data from the Virginia Tech Soil Testing Laboratory and selected commercial soil testing laboratories by the Virginia Department of Conservation and Recreation (DCR) and the Department of Environmental Quality (DEQ) for the intended purpose of writing nutrient management plans (NMP) as required for permitted operations. In addition, DCR has used the Land Grant University (i.e. Virginia Tech) recommendations as the accepted standard for determining nutrient and fertilizer needs in developing NMPs. In Virginia, certified nutrient management planners write NMPs for permitted operations using data from routine soil testing as the primary tool of determining nutrient needs for crops to be grown in agricultural fields. Nutrient management plans are required for operations permitted under 9 VAC 25-192, 9 VAC 25-32 and 9 VAC 25-630. DCR is the state agency responsible for training and certifying nutrient management planners (4 VAC 5-15) as well as approving NMPs for permitted operations. In the process of developing a NMP, the results from routine soil testing remain with the permitted operation. These data are to be made available during on-site inspections by DEQ but they are not reported directly to DEQ. In the past, the exchange of soil samples between the soil testing laboratory at Virginia Tech and commercial laboratories has been conducted by DCR to ensure consistency among laboratories, but until now, the quality and accuracy of routine soil testing data used for determination of nutrient needs in the development of NMPs has not been questioned by either DCR or DEQ. In fact, in the past DEQ has never expressed an interest in these data and if these data were provided to DEQ we would question what they would do with the data in terms of regulatory enforcement and/or the protection of environmental quality in the Commonwealth.

#### Recommended Changes/Amendments to the Regulation

Exclusion of routine soil and manure testing when used for determining crop nutrient needs.

Routine soil testing data and manure analysis data are used solely for the purpose of determining crop nutrient needs during the development of nutrient management plans. As such there are no state requirements that these data be reported directly to DEQ, DEQ does not have any intended use for these data and they are not used directly to enforce any state water quality standards. Thus we recommend

that all laboratories that conduct routine soil testing and manure analysis analyses for the purpose of determining crop nutrient needs and the writing of NMPs be excluded (exempted) from these regulations.

Routine soil testing and manure analysis to determine crop nutrient needs. If exclusion (exemption) is not possible, we recommend the following. Since routine soil testing data and manure analysis data are used solely for the purpose of the determination and management of crop nutrient needs during the development of nutrient management plans for permitted operations and since this data are not reported directly to DEQ and they are not used directly to enforce any state water quality standards, we recommend the following amendments to the proposed regulations.

For laboratories conducting routine soil testing and manure analysis for the purpose of determining crop nutrient needs, there should be no distinction in the requirements for commercial and noncommercial laboratories. We recommend that the minimum standards of operation as described under Chapter 45 and developed by DEQ be used for all laboratories conducting these analyses. By design, soil fertility tests have traditionally been relatively simple tests as noted in the following: "It is a basic principle of soil testing that simple rapid chemical analytical procedures can be designed to accurately measure, or be a measure of the level of plant-available nutrients" (*Soil Testing and Plant Analysis*, third edition, Number 3 in the *Soil Science of America Book Series*, 1990). We believe that we have a strong argument for including routine soil testing and manure analysis procedures used to generate data solely for the purpose of determining crop nutrient needs during the development of nutrient management plans under the current definition of "simple test procedures." Because of the simple nature of soil testing procedures and the intended use of these data, we recommend very strongly that all laboratories conducting routine soil testing and manure analysis for the purpose of determining crop nutrient needs be certified based on the standards of Chapter 45 laboratories.

Proficiency testing will be an important component of these standards. Currently, the Virginia Tech Soil Testing Laboratory as well as the commercial soil testing laboratories that provide routine soil testing data for Virginia's producers participates in the North America Proficiency Testing Program (NAPT)(<http://www.soiltesting.org/proficiencytesting.html>; <http://www.usual.usu.edu/napt/>). NAPT is a national program that is sanctioned by the Soil Science Society of America and includes 157 laboratories throughout North America.

#### NELAC

NELAC has no standards specified for routine soil testing for procedures like soil pH and partial extractions such as the Mehlich 1 and Mehlich 3 extracting solutions, or for other procedures used strictly to generate management guidance recommendations. Thus we seriously question the scientific validity of attempting to apply NELAC standards in a manner which was originally not intended and frankly not necessary given the intended use of routine soil test and manure analysis data and the absence of state regulatory standards for these data.

The major concerns for meeting the requirements of the NELAC program are the anticipated increase in operating costs for the laboratory as well as increased turn around time for samples. Timely turn around of samples is very important for our clientele.

#### Economic impacts

Currently the VT-STL analyses approximately 45-50,000 soil samples per year. Based on estimates from DCR for crop acreage included in permitted operations, the laboratory analyzes approximately 3500 soil samples from permitted operations per year. Admittedly we have no way of evaluating at this point the true economic impacts of implementing the 2002 NELAC Standards. However based on the NELAC documents and a laboratory inspection conducted in August 2003 by DEQ, we estimate conservatively that a full implementation of the 2002 NELAC standards will increase our annual operating costs by \$15-20,000 per year. In addition, we anticipate that our turn around time for samples will be increased significantly. These estimated increased costs for operation will result from a combination of several factors including the use of a smaller number of samples in each batch analyzed, increased frequency of analyzing standards and controls in each batch, increase frequency of instrument calibration, increased

time of sample exposure for some instruments, etc. Given the nature of the VT-STL, we have concluded that it would be impractical to separate out soil samples from permitted operations and analyze those separately, thus we would be forced to run all of our samples (45-50,000/yr.) according to NELAC standards.

VT-STL is currently mandated by the State to provide free routine soil testing for commercial crop production. The VT-STL has a fixed operating budget that has declined or stayed steady in recent years. VT-STL does not anticipate increased funding from the State in the near future. Because the State mandate is to provide free testing, VT-STL has no way to offset the increased cost incurred in meeting this program. It is doubtful that VT-STL will be able to continue to provide routine soil testing data for determining crop nutrient needs for Virginia's permitted operations if VT-STL is required to meet the NELAC standards and no additional revenues are available to cover the increase in costs.

We strongly recommend, therefore, that the land grant university and commercial laboratories conducting routine soil testing and manure analysis for the purpose of determining crop nutrient needs be exempted from the requirements of this program.

**Commenter:** Virginia Tech Department of Crop and Soil Environmental Sciences

**Text:** Comments from the head of the Department of Crop and Soil Environmental Sciences Department at Virginia Tech address in more detail specific soil testing procedures. The conclusion reached by this commenter is the same as that reached by VT-STL.

While I firmly embrace the intentions of this proposed regulation, to provide consistent and reliable data from laboratory sources required by Virginia statutes or regulations to report such data to DEQ programs, I strongly feel that the proposed regulations clearly step outside this mandate in attempting to require routine soil and manure testing laboratories, which do not conduct any "environmental analyses" and are not required by any existing mandate to report their management-oriented results directly to any state agency to meet the expensive and excessive rigor of the NELAC standards.

1. NELAC standards were not designed to include specific routine soil testing for procedures like soil suspension pH and partial extractions such as the Mehlich 1 and Mehlich 3 extracting solutions, or for any other procedures used strictly to generate management guidance recommendations. The reason is simple. The originators have no experience with soil testing procedures and apparently no knowledge of the precision and accuracy achievable or required to provide repeatable results in the field. Some of the recommended techniques are generally deemed inappropriate for soil testing (extended washing of pH electrodes, for example, creates a problem in measuring soil pH because of the junction potential created in contact with charged colloids at ionic strengths common in soil suspensions), and will actually decrease precision (accuracy is addressed below).

2. It was precisely the field tested and proven efficacy of these procedures for management purposes which led farmers to trust them for decades, and more recently, nonpoint source agencies to co-opt these well-researched, precedent-setting management tools into their bag of best management practices. All recognized that lab precision was the strongest link in the chain and even with weak links of sampling, interpretations across various soils, and gross limitations on application equipment precision, the results were highly effective for the intended purpose. Even very early in the life of soil testing, laboratory precision exceeded the ability of field managers to implement precise applications. With modern instrumentation and widely adopted QA/QC procedures used by soil testing labs, that precision has increased 10-fold or more. Measuring soil pH to an accuracy of  $\pm 0.003$  is simply a ludicrous waste of time for a routine soil testing lab which requires results no more precise than the nearest 0.1 of a unit. Spiking of a partial extractant in the presence of a charged soil colloid is likewise a meaningless exercise, an expensive waste of time, and for the number of samples we process, a source of unnecessary pollution.

3. I would add that there is an argument dating back nearly 50 years in the history of soil chemistry stating that pH cannot be accurately measured in soil suspensions, that the “numbers” so obtained are without sound theoretical basis. This troubling question for the soil chemistry purist matters little to the farmer. He bases liming practices on soil pH measurements because the results obtained by inserting a pH electrode into a soil suspension have been found, through extensive field testing, to predict the conditions for crop growth with sufficient accuracy to tell him whether or not he needs to add lime to achieve an economic benefit. He simply does not care whether or not he is getting an accurate measure of the  $-\log(H^+)$ , as long as the “number” is consistent and correlates with plant response.

4. Soil test methods such as partial extractants differ from aqueous solutions and total metal analysis, in much the same way as the theoretical pH measurement above, in that there is no universal standard for plant nutrient availability against which they can be calibrated in the true sense of the word. Soils vary in physical and chemical properties because of soil forming processes, past management practices, and even the time of year the soil is sampled. As a result the soil test “numbers” for different soils with similar plant nutrient availability will vary. For this reason, considerable latitude must be given to the interpretation of the results. Soil scientists have been very careful in developing recommendations to actually measure the laboratory “number” against the desired result in the field, in this case, plant nutrient uptake. This field calibration of lab numbers against field results is a long and expensive process, requiring decades of research to develop and evolve the guidelines which have become our soil and manure recommendations. But without this extensive field testing of laboratory numbers against field response, the results are virtually meaningless. Again, what level of precision and accuracy of the laboratory number is required to achieve the desired result? We believe strongly in QA/QC and proficiency testing. We have standard methods which are implemented throughout similar labs across the region and country, and participate in proficiency testing and laboratory analytical exchanges to verify our precision and relative accuracy. We have described these to DEQ and explained that our current QA/QC procedures have been proven over and over to provide more accurate and precise results than are required to achieve field performance. Farmers and researchers have found our procedures to be adequately precise, and other state agencies concerned about nonpoint source pollution have recommended and then required them for making management recommendations. I know from experience that if duplicate samples varied by 0.2 pH units or 3 ppm extractable P (which our QA/QC would find unacceptable), the management recommendation is unlikely to change.

5. Imposition of the NELAC standards, with appropriate study and consideration for complications in analyzing soil and manure matrices, could perhaps be justified if DEQ were to actually establish environmental standards related to the levels extracted, and require that routine soil and manure labs submit sample results to them in compliance with some law or regulation. They have not. No routine soil test point data produced by the VT soil testing lab has ever been related to an offense, a failure to comply, or a notice of violation. At this point, DCR may require that land managers follow these best available recommendations, and even that they keep a copy with their plans, but does that imply that there is a real and present danger to the Commonwealth if the pH on that report is off by 0.005 units? Absolutely not.

DEQ does not specify limits for the parameters to be monitored in soils. They only require monitoring. If DEQ does decide to specify limits for these parameters, they will have to consider the fact that soil test “numbers” from partial extracts are useful only because they have been tested in the field against the parameters we are attempting to predict with that extract. They are absolutely meaningless without a field calibration process, and the results will without question vary greatly with other soil and physical properties.

We request that DEQ grant routine soil and manure testing an exemption from this regulatory process on the basis that they have never shown a compelling interest in soil and manure testing “numbers” for management recommendations and have never required or even requested these laboratories to provide DEQ with such results.

**Response:** Legally the laboratory analysis being done by the VT-STL and A&L Laboratory is covered by the certification program. Section 2.2-1105 of the *Code of Virginia* requires that all laboratories be certified “before any tests, analyses, measurements or monitoring performed by a laboratory may be used for the purposes of Chapter 13 (§10.1-1300 et seq.) of Title 10.1, the Virginia Waste Management Act, and the State Water Control Law.” §2.2-1105 B. The law does not limit certification to requirements having specific limits. Under Title 62.1, Chapter 3.1 of the State Water Control Law, DEQ has promulgated general permits for confined animal feeding operations (§62.1-44.17:1) and poultry waste management (§62.1-44.17:1.1). These general permits require soils monitoring as part of a Nutrient Management Plan (NMP). The Department of Conservation and Recreation (DCR) carries out the Nutrient Management Program. The general permits stipulate that DCR approves the NMP, and that the NMP will be implemented and maintained on site. The general permits list six parameters that must be monitored in soils. No limits are set; only monitoring frequency and sample type are specified. The general permits, under Part II, subsection A 2, require that “[u]nless otherwise specified in this permit all sample preservation methods, maximum holding times and analysis methods for pollutants shall comply with requirements set forth in *Guidelines Establishing Test Procedures for the Analysis of Pollutants* (40 CFR 136 (1994)).” These general permits have been effective since 1994 (CAFO) and 2000 (poultry waste management).

The State Water Control Board, on August 31, 2004, approved amendments to the general permits for animal feeding operations and poultry waste management (9 VAC 25-192 and 9 VAC 25-630), and adoption of a VPDES general permit for larger, concentrated animal feeding operations (9 VAC 25-191). In these proposals, DEQ retains the requirements of subsection A 2, cited above, with a replacement of the 1994 edition of 40 CFR 136 with the 2001 edition. In addition, language was added in 9 VAC 25-192-70 Part I.A.9, 9 VAC 25-191-50 Part I.B.8, and 9 VAC 25-630-50 Part I.A.5 stating that “Analysis of soil and waste shall be according to methods specified in the facility’s approved nutrient management plan.”

The commenters ask for an exemption from the requirements of the regulations developed under §2.2-1105. However, the general permits require a nutrient management plan (NMP) to be developed and for soil and waste monitoring to be carried out as part of that plan. While there are no limits set for the parameters listed to be monitored in soils or waste, there is a requirement that any analysis done must comply with methods specified in the NMP. The NMP is enforceable through the permits (9 VAC 25-191-50 Part II.C.1, 9 VAC 25-192-70 Part I.B.7, and 9 VAC 25-630-50 Part I.B.6.). DCR is currently proposing changes to the nutrient management training and certification program regulation (4 VAC 5-15) that specifies that soil be analyzed by methods specified in Agronomy Monograph #9, American Society of Agronomy, or other methods approved by DCR. Regardless of the specific methods specified in the NMP, these methods will be used to conduct monitoring required by regulations promulgated under the State Water Control Law, and thus cannot be exempt from the regulations.

Alternatively, the commenters ask that the laboratories in question be treated as noncommercial laboratories. They are providing this service to the permitted farming operations in question. DCR is funding this laboratory work to a great extent. It does not matter whether the laboratory service provided is profitable or not. Under the program, laboratories that provide service to other legal entities will be considered commercial and will be required to meet the 2003 NELAC standards. Exceptions have been provided where the interpretation of “providing laboratory services to others” might go to an extreme unintended by the program. For example, a local government laboratory providing laboratory service to schools within the locality would not be considered a commercial laboratory. The schools and the laboratory are part of the same legal entity, the local government. Even so, under the standards for noncommercial laboratories, the requirements of concern – the quality controls – would be the same.

With regard to proficiency tests (PTs), those cited by the commenters may well be approved for the work they are doing. Where PTOB/PTPA-accredited PT providers have not provided PTs for a matrix, technology/method, or analyte/analyte group, the laboratory may use PTs from a provider approved by the accrediting authority. See also response to issue 84.

No change has been made to the regulations based on these comments.

15. **Subject:** Lab Certification Database

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Fairfax County Water Authority, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The regulation does not address development and maintenance of the lab certification database by DGS-DCLS required to track certification of each lab and each field of testing. The NELAC national database that is cited in the regulation does not exist. The expense of constructing a database big enough to maintain all fields of certification or accreditation for just the laboratories involved in the VA program would be extremely high. There needs to be a mechanism in place to keep current information on the accreditation status available. This must include time frames within which the database will be modified following an action (certification, changes, decertification, etc.), accessibility by labs and the public, procedures for correcting errors, etc.

**Response:** DGS-DCLS and DEQ executed a Memorandum of Understanding in 2000. Part of this MOU dealt with the keeping of data on the accredited laboratories. A system will have to be developed to meet the agreement developed between DEQ and DCLS and to meet the requirements for accrediting authorities under Chapter 6 of the NELAC standards. No change has been made to the regulation based on this comment.

### **SPECIFIC COMMENTS: 1 VAC 30, CHAPTER 45**

#### **Definitions (1 VAC 30-45-40)**

16. **Subject:** Definition of "aliquot"

**Commenter:** Department of Environmental Quality Water Program (DEQ WATER)

**Text:** " 'Aliquot' means ~~something that is contained an exact number of times in another, such as aliquot samples for testing or analysis~~ **a measured portion of a sample taken for analysis.** "

This edited definition of aliquot is preferable for chemical applications per *Random House Dictionary of the English Language Unabridged edition, 1967*. The "exact number of times" definition is for mathematical applications.

**Response:** The meaning of aliquot is strictly speaking the definition as proposed. However, the commenter's proposed change is closer to the meaning of the word as it is used in the proposed regulations. The proposed change has been made.

17. **Subject:** Definition of "batch"

**Commenter:** DEQ WATER

**Text:** "Batch" needs to include the definition of "preparation batch - means a batch of one to 20 environmental samples of the same matrix being prepared together with a maximum time between the start of processing of the first and last sample in the batch of 24 hours." Much of the quality control required in Article 4 is based on a preparation batch rather than an analytical batch.

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The definition of “Analytical Batch” states the analytical batch can exceed 20 samples. Various EPA Methods limit the batch size to 20 samples. This definition is inconsistent with current methods and practices.

The definition of “Batch” separately from the definition of “Analytical Batch” is redundant and confusing.

**Response:** Changes to the definition of “batch” have been made based on these comments. “Analytical batch” and “preparation batch” are included under the definition of “batch.”

18. **Subject:** Definition of “blank”

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The definition of blank is very narrow and does not encompass many types of blanks such as: Equipment, Field, Instrument, Method and Reagent.

**Response:** The addition of quality control provisions has made a fuller definition of “blank” necessary. “Field blank” and “method blank” which are used in these added provisions are defined under “blank.” These two types of blanks are discussed throughout the added provisions.

19. **Subject:** Definition of “environmental analysis.”

**Commenter:** Department of Environmental Quality Waste Program (DEQ WASTE)

**Text:** The exemptions included in the definition of the term "Environmental analysis" should be clarified to include the sampling of soil and sediments.

"1. Sampling of air, water, soil, sediments, or waste"

"2. Field testing and measurements of air, water, soil, sediments or wastes except..."

As written, the definition could be read to *include* sampling and field measurements of soil and sediments (and non-waste solids) rather than exclude as intended.

**Response:** The suggested change has been made for the reason cited.

20. **Subject:** Definition of “environmental analysis” [also 1 VAC 30-46-40]

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** “Environmental analysis” is being interpreted as those tests, analyses, measurements or monitoring required by various regulations, which is very different than the intent which is tests, etc. “used for the purposes” of various laws. The difference is that tests, etc. used to support activities associated with these laws may not be required. For example, ambient monitoring data collected to support 303(d) lists is not required, but it is “used for the purposes” of the CWA. Data in this example is crucial to decisions regarding the need for TMDLs. The tremendous resources will be dedicated to development of these TMDLs as well as activities by point and non-point sources to meet limits required of TMDLs. However, under the current definition, such data would not need to meet the requirements of this chapter. There is no reason why such data should not meet the same quality guidelines as any other data used to make decisions under the CWA. This definition must be changed to include such data under this regulation. This also requires a change in 1 VAC 30-45-50 A.

**Response:** DGS-DCLS interprets the definition of “environmental analysis” differently. The first sentence of the definition states that environmental analysis is any test, analysis, measurement or monitoring “used” for the purposes of the air, waste or water law. The second sentence further defines the phrase “used for the purposes of” as any test, analysis, measurement or monitoring “required by” any of the vehicles used to carry out the laws, i.e. regulations, permits, orders. This explanation of “used for the purposes of” does not negate the plain meaning of that phrase. Any monitoring, measurement, analysis or test that is done as a result of the laws requirements such as data collected to support requirements in the law or regulations is within the definition of “environmental analysis.” A change has been made to the definition to connect it more closely to the statutory wording. The word “by” has been replaced by “pursuant to.”

21. **Subject:** Definition of “environmental laboratory” or “laboratory”

**Commenter:** Dominion

**Text:** The proposed regulation too broadly defines “environmental laboratory” or “laboratory” as a facility or a defined area within a facility where environmental analysis is performed. This definition could, for example, allow a small enclosure intended for weather protection during field testing to be classified as a laboratory. The definition should clarify that locations used for field testing are not intended to be deemed “laboratories.”

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, UOSA

**Text:** It is unclear as to whether some field tests such as pH and TRC are excluded from certification in this program. The definition under “Field testing and measurement” defines field testing as: “Any test for parameters under 40 CFR Part 136 for which the holding time indicated for the sample requires immediate analysis...”. This should be sufficient, however, the exception under definition of “Environmental Analysis” creates unnecessary confusion: “Field testing . . . , except when performed in an environmental laboratory rather than at the site where the sample was taken.” Many laboratory owners and utilities that routinely perform field tests at the specific sites, have constructed facilities to protect equipment such as pH meters, titrators, etc. and to protect personnel from the elements. These facilities may be construed as laboratories, although only field tests are performed there. This exception may create an absurd situation, where a test would be classified as a field test if the pH meter is taken outside of the building, or as a laboratory test if it’s performed on the other side of a threshold. The regulations should limit the definition of the field tests to those tests for which the holding time requires immediate analysis.

**Response:** Shelters to protect personnel and equipment in the field from weather are not considered to be environmental laboratories for the purposes of the certification program. A provision has been added to the definition of “environmental laboratory” to make this interpretation clear.

22. **Subject:** Definition of “field of testing”

**Commenter:** DEQ WATER

**Text:** “‘Field of Testing’ means an approach to certifying laboratories by program, *matrix*, method/*technology* and analyte/*analyte group*.”

‘Program’ refers to CWA, RCRA, and such, all of which have requirements for the analyses of multiple matrices. Many of the approved methods allow for the analysis of several matrices. When “program, method, analyte” is used as the basis for certification, the lab would be free to select one matrix to analyze for proficiency testing and then be certified for all matrices allowed in a given method. Matrix is

a definite factor in determining a laboratory's capability of performing given analytical methods. Just because a lab is successful in analyzing water, doesn't mean they are equally capable of analyzing soils, oils and biosolids using the same method.

DEQ WATER provides related comments on the use of "program" rather than "matrix." DEQ comments that the following provisions in 1 VAC 30, Chapter 45 need to be revised if DCLS chooses to use the "matrix, method/technology, and analyte/analyte group" approach to field of testing: 50 C; 70 F 1 m and K 2 e; 90 B 2 b, B 2 c, and B 3; and 610 B 10. DEQ also suggests adding "matrix" to the language of the following provisions in 1 VAC 30, Chapter 46: 50 C, 70 E, and 90 B 2 c and B 3.

DEQ WATER made some pertinent comments related to this issue when it addressed these cited provisions. These comments are included here:

This certification scheme will be of greater value for the determination of a laboratory's ability to perform environmental analyses for permit compliance. It also brings the noncommercial and commercial lab requirements in line with one another. See comment on Section 1 VAC 30-45-40 above. Several test methods are designed for the analysis of more than one matrix. The lab must be required to demonstrate the ability to analyze each matrix for which data is reported using a given method.

**Response:** "Field of testing" has been renamed "field of certification." The approach to certification has been changed as recommended for the reasons stated by DEQ.

23. **Subject:** Definition of "matrix"

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Augusta County Service Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** *Drinking water is included in a definition of a "Matrix": this chapter does not provide certification for Drinking Water laboratories, therefore drinking water should not be listed.*

**Response:** The definition of matrix should not have included drinking water. Drinking water has been dropped from the list of matrix types.

24. **Subject:** Definition of "National Institute of Standards and Technology"

**Commenter:** DEQ WATER

**Text:** "National Institute of Standards and Technology" ...system under which private sector companies and interested states can be certified by NIST to provide NIST-traceable proficiency testing (PT) samples to these laboratories testing drinking water and wastewater."

NIST-traceable PTs are now available in other matrices (soil and oil for example). Limiting NIST definition to only drinking water and wastewater would allow non-NIST-traceable PTs for other matrices.

**Response:** The definition of "NIST" has been edited as suggested.

25. **Subject:** Definition of "noncommercial environmental laboratory" [also 1 VAC 30-46-40]

**Commenter:** DEQ WATER

**Text:** Definition of "noncommercial environmental laboratory" refers to sewage treatment facilities, which would exclude wastewater treatment facilities. Recommend replacing the term "sewage" with the general term "wastewater" so all types of wastewater treatment facilities are included.

**Response:** The definition of “sewage” has been eliminated and replaced with a definition of “wastewater.” “Noncommercial environmental laboratory” includes references to a “treatment plant” and to a “treatment facility.” To be consistent, “plant” and “facility” have been replaced by the word “system.” The intent of the change is to convey the meaning that the plant or facility has a system that may include storage, treatment, recycling, and reclamation of wastewater. Wastewater includes both domestic sewage and industrial waste.

26. **Subject:** Definition of “noncommercial environmental laboratory”

**Commenter:** Solite Corporation and Giant Resource Recovery Inc. (GRR)

**Text:** The proposed definition of “Noncommercial environmental laboratory” could be construed to exclude the GRR laboratories because GRR performs environmental analysis for its sister company, Solite. The definition should be revised to make it clear that a laboratory can perform analyses for another legal entity, where such entity is under common ownership and control with the laboratory, without losing its noncommercial status. In addition, GRR periodically performs analyses for its waste fuel customers that are not “prequalification analyses.” Section 2(c) of the definition of “noncommercial environmental laboratory” should be revised to clarify that such analyses can be performed by a noncommercial environmental laboratory.

Section 1 VAC 30-45-40 defines a “non-commercial environmental laboratory” as:

1. An environmental laboratory where environmental analysis is performed solely for the owner of the laboratory,
2. An environmental laboratory where the only performance of environmental analysis for another person is one of the following:
  - a. ...
  - b. ...
  - c. Environmental analysis performed by an environmental laboratory owned by a corporation as part of the prequalification process for a potential customer as required by a hazardous waste management permit under 9 VAC 20, Chapter 60, Part XI.

The wording of paragraph c should be revised as follows: “Environmental analysis performed by an environmental laboratory as part of the prequalification process or to confirm the identity or characteristics of material supplied by a potential or existing customer or generator as required....”.

**Response:** The change suggested by the commenter is within the original intent of the provision. This change has been made.

27. **Subject:** Definition of “noncommercial environmental laboratory”

**Commenters:** VAMWA, HRSD

**Text:** If DCLS maintains the two-chapter approach despite DPB’s objection, VAMWA and HRSD wish to note the need for a new paragraph 2.g. in the definition of noncommercial environmental laboratory, as follows:

*Environmental analysis performed by an environmental laboratory owned by a local government (including an authority or sanitation district) for other local governments when the environmental analysis pertains solely to the purpose for which the authority or sanitation district was created, provided the laboratory performs testing primarily for its own use.*

Along the same lines as paragraphs 2.a. through 2.f., which attempt to reflect the unique role of local government facilities in meeting the needs of Virginians, the new paragraph proposed above is necessary to achieve consistency with existing state law establishing as state policy the promotion of intergovernmental cooperation. Paragraph 2.g. is limited to cooperation between local governments, which are usually involved in testing similar waste streams (*i.e.*, municipal wastewater). The primary use test included in the last of the line of the proposed paragraph would ensure that the majority of the testing performed at the facility is for the facility's own waste streams. While VAMWA and HRSD believe the primary purpose test is unnecessary, we have included this language in recognition of DCLS' general interest in limiting the use of government agencies under Chapter 45 to testing wastes they are already treating or handling themselves.

**Response:** The exceptions provided in the proposed definition of "noncommercial environmental laboratory" for municipal and local government laboratories all concern work that these laboratories might do within their own legal geographic boundaries. The commenters suggest that providing services for other local government entities outside the laboratory's chartered boundaries fits within the other exceptions provided for local government laboratories. All the other exceptions encompass situations where the provision of laboratory services is part of a larger interconnected or integrated organization or legal entity. For example, local government laboratories may provide laboratory service for the school system when the school system is part of the same local government. The laboratory would not be considered commercial; it is providing a service for an organization within its own "corporate" world. For another example, when a private firm is contracted by a local government to operate a wastewater treatment plant and to run the laboratory at that plant, the private firm is not considered to be a commercial laboratory. The exceptions are preceded by language that states that this is the only provision of laboratory service for another legal entity. The work contemplated in this proposed change, in contrast, is commercial work. The laboratory services provided are for many other legal entities. There are no larger interconnected or integrated organizations at work. No change has been made to the regulations based on this comment.

28. **Subject:** Definition of "person"

**Commenter:** Solite Corporation and Giant Resource Recovery Inc.

**Text:** The definition of "person" within the context of the definition of "noncommercial laboratory" should be revised to make it clear that a laboratory can perform analyses for another legal entity, where such entity is under common ownership and control with the laboratory, without losing its noncommercial status. The definition of "person" should be revised as follows:

"Person" means an individual, corporation, partnership, association, company, business, trust, joint venture or other legal entity, and may encompass more than one affiliated entities, such as subsidiaries of the same ultimate parent company.

**Response:** This change to the definition of "person" is unnecessary. The definition of "noncommercial environmental laboratory" specifies under "2" those instances of working for another person that would be considered noncommercial. GRR provides laboratory services for Solite. Their operations are interconnected. GRR is not providing commercial laboratory services generally outside the context of the work being done with Solite. Other companies send their waste to be prequalified for burning at the Solite facility. Again, the lab tests necessary to prequalify this waste is pertinent only to the operation of the aggregate plant which GRR is supporting. No change has been made to the regulations based on this comment.

29. **Subject:** Definition of "proficiency testing (PT) field of testing"

**Commenter:** DEQ WATER

**Text:** “Proficiency testing (PT) field of testing’ means the approach to offer proficiency testing by ~~regulatory or environmental program~~, matrix type, **method/technology**, and analyte/**analyte group**.”

CWA, RCRA, SDWA, etc. often incorporate methods from other programs, which makes them inappropriate for use as a distinguishing identifier. The PT field of testing scheme of relying on ‘program, matrix, analyte’ eliminates “methods”. As written (without inclusion of method/technology) in the proposed regulation, a lab would be allowed to analyze a single PT for “CWA, Wastewater, Copper” using a colorimetric method. Based on that result, they would have met the PT requirement for certification in the analyses of copper in wastewater under the CWA using Graphite Furnace Atomic Absorption Spectrometry, Flame Atomic Absorption Spectrometry, Inductively Coupled Plasma - Atomic Emission Spectrometry and Inductively Coupled Plasma-Mass Spectrometry, which require use of totally different types of instrumentation. That single PT result would give no indication of the lab’s ability to perform the more complex methods.

This definition is also inconsistent with 1 VAC 30-45-50 C which includes technology and methods as a basis for certification.

**Response:** For the reasons stated, DGS-DCLS has made the proposed change.

30. **Subject:** Definition of “proficiency test (PT) sample”

**Commenter:** UOSA

**Text:** The regulation defines “Proficiency test (PT) Sample” as “...a sample, the composition of which is unknown to the analyst,...” Must a PT sample also be unknown or “blind” to the entire laboratory as are DMR-QA study samples or can a lab manager use standard reference material from a QC/PT provider, in which the lab manager knows the true concentration, but does not reveal this information to the analysts in that particular lab? Please clarify whether PT samples must be fully blind to all lab personnel.

**Response:** The PT sample must be unknown or “blind” to both the laboratory and the analyst. A change has been made to this definition to make this requirement clear.

31. **Subject:** Definition of “reference material”

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The definition of Reference Material includes the language “are sufficiently well-established” which is vague. Recommend change to: “have certified values.”

**Response:** The phrase “are sufficiently well-established” in the context of the definition points to the fact that these materials have certified values. This definition of reference material is used in NELAC and ISO. No change has been made to the regulations based on this comment.

32. **Subject:** Definition of “simple test procedures”

**Commenter:** DEQ WATER

**Text:** Simple test procedures should include *E. coli* and *Enterococci* testing. These two organisms have recently been added to VPDES permits due to changes in the Water Quality Standard.

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** Simple test procedures are arbitrarily selected and do not take under account potential changes and additions to future regulatory requirements. As of now, E.coli and Enterococcus testing should be added.

**Response:** The tests for *E. coli* and *enterococcus* have been added to the list of simple test procedures. Also see the response to issue 33.

33. **Subject:** Definition of “simple test procedures”

**Commenter:** Solite Corporation and Giant Resource Recovery Inc.

**Text:** The proposed definition of “simple test procedures” does not include certain physical chemistry analyses that are as simple as the procedures listed. The definition should be revised to include test procedures to determine water, heat, ash and chloride content, specific gravity, pH, and viscosity.

At the end of the definition of “Simple test procedures” insert:

3. All physical chemistry analyses including, but not limited to, specific gravity, pH, water content, heat content, ash content, viscosity, and chloride content.”

**Response:** The definition of “simple test procedures” was developed during the *ad hoc* advisory group meetings. The group developed this list in trying to establish standards for a third tier of environmental laboratories. The list was developed to define the third tier. The use of the third tier was dropped long ago. The list is still in use to set a lower fee for small wastewater laboratories. DGS-DCLS had determined that these laboratories need to have lower fees because they will have more work to do to meet the standards set by 1 VAC 30-45. No change has been made to the regulation based on these comments.

34. **Subject:** Definition of “Test, analysis, measurement or monitoring required by the Virginia Water Control Law”

**Commenter:** DEQ WATER

**Text:** “Test, analysis, measurement or monitoring required ~~by~~ *pursuant to* the “Virginia Water Control Law” means any method or analysis required by the Virginia Water Control Law (§ 62.1-44.1 et seq.); by the regulations promulgated under this law (9 VAC 25); ~~including any method of analysis listed or adopted by reference in 9 VAC 25-31, 9 VAC 25-32, 9 VAC 25-110, 9 VAC 25-120, 9 VAC 25-151, 9 VAC 25-180, 9 VAC 25-190, 9 VAC 25-192, or 9 VAC 25-210; or by any permit or order issued under and in accordance with this law and these regulations~~ *associated with it.*

Citing specific regulations potentially limits the testing requirement to only those VAC’s listed. Such permits as Shellfish Processing Facilities, Ready-Mixed Concrete Plants and Car Washes are omitted. DEQ is continually adding new regulations that would require additional changes to this regulation. By citing the Virginia Water Control Law (§ 62.1-44.1 et seq.) it mirrors the wording in § 2.2-1105 and allows subsequent DEQ regulations to be automatically included without additional regulatory process.

**Response:** Changes have been made to this definition and the related definitions for air and water for the reasons cited.

35. **Subject:** Definition of “test method”

**Commenter:** DEQ WATER

**Text:** "Test method" means an adoption of a scientific technique for a specific measurement ~~problem~~, as documented in a laboratory SOP or published by a recognized authority.

NELAC's current definition is "an adoption of a scientific technique for performing a specific measurement, as documented in a laboratory SOP or as published by a recognized authority." Where possible, Chapters 45 and 46 should include the same definitions.

**Response:** The change has been made for the reason cited.

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The definition of "Test Method" does not meet the requirements outlined in 30-45-730 "Test Methods and Standard Operating Procedures" D.1

**Response:** The definition of test method as revised is a good general definition. The requirement of 1 VAC 30-45-730 D 1 specifies those test methods that laboratories must use. No change to the regulation has been made as a result of this comment.

36. **Subject:** Definition of "waste" is needed

**Commenter:** DEQ WASTE

**Text:** Although used, the term "waste" is not defined. The following definition of "waste" is suggested: ***"Waste means any solid, hazardous or radioactive waste as defined by the Waste Management Act. Waste may be in gaseous, solid, liquid or semi-solid form."***

**Response:** The terms "air" and "water" are also not defined. Providing these definitions is unnecessary. The regulations make clear that laboratories performing tests, analyses, measurements and monitoring under Virginia's waste management law and regulations must be certified under the environmental laboratory certification program. The regulations that carry out the waste management program are referenced. There should be no confusion as to what "waste" means in the context of these regulations. No change has been made to the regulations based on this comment.

37. **Subject:** 1 VAC 30-45-40 and 1 VAC 30-46-40. Definitions generally.

**Commenter:** DEQ WASTE

**Text:** These regulations are designed to apply to a variety of environmental statutes through which terms are defined that may conflict with the definitions provided in the proposed regulations. To minimize potential conflict it may be wise to establish which definition takes precedence. For example, under the VHWMR, the terms *facility*, *owner*, *operator*, *person*, and *POTW* are defined differently than in the proposed regulations.

The following is found in the VHWR at 9 VAC 20-60-12 B and may serve as a guide.

*"9VAC20-60-12. Definitions derived from the Code of Virginia.*

*A. Chapter 11.1 (§10.1-1182 et seq.) and Chapter 14 (§10.1-1400 et seq.) of Title 10.1 of the Code of Virginia define the meaning of terms as used in the text of the statutes. Terms not otherwise defined in these regulations or an incorporated reference text shall have the meaning as established in the statutes.*

*B. Where a term is defined in these regulations or an incorporated reference text, the term shall have no other meaning, even if it is defined differently in the Code of Virginia or another regulation of the Virginia*

Administrative Code. The board has authority to adopt regulations only as granted to it by the Code of Virginia, and nothing herein shall be interpreted as extending the effect or scope of a regulation beyond that authority."

**Response:** This suggestion is helpful. 1 VAC 30-45-40 has been revised to include some of the suggested language.

### **Scope of Certification (1 VAC 30-45-50)**

38. **Subject:** Scope of certification and field of testing (subsection C)

**Commenter:** DEQ WATER

**Text:** "Certification shall be granted for a specific *matrix*, ~~field or fields of testing, including the technology and methods used by the noncommercial environmental laboratory,~~ and the individual analytes or analyte groups determined by the particular method."

This certification scheme will be of greater value for the determination of a laboratory's ability to perform environmental analyses for permit compliance. It also brings the noncommercial and commercial lab requirements in line with one another. See comment on Section 1 VAC 30-45-40 above.

**Response:** See the response to issue 22.

### **Individual Laboratory Sites and Mobile Laboratories (1 VAC 30-45-60 B) [also 1 VAC 30-46-60 B]**

39. **Subject:** Multiple Laboratory Operations within a Municipality or Authority

**Commenter:** Hanover County Department of Public Utilities

**Text:** There are no provisions provided to reduce the financial and administrative burden for those municipalities or service authorities that operate and maintain multiple treatment facilities with onsite laboratories. Under the current proposed regulation there is no indication whether or not the laboratory manager position would be required to work within the confines of the laboratory they oversee. We monitor four County-owned wastewater treatment plants through three laboratories. The wastewater operators on site staff those laboratories and conduct the analysis. One of the laboratories currently has an additional position, the laboratory manager, who is also responsible for maintaining the QA/QC Program and providing material support to all the laboratories. This situation has not been addressed in the proposed regulation. There should be a provision that does not require a laboratory manager or QC officer to be staffed at each laboratory when multiple laboratories are owned and operated by a municipality or service authority.

**Response:** A change to the provision covering individual laboratory sites has been made to the regulation. This change gives a locality or industrial company the opportunity to request that a laboratory system with dispersed laboratory sites be considered one laboratory. This approach would allow such laboratories to file one application only with one fee covering the entire system. These laboratories would be charged however for the cost to DGS-DCLS of performing the additional necessary on-site assessments at the satellite laboratories. A change to the fee provisions has been made to reflect this requirement.

### **Process to Apply (1 VAC 30-45-70)**

40. **Subject:** 1 VAC 30-45-70 D and 1 VAC 30-46-70 D. Responsibilities of the owner or operator. 1 VAC 30-45-90 C: Changing certification status. 1 VAC 30-46-90 C: Changing accreditation status.

**Commenter:** DEQ WASTE

**Text:** For both commercial and non-commercial labs, either the owner or operator may submit an application for a laboratory but a notification is required only for ownership changes. It seems that a similar notification should be required for operator changes since the two persons are defined as essentially the same person for purposes of this regulation and appear to be inter-changeable throughout- with this one exception. If the intent is to ensure a clearly delegated line of responsibility to the owner, the owner should have to participate in all applications in a formal way. Or conversely, notification should be required for operator changes as well. Although operator changes would fall into the notification requirements for changes in key personnel, the regulations establish an operator as something beyond key personnel by allowing that entity to submit an application *in lieu* of the owner.

Second, the inclusion of what is essentially a discretionary fee does not seem appropriate. If there are situations where a transfer fee is anticipated to be necessary- or unnecessary, these should be spelled out in the regulation. As there does not appear to be an authority to which a lab may appeal a decision made by DCLS, subjective decisions should be avoided.

**Response:** The terms “owner” and “operator” are interchangeable throughout. The intent of using both terms was to ensure that an operator of a laboratory that is not the owner would be covered by the regulation. This comment points out the flaw in the definition of “owner.” The definition as previously proposed covers “owner” or “operator.” These terms however were defined as a person who owns or operates an environmental laboratory. The definition has been changed to define “owner” only. The definition states that an owner is a person who owns, operates, leases or controls the laboratory. So the requirements pertinent to an owner are pertinent to an operator as well. In most cases the owner and operator are the same. Where provisions cover situations where an operator might be a different person than an owner and function for an owner, those provisions remain. Otherwise the phrase “owner or operator” has been revised to read “owner.” Owners are assumed to be operators unless the application indicates otherwise.

The provisions governing fees charged when ownership is transferred (1 VAC 30-45-130 F 3) have been revised to clarify when these fees would be charged. In addition, the appeals provisions have been revised for clarity.

41. **Subject:** Renewal applications, completeness determinations and interim certification (subsections C, G and H) [also 1 VAC 30-46-70]

**Commenter:** Solite Corporation and Giant Resource Recovery Inc.

**Text:** The proposed permit renewal process is flawed. Assume that an applicant submits a timely renewal application 90 days prior to expiration of its certification. Sixty days later DGS-DCLS notifies the applicant that the application is incomplete. The applicant then has just 30 days to submit additional information and persuade DGS-DCLS to grant an interim certification under 1 VAC 30-45-70 H. If DGS-DCLS fails to act the applicant will be forced to close when its certification expires. Again, fundamental fairness dictates that a laboratory should not lose certification until a final determination has been made on a renewal application.

**Response:** Permit renewal should be a simple process. The renewing laboratory should be aware of the application requirements at this stage. DGS-DCLS therefore should not have to request additional information. The only element left to be done to determine whether certification should be renewed is the on-site assessment. The provisions on completeness determination (-70 G) and granting of interim certification (-70 H) have been revised to allow certification to remain intact if the laboratory has sent and DGS-DCLS has determined that the renewal application is complete.

42. **Subject:** Scope of certification and the application process (subsection E) [also 1 VAC 30-46-70 E]

**Commenter:** DEQ WATER

**Text:** Submission of applications for modifications to certification needs to include the addition of “program” **IF** the regulation’s proposed scheme for field of testing (program, method, analyte) is to be followed. If DEQ’s requested scheme for field of testing (matrix, method/technology, analyte/ analyte group) is employed, “matrix” should be added. A laboratory should be able to modify any portion of their field of testing without having to undergo a separate application.

**Response:** Appropriate revisions have been made to 1 VAC 30-45-70 E. See also the response to issue 22.

43. **Subject:** Contents of application. (subsection F 1 j) [also 1 VAC 30-46-70]

**Commenter:** Department of Environmental Quality Air Program (DEQ AIR)

**Text:** Change wording to read "Name, ***title*** and telephone number of laboratory contact person."

**Response:** The suggested addition has been made to 1 VAC 30-45-70 F 1 j.

44. **Subject:** Contents of application. (subsection F 1 j)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** It is not necessary to list a name and phone number of a “laboratory contact person” when the applicant laboratory has already listed the names and phone numbers of the “responsible official,” the laboratory manager, and the quality assurance officer. This is redundant and should be deleted.

**Response:** If the laboratory contact is not the responsible official, laboratory manager or the quality assurance officer, then the information request is not redundant. No change has been made to the regulations based on this comment.

45. **Subject:** Contents of application. (subsection F 1 k)

**Commenter:** Hanover County Department of Public Utilities

**Text:** Public water system is used as one of the examples for “laboratory type.” This chapter does not provide certification for Drinking Water laboratories. Therefore, public water systems should not be listed as a laboratory type to be certified.

**Response:** Some local government laboratories provide services for both a drinking water and a wastewater facility. No change has been made to the list of examples.

46. **Subject:** Completeness determination (section G) [also 1 VAC 30-46-70 G]

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** There appears to be no time period set in regulation as to when the lab application will be deemed complete by DCLS during the initial certification process. There must be a time period designated in the regulation protecting labs from participating in the process for extended periods of time without knowing that their application is complete.

**Response:** During the initial certification process, the completeness determination may extend beyond 60 days. There will be a lot of applications to process. Every effort will be made to make the completeness determinations within a reasonable time. No change has been made to the regulations based on this comment.

47. **Subject:** Interim certification (subsection H) [also 1 VAC 30-46-70 H]

**Commenter:** DEQ WATER & AIR

**Text:** The following should be added - "4. Interim accreditation status shall not exceed twelve months."

This should be adequate time for DCLS to conduct an on-site inspection and grant or deny certification. The on-site inspection is the most crucial part of the certification process in determining if the procedures being performed in the lab are meeting regulatory requirements. Allowing an interim accreditation status to exist indefinitely would greatly weaken the certification program.

Comment on 1 VAC 30-46-70 H 1: At 4.5.1, the NELAC standards (2002) require that interim accreditation status should not exceed 12 months.

**Response:** The suggested revision has been made for the reason cited.

48. **Subject:** Interim certification (subsection H) [also 1 VAC 30-46-70 H]

**Commenter:** Solite Corporation and Giant Resource Recovery Inc.

**Text:** The proposed certification process is inconsistent with the environmental permitting process administered by U.S. EPA and Virginia DEQ and does not afford reasonable due process to environmental laboratories. Traditionally, when EPA and DEQ have subjected new economic sectors to permit requirements – and certification is clearly a form of permit – existing facilities have been allowed to continue to operate, so long as they apply for a permit in a timely manner, until a final permit decision has been made and any appeals exhausted. Under the proposed regulations, an environmental laboratory could lose the right to operate even if it makes a timely application, simply because DGS-DCLS has failed to make a final determination on certification. Although 1 VAC 30-45-70 H provides for interim certification, findings must be made by DGS-DCLS for interim certification to be granted. Should DGS-DCLS for any reason fail to do its job, the laboratory could be forced to close two years after the effective date of the regulations.

Any applicant that has submitted a complete application, or, if DGS-DCLS has requested additional information, has not failed to comply with the request, should automatically have interim certification status until such time as a final determination on certification has been made and any appeal has been decided.

Revise section H as follows:

1. A laboratory in existence on the effective date shall be deemed to have interim certification pending final determination unless such laboratory’s application is incomplete and it has failed to submit additional information required by DGS-DCLS in a timely manner.

.....

3. Interim certification expires when DGS-DCLS issues a final determination on certification, unless such determination is subject to appeal.

**Response:** The right to appeal under the certification program is no different than that right under any Virginia environmental program. The Virginia Administrative Process Act governs all these programs with

regard to appeals. Laboratories that are in the process of appealing a denial of certification or a decertification have the right to continue to operate during the appeal process.

With regard to making a final determination on certification, the laboratory will be given interim certification both on initial application and on renewal, as long as the laboratory applies in a timely fashion and provides information in a timely fashion so that a completeness determination can be made.

That DGS-DCLS may fail to review all the laboratories to be certified is speculation. If for some reason, the agency cannot complete the task in the time allotted, the laboratories will not be “forced to close.” The agency will extend the time needed to complete the work or will grant all remaining laboratories interim certification. No change has been made to the regulations based on this comment.

49. **Subject:** Certification period (subsection K 4)

**Commenter:** Solite Corporation and Giant Resource Recovery Inc. (GRR)

**Text:** In view of the time and resources required of both the applicant and the Division to complete the certification process, and the proficiency testing required to maintain certification, a certification period of only two years is too brief. Certification should be for at least 5 years, and preferably 10 (GRR and Solite’s Hazardous Waste Permits are for 10 years; see 40 CFR § 270.50(a)).

Revise paragraph 4 as follows:

4. Certification shall expire ten years after the date on which certification is granted, unless the laboratory has submitted a timely application for renewal.

**Response:** A period of 5 or 10 years is too long between reviews of a laboratory’s operation. No change has been made to the regulations based on this comment.

50. **Subject:** Denial of certification (section L)

**Commenter:** Solite Corporation and Giant Resource Recovery Inc.

**Text:** The proposed certification process is deficient in the due process rights that are afforded to applicants. The Virginia Administrative Process Act does not require the agency to establish a process that insures fairness and attempts to resolve disputes through negotiation prior to a final agency decision. Two changes are needed. First, DGS-DCLS should establish an internal appeal procedure that would precede a final agency action denying certification to or decertifying an environmental laboratory. This procedure would include notice of intent to deny certification or decertify a laboratory, and opportunity for an informal hearing before a senior DGS-DCLS official who has not been involved in consideration of the application or proposed decertification. Second, a denial or decertification should not be effective while it is being appealed unless DGS-DCLS determines that continued operation of the laboratory constitutes an imminent and substantial endangerment of public health or the environment.

Revise paragraph 2 by adding the following new subparagraph d:

d. DGS-DCLS, prior to denying certification to an environmental laboratory in total or in part, shall provide prior notice and reasonable opportunity for such laboratory to take any necessary corrective action to avoid denial.

**Response:** The appeals provisions have been revised to clarify the process. The language did not reflect the intent of the proposed regulations which was to provide informal fact finding as well as a formal hearing under Article 3 of the Virginia Administrative Process Act. In addition, the revised language seeks to convey the agency’s intent to work with the covered laboratories during the application process.

51. **Subject:** Denial of certification (subsection L 2 c)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** Needs to specify “during normal business hours as specified in the application” instead of “during normal business hours.”

**Response:** The suggested change has been made to clarify the meaning of the provision.

52. **Subject:** Reapplication following denial of certification (subsection M 1) [also 1 VAC 30-46-70 M 1]

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, UOSA, and Solite Corporation/Giant Resource Recovery Inc.

**Text:** There is no reason for a laboratory to wait six months to reapply for certification. This has no regulatory or technical basis, is overly harsh, unreasonable and essentially acts as a “death sentence” to any laboratory that loses its certification.

**Commenters:** VAMWA, Amherst County Service Authority; Chesterfield County Utilities Department; City of Danville Utilities Department; City of Fredericksburg; HRSD; County of Henrico Department of Public Utilities; Town of Onancock; Rivanna Water & Sewer Authority; City of Roanoke Public Utilities; and County of Spotsylvania Utilities Department.

**Text:** VAMWA has similar objections to 1 VAC 30-45-80 M, which prohibits a lab from reapplying for certification until six months after denial. Again, rather than idling public facilities and workers, DCLS’ regulations should encourage the facility to quickly address any deficiencies, meet the standards for certification, and return to serving the public as soon as possible.

**Commenter:** Addison-Evans Water Production & Laboratory Facility, Chesterfield County

**Text:** Addison-Evans WP&LF has similar objections to 1 VAC 30-45-80 M, which prohibits a lab from reapplying for certification until six months after denial. Again, rather than idling public facilities and workers, DCLS’ regulations should encourage the facility to quickly address any deficiencies, meet the standards for certification, and return to serving the public as soon as possible.

**Commenter:** LAVA [on 1 VAC 30-46-70 M 1]

**Text:** Several notable issues arise from the current regulations treatment of revocation. First is the six-month period before recertification. Regardless of whether NELAC specifies this period, this represents a punitive sanction against any laboratory, which may experience an incidental problem. Such problems could be fixed in much less time. It would seem that an accelerated corrective action would be preferred to a lengthy wait period, which would only act to adversely effect a laboratories ability to correct and continue its work.

**Response:** The commenters state that rather than requiring a laboratory wait for six months before reapplying, DGS-DCLS “should encourage the facility to quickly address any deficiencies, meet the standards for certification, and return to serving the public as soon as possible.” Indeed the agency will do so prior to notifying the laboratory that it intends to deny certification. DGS-DCLS will have already notified the laboratory of any deficiencies following the on-site assessment. The laboratory will have had time to correct those deficiencies. This is true of the requirement for proficiency testing. There will be an opportunities to correct any problems the laboratory had with its PTs. Once DGS-DCLS determines that

a laboratory must be denied certification, the notice will be sent. Following this notice, the laboratory will have the opportunity to address the problem again that places it in the position of being denied certification. When an application is denied, there is an opportunity for administrative appeal, both an informal fact finding and a formal hearing pursuant to Virginia's Administrative Process Act, and appeal through the courts. During these appeals, the laboratory continues to operate if it has been certified previously. Otherwise, the owner must find a contract laboratory to carry out the tests and analyses required under the air, waste or water laws and regulations.

### **Maintaining Certification (1 VAC 30-45-80)**

53. **Subject:** Record retention (section D)[also 1 VAC 30-45-90 C 5, 1 VAC 30-45-510 D, and 1 VAC 30-45-650]

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** In 1 VAC 30-45-80 D., the regulation requires that certification records be maintained for a minimum of 3 years. In VAC 30-45-90 C. 5., the regulation calls for maintaining records for 5 years when there is a change in ownership. The section on PT records requires that they be maintained for 5 years. The section in Quality Systems requires maintenance of records for 3 years. The regulation must be consistent on how long all records should be maintained, which is no more than is absolutely necessary.

**Response:** The regulation provisions with regard to how long certification records must be maintained have been made consistent. The time given is 3 years, unless the governing environmental regulation requires a longer time.

### **Changing Certification Status (1 VAC 30-45-90)**

54. **Subject:** Notification of changes in certification (subsection A 1); changes to key accreditation criteria [1 VAC 30-46-90 A 1; also pertinent to 1 VAC 30-45-90]

**Commenter:** DEQ WATER

**Text:** Allowing notification of changes within 30 days of the change for test methods and analytes is in contradiction of A 3 of this same section. These items will affect the scope of accreditation and cannot be altered without approval from DCLS.

**Text:** "A. Changes to key accreditation criteria...1. The accredited laboratory shall notify DGS-DCLS as set out in subdivision 2 of this subsection of any changes in key accreditation criteria within 30 calendar days of the changes. Accreditation criteria are laboratory ownership, location, key personnel, ~~test methods, analytes,~~ and major instrumentation."

Changes in ownership, location, personnel or instrumentation, may or may not affect accreditation status. Any changes to test methods and analytes will, however, result in a change to the Fields of Accreditation. Section 1 VAC 30-46-90 B deals with changes to scope of accreditation.

**Response:** Substantial revisions have been made to 1 VAC 30-45-90. The contradiction noted in the comment has been repaired. Test methods and analytes have been eliminated as key accreditation criteria. Additional changes were made to clarify modifications to a laboratory's certification.

55. **Subject:** Changes to key certification criteria (subsection A 1)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** Must provide definition of “Key Personnel” in section 1 VAC 30-45-40 “Definitions”

**Response:** A definition of key personnel is not necessary. The laboratory manager and the quality assurance officer are key personnel. However, in large laboratories, other personnel may be considered key to the running of the laboratory operation. The provision is ambiguous and allows the laboratory to report the changes based on its own judgment. No change has been made to the regulations based on this comment.

56. **Subject:** Changes to key certification criteria (subsection A 2) (also 1 VAC 30-46-90 A 2]

**Commenter:** DEQ AIR

**Text:** Need to clarify how long (i.e. two weeks) after initial notification that written notification (i.e. preferably on letterhead) must be submitted.

**Response:** The provisions on initial notification have been eliminated. Under the revised provisions, a laboratory must apply for approval for any modification to a matrix, technology/test method, or analyte/analyte group before the modification can be made.

57. **Subject:** Changes to key certification criteria (subsection A 3) [also 1 VAC 30-46-90 A 3]

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The regulation intends that changes to “key criteria” be reviewed and approved by DGS-DCLS prior to the change, this will not always be possible. For example, if an employee must be fired, how can DGS-DCLS be notified and the termination of the employee be approved by DGS-DCLS prior to termination?

**Response:** The provision as proposed required DGS-DCLS to be notified of “key personnel” changes only. The provision did not require DGS-DCLS to approve the change. No change has been made to the regulations based on this comment.

58. **Subject:** Changes to scope of certification (subsection B 2) [also 1 VAC 30-46-90 B 2]

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The statement “DGS-DCLS may require additional material to complete its review” is far too vague for regulation and must be better defined with specifics. This language will introduce variability in how changes to accreditation take place, leading to lack of equity among laboratories in how they are regulated.

**Response:** The sentence has been eliminated. Generally, the material required to review a modification to a scope of certification is the material listed in subdivision B 2. It is possible that additional information will be requested of the laboratory in order to more fully understand the modification the laboratory wishes to make.

59. **Subject:** Changes to scope of certification (subsection B 2 b) [also 1 VAC 30-46-90 B 2 b]

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The text refers to quality control performance as information demonstrating lab capability, but regulation defining acceptable quality control performance is not provided. Therefore this part of the regulation is not enforceable as written. This section also requires that “pertinent” information be provided to show capability, this term is far too vague for regulation, cannot be audited or enforced; it must be removed unless clarification is provided.

**Response:** Provisions specifying quality control elements generally and for specific types of testing have been added to 1 VAC 30-45.

60. **Subject:** Changes to scope of accreditation (subsection B 3) [also 1 VAC 30-46-90 B 3]

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Fairfax County Water Authority, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** There should be specific criteria developed to determine when changes to the scope of accreditation would require an on-site assessment. It is not clear if an additional on-site assessment will result in charging additional fees to the laboratory.

**Response:** The provisions of 1 VAC 30-46-90 B have been rewritten to clarify many issues . Subdivision B 3 indicates that the addition of a new technology or test method requiring specific equipment may require on-site assessment. If on-site assessment is required, then labor and travel costs will be charged to the laboratory.

61. **Subject:** Changes to scope of certification (subsection B 4) [also 1 VAC 30-46-90 B 4]

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The regulation must provide a timeframe within which DGS-DCLS will amend a laboratory's certificate of accreditation relative to the time the request is made.

**Response:** A provision has been added to subsection B stating a time frame for DGS-DCLS to make a decision on a modification to a scope of certification.

62. **Subject:** Transfer of certification (section C)

**Commenter:** Solite Corporation and Giant Resource Recovery Inc.

**Text:** Transfer of certification should not be limited to ownership changes that do not affect personnel, equipment, and facilities. So long as a change in ownership does not adversely affect the laboratory a transfer of certification should be allowed. If the new owner brings in new personnel who have equal or superior qualifications, or replaces equipment with equivalent or better equipment, that should not preclude transfer of the certification.

**Response:** DGS-DCLS cannot preclude a transfer of laboratory ownership. DGS-DCLS needs to review the transfer if personnel, equipment or facilities are affected. These elements are critical to laboratory performance. Otherwise the transfer of ownership can be made without a review. No change has been made to the regulations based on this comment.

### **Decertification (1 VAC 30-45-100)**

63. **Subject:** Reasons for decertification in total (subsections A 2 and A 3) [also pertinent to 1 VAC 30-45-70 L 1 and to 1 VAC 30-46-70 L 1 and 1 VAC 30-46-100 A]

**Commenter:** VAMWA, VA AWWA/WWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** Laboratories should not be decertified, in total, due to employee falsification of data or information because a quality system cannot prevent this from happening and the ability of a permittee to meet permits requirements should not be dependent on the action of a single individual. Such a situation should elicit another quality system review and corrective action where necessary.

**Commenters:** VAMWA, Amherst County Service Authority; Chesterfield County Utilities Department; City of Danville Utilities Department; City of Fredericksburg; HRSD; County of Henrico Department of Public Utilities; Town of Onancock; Rivanna Water & Sewer Authority; City of Roanoke Public Utilities; and County of Spotsylvania Utilities Department.

**Text:** VAMWA has significant concerns with the decertification and reapplication provisions as applied to our members' government-owned laboratories. In particular, 1 VAC 30-45-100 A states that DCLS "shall decertify an environmental laboratory in total" in the event of certain types of fraud or falsification by an employee. Obviously, an instance of fraud or falsification is a serious offence that requires an appropriate response. The laboratory owner would typically terminate an employee committing such an act. However, revoking the facility's certification, which in this program is essentially its license or operating permit, is simply too harsh and not in the public interest. This is rarely done even in cases of bad actors directly negatively impacting the environment. It seems hard to justify for violations that may or may not have an actual adverse environment. Rather than punishing another government agency, DCLS' focus in this regulation should be to work with the agency to ensure laboratory operations resume to normal as fast as possible. To be able to do this, DCLS should retain discretion over decertification decisions rather than making decertification mandatory. To do this, DCLS should change "shall" to "may" in section 100 A.

**Commenters:** VA AWWA/WWEA LPC; Augusta County Service Authority; Fairfax County Water Authority, Water Quality Laboratory; Hanover County Department of Public Utilities; Town of Round Hill Utility Department; and the Upper Occoquan Sewage Authority.

**Text in addition to that above:**

This mandatory death penalty discourages a facility from investigating questionable data and notifying the regulators of incidents of falsification.

There are also practical issues to be addressed. A municipality cannot be expected to budget every year for the contingency that they will lose certification for one or more parameters for 6 months and must contract the analyses with a commercial lab.

**Commenter:** Addison-Evans Water Production & Laboratory Facility, Chesterfield County

**Related but Variant Text:** Addison-Evans WP&LF has significant concerns with the decertification and reapplication provisions as applied to government-owned laboratories. In particular, 1 VAC 30-45-100 A states that DCLS "shall decertify an environmental laboratory in total" in the event of certain types of fraud or falsification by an employee. Obviously, an instance of fraud or falsification is a serious offence that requires an appropriate response. The laboratory owner should be required to immediately remove an employee committing such an act from their listing of laboratory analysts (stop them from performing lab analyses), inform DCLS of the incident and not allow this person to be placed back on the analysis listing unless approved by DCLS. Laboratory management should also follow guidance provided by DCLS in referring such a case to law enforcement agencies for possible civil or criminal action against the individual(s) involved. The laboratory should not be penalized unless DCLS determines the laboratory's management did not properly address the issue. Automatically revoking a laboratory's certification in

such cases discourages a facility from investigating questionable data and notifying the regulators of incidents of falsification. DCLS' focus in this regulation should be to work with the agency to ensure laboratory operations resume to normal as fast as possible. DCLS should retain discretion over decertification decisions rather than making decertification mandatory. DCLS should change "shall" to "may" in section 100 A. There are also practical issues to be addressed. A municipality cannot be expected to budget every year for the contingency that they will lose certification for one or more parameters for 6 months and must contract the analyses with a commercial lab.

**Response:** The statute requires that laboratories be decertified in total when falsification of data is determined. The appeal process provides ample opportunity to work out a solution if the only problem is a bad employee, or a bad employee encountering a faulty internal audit process.

Local government laboratories should not expect to be treated differently than other laboratories covered by this program. Every effort should be made to ensure that laboratory fraud does not occur. Laboratory management and internal audits may be able to catch fraud in progress. In addition, other laboratories – industrial and commercial – have the same budgetary concerns that local government laboratories do.

No change has been made to the regulations based on this comment.

64. **Subject:** Responsibilities of laboratory and DCLS when accreditation is withdrawn in part (subsection D 2) [also 1 VAC 30-46-100 C 2]

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Fairfax County Water Authority, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The regulation must provide a timeframe within which DGS-DCLS will amend a certificate of accreditation.

**Response:** A laboratory that has lost its certification or accreditation must return the certificate once all appeals are completed. DCLS will amend a certificate once all appeals are completed. No change has been made to the regulations based on this comment.

**Appeal Procedures (1 VAC 30-45-110)**

65. **Subject:** Notification

**Commenter:** Solite Corporation and Giant Resource Recovery Inc.

**Text:** The proposed certification process is deficient in the due process rights that are afforded to applicants. The Virginia Administrative Process Act does not require the agency to establish a process that insures fairness and attempts to resolve disputes through negotiation prior to a final agency decision. Two changes are needed. First, DGS-DCLS should establish an internal appeal procedure that would precede a final agency action denying certification to or decertifying an environmental laboratory. This procedure would include notice of intent to deny certification or decertify a laboratory, and opportunity for an informal hearing before a senior DGS-DCLS official who has not been involved in consideration of the application or proposed decertification. Second, a denial or decertification should not be effective while it is being appealed unless DGS-DCLS determines that continued operation of the laboratory constitutes an imminent and substantial endangerment of public health or the environment.

Revise section A as follows:

A. DGS-DCLS shall notify an environmental laboratory in writing of its decision to deny certification or to decertify an environmental laboratory. Prior to such notification, DGS-DCLS shall notify the laboratory of its intent to deny certification or decertify a laboratory, and provide opportunity for an informal hearing before a senior departmental official who has not been involved in consideration of the application of the

laboratory or of the proposed decertification. Such official shall review the proposed action and submit written findings and recommendations to the Director of DGS for a final decision.

**Commenter:** LAVA

**Text:** Several notable issues arise from the current regulations treatment of revocation. Second, is the lack of a formal appeals process and the staying of decertification during the appeal. Some protection should be granted to the regulated community should issues involving reasonable debate be raised.

**Response:** Substantial changes have been made to the provisions on appeal. The intent of the proposed regulations was to provide the informal fact finding and formal hearing process in Article 3 of the Virginia Administrative Process Act. The proposed provisions did not convey that intent. The revised provisions do.

### **Fees (1 VAC 30-45-130)**

66. **Subject:** Description of the fee [also 1 VAC 30-46-150]

**Commenter:** Hanover County Department of Public Utilities

**Text:** There is no description of the fee. Is this an application fee or a certification fee that needs to be paid at the time of application? 1 VAC 30-45-70 G 5 states that DGS-DCLS may deny any application from a laboratory and require the laboratory submit a new application if the laboratory does not submit additional information required by DGS-DCLS within 90 days of receiving a notice that requires additional information. There is no indication that an additional fee submittal is required as well.

**Response:** 1 VAC 30-45-130 A has been revised to clarify and respond to this comment. The application fee is the fee assessed to cover the applicant's portion of the program costs. The same fee is due at renewal and if a laboratory must reapply. There are other, additional fees that are charged for additional review (see 1 VAC 30-45-130 F through H).

67. **Subject:** Test category fees (subsection E 3) [also 1 VAC 30-46-150 E 3]

**Commenter:** DEQ WATER

**Text:** "Whole Effluent Toxicity" should be changed to "***Aquatic Toxicity Tests***" This would more accurately reflect the type of testing being required by statute § 2.2-1105 and terminology used in 40 CFR part 136.3. Benthic testing is not mentioned and should be included.

**Response:** The suggested changes have been made for the reasons cited.

68. **Subject:** On-site assessment fees and third-party assessors (subsection G) [also 1 VAC 30-46-150 G]

**Commenter:** VAMWA, VA AWWA/WWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The document is vague about whether an on-site inspection will be conducted following the initial set of applications and whether the laboratory is responsible for these costs. In the section concerning on-site assessment fees, it states, "When with the concurrence of the applicant laboratory, DGS-DCLS uses approved, third-party on-site assessors, the cost of the on-site assessment shall be paid by the applicant." What is the motivation behind this that would make a laboratory "concur" to pay for a third-party assessment?

**Response:** Information about the cost of third-party on-site assessors has been provided in 1 VAC 30-45-70 I. The provisions in this subsection have been deleted. Laboratories may want to take advantage of third party on-site assessors during the initial certification period. If they do, the laboratories will pay the fees charged by these assessors. This is an option and not a requirement.

### **Petitioning for a Variance (1 VAC 30-45-140)**

69. **Subject:** General support and due process requirements (subsection F).

**Commenter:** Solite Corporation and Giant Resource Recovery Inc. (GRR)

**Text:** In general GRR and Solite support the proposed variance procedures. However, certain aspects of the procedures should be clarified. Specifically, before a variance is terminated the petitioner should be given notice and an opportunity to correct any deficiencies.

**Response:** DGS-DCLS appreciates Solite/GRR's support for these provisions. A revision to this section has been made based on this comment.

70. **Subject:** Petition processing (subdivision C 2)

**Commenter:** Solite Corporation and Giant Resource Recovery Inc.

**Text:** Subsection C 2, third sentence, insert "finds" in lieu of "continues to believe." Subsection E 2, insert at the end ", after prior notice and reasonable opportunity for the petitioner to take corrective action to avoid such termination." Section F, after the word "petition", insert: ", in whole or in part, or to modify or terminate a variance, ".

**Response:** The changes to subdivision C 2 and subsection F have been made. The variance will have a termination date. It will not be open-ended.

71. **Subject:** Time to issue a final decision (section D) [also 1 VAC 30-46-160 D]

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Fairfax County Water Authority, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The regulation must provide a timeframe within which the director will issue a final decision on petitioning for a variance to accreditation, after receipt of comments and after the public hearing.

**Response:** The director will issue the final decision after reviewing the comments received. Since the director will have already made a tentative decision, there is no need to assume that he will take a long time to make the decision. The time needed to review comments may vary. It is probably more important to carefully weigh the comments than to establish a deadline for a decision. No change has been made to the regulations based on this comment.

### **Personnel (Article 1)**

72. **Subject:** Laboratory manager (subsection 200 A 1)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** Text suggests that "a" lab manager be designated for general laboratory oversight. However laboratories may have more than one laboratory manager, as recognized by NELAC. The text must be

changed to allow for more than one laboratory manager, technical director, etc. for each laboratory. Also see 30-45-350 A, 30-45-400 C 1, 30-45-610 C 2.

**Response:** 1 VAC 30-45-200 does not preclude a laboratory designating technical directors in addition to a general laboratory manager. The provision focuses on the issue of the laboratory manager only. In general, anything not precluded by regulatory language is allowed. To make this clear, however, additional language from the NELAC 2003 standards at 4.1.1.1 has been added to subsection A of 1 VAC 30-45-200.

73. **Subject:** Laboratory manager (subsection 200 A 2)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Augusta County Service Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** "The title of this person may include but is not limited to..."  
If the title is "not limited" to the examples, then the sentence is superfluous. Delete it.

**Response:** The point of the provision is to require that a laboratory manager be designated but not to require what the title of that person should be. No change has been made to the regulations based on this comment.

74. **Subject:** Quality assurance officer (subsection 210 A)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The section states "where staffing is limited." Staffing is limited in most of the laboratories, regardless of the number of employees. It is not clear how the laboratory, or DGS-DCLS will determine that staffing is limited.

**Response:** The provision stopped short of defining what limited staffing is. It is not necessary to define limited staffing. Most of us know it when we see it. However assigning a separate person to be quality assurance officer is a good practice. Where possible, this practice should be followed. In a lab staffed by fewer than three people, having the laboratory manager be the quality assurance officer makes sense. No change has been made to the regulations based on this comment.

75. **Subject:** Quality assurance officer (subsection 210 B)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** It is not clear what constitutes a "documented training for quality assurance officer." Smaller laboratories will probably not have anyone on staff with documented training.

**Response:** 1 VAC 30-45-210 B requires that someone in the laboratory be trained in quality assurance and quality control procedures. Training courses are available. If no one in the laboratory currently has the training, then someone needs to be trained in this discipline. No change has been made to the regulations based on this comment.

76. **Subject:** Laboratory personnel requirements and management responsibilities (section 220)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** "The laboratory shall have sufficient personnel...." This sentence is vague and leaves too much room for inconsistent interpretation. Either a standard should be developed or the sentence removed.

**Response:** Some standards should be general enough to apply in many different circumstances. While this ambiguity can lead to inconsistent interpretation, it also gives the organization or person to whom it applies an opportunity to discuss the standard's interpretation. The provision could specify the education, training, technical knowledge of the personnel and define a sufficient level of personnel. Providing this level of specificity would create a standard that ignores variation. It would also create criticism from regulated laboratories about the level of specificity imposed. No change has been made as a result of this comment.

77. **Subject:** Absence of laboratory manager or quality assurance officer (section 230)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** Regulation requires laboratory manager deputies, but this may not be possible in "one man" laboratories. This requirement must be amended to address this situation.

**Response:** The comment is correct in that the provision is too open-ended. The provision has been revised. The provision now addresses only the laboratory manager. The provision now requires a full-time staff member to perform the manager's duties if the manager will be absent more than 15 consecutive calendar days.

### **On-Site Assessment (Article 2)**

78. **Subject:** Frequency of on-site assessment (section 300 B)

**Commenter:** DEQ AIR

**Text:** A sentence needs to be added which states ***"An on-site assessment of each accredited laboratory must be completed at least every two years."***

The proposed provisions do not specify how often on-site assessments must be conducted.  
[Statement obtained from July 12, 2002 NELAC Standards Chapter 3 - On-Site Assessment Section 3.3.1  
<http://epa.gov/ttn/nelac/standard/chapter3.pdf> ]

**Response:** The provision has been revised to clarify when on-site assessments will occur: initially and at renewal every two years.

79. **Subject:** Frequency of on-site assessment (section 300 B)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** A condition for more frequent, unscheduled on-site assessment includes a "poor performance on a proficiency test sample." It is not defined what poor performance means. If a sample was measured for many parameters and the vast percentage fails, an on-site assessment would be understandable. But

without defining further, does that mean if 2 parameters are missed out of 30, that an additional assessment would be likely? If so, does the lab pay for “an additional, unscheduled assessment?”

On-site assessments can be triggered by “other information concerning the capabilities or practices of the certified laboratory”. This language is far too vague and must be made more specific to determine if the regulation is being followed. The regulation cites the tools used to determine capability; specifics must be used in the regulation or this text must be removed.

The text cites that “a major change” in a laboratory’s operations might trigger an on-site assessment, but no specifics are offered. This language is far too vague to be used in regulation. Factors such as “key certification criteria” must be used in the regulation for this purpose because they have been defined and are clearly communicated to all stakeholders. The current language is unacceptable for regulation.

**Response:** 1 VAC 30-45-300 B has been rewritten to provide more specificity and to connect the requirement for other on-site assessment to other requirements in this chapter.

80. **Subject:** Areas to be assessed (subsection 330 A)

**Commenter:** VAMWA, VA AWWA/WWEA LPC, Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** Unless there are specific standards provided for each of the items listed in this section they must be deleted because compliance with the regulation cannot be determined independently. For example, how will DGS-DCLS determine “adequacy of the laboratory facility” or if the “quantity, condition and performance of laboratory instrumentation and equipment” is acceptable? Vague language such as these examples will only lead to discrepancies regarding compliance with the regulation, which is unacceptable. The regulation must be unambiguous and crystal clear. Additionally, A.9 refers to a “plan”, but there is no definition of what this “plan” is.

**Commenter:** VAMWA, VA AWWA/WWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The section lists nine areas that are “...evaluated in an-onsite assessment...” but seems to leave other areas out, such as the laboratory’s record system. It should plainly state, “...the laboratory will be evaluated against the standards set forth in Article 4, Quality System of the regulation.” Keep it simple.

**Response:** To eliminate ambiguity, the provisions of 1 VAC 30-45-330 have been revised.

81. **Subject:** Documentation of on-site assessment (subsection 400 B 4)

**Commenter:** VAMWA, VA AWWA/WWEA LPC, Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The regulation should make clear that comments and recommendations are not requirements for laboratories to follow; the laboratory may choose not to follow them without compromising certification.

**Response:** By definition, recommendations and comments are not requirements. The assessment findings and requirements are the part of the on-site assessment report that must be followed to obtain certification. No change has been made to the regulations based on this comment.

82. **Subject:** Documentation of on-site assessment (subsection 400 C 1)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The section states: “The assessment report shall not be released to the public until findings of the assessment and the corrective actions have been finalized (...).” All public data/information is of course subject to release under the Freedom of Information Act. However, no text or guidance is provided on how it is determined whether an assessment report is released (e.g. upon request and under the guidance of the Freedom of Information Act). Also it should state that the laboratory be notified when such information is released by the assessor.

**Response:** The commenter states “[a]ll public data/information is of course subject to release under the Freedom of Information Act.” While generally true, the drafts of the final report can be withheld. Drafts do not reflect the final decisions of the assessment team. The provision has been revised however to indicate that when DGS-DCLS sends the laboratory the on-site assessment report, the report can then be released to the public under the requirements of the *Virginia Freedom of Information Act*. Related to this issue is the requirement of 1 VAC 30-45-400 C 2. The provision contradicts the requirements of the *Virginia Freedom of Information Act* and has been deleted.

83. **Subject:** Documentation of on-site assessment (subsection 400 C 3)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** Any specific requirements that are not included in the current regulation but are included on checklists and which will impact the decision of DGS-DCLS to certify the laboratory must be included in the regulation to allow laboratories to adequately prepare for assessments.

**Response:** Any checklists used by assessment personnel will be based on the requirements of 1 VAC 30-45. The regulations specify the requirements. A checklist is a tool that lists the requirements in a format usable by the assessors. No change has been made to the regulation based on this comment.

### **Proficiency Testing (Article 3)**

84. **Subject:** Laboratory enrollment in proficiency testing program – required level of participation (section 500)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The regulation intends to implement the NELAC version of a PT program without including all of the qualitative assessments and conditions included in the appendices of the NELAC PT chapter. These appendices must be referenced in the regulation to ensure effective implementation of a PT program for non-commercial laboratories.

**Text:** It is not clear what is the process by which DGS-DCLS plans to approve PT providers. NELAC established a PT Oversight Board to approve PT providers. DGS-DCLS should recognize NELAC-approved PT providers, or provide criteria, which they will use to approve PT providers. The impact of DGS-DCLS approving a provider that does not meet stringent quality requirements could be detrimental to VA laboratories.

**Response:** The qualitative assessments and conditions in the appendices of the NELAC PT chapter (Chapter 2) pertain to the requirements for the organizations that accredit proficiency test providers and to

the test providers themselves. These appendices are: Appendix A – PT Provider Approval Criteria (responsibilities and requirements for a proficiency testing provider in order for that provider to become a Proficiency Testing Oversight Body (PTOB)/Proficiency Test Provider Accreditor (PTPA); Appendix B – PT Sample Design & Acceptance Guidelines (sample formulation criteria for PT samples); Appendix C – PT Acceptance Criteria and PT Pass/Fail Criteria (acceptance criteria to be used by any NELAP-designated PTOB/PTPA-approved Proficiency Test Provider); Appendix D – Proficiency Testing Oversight Body/Proficiency Test Provider Accreditor (qualifications for a PTOB/PTPA); and Appendices E through H: requirements for various categories of proficiency testing samples such as microbiology and environmental toxicology.

Laboratories should use providers approved by NELAC that fulfill the requirements of Appendices A through H of Chapter 2 of NELAC. Language has been added to 1 VAC 30-45-500 A 2 to make that clear. Subdivision A 2 has been revised to specify the action that laboratories should take when approved providers are not available through NELAC PTOB/PTPAs. NELAC, in its *Proficiency Testing FAQs*, says the following about this issue:

For programs and compounds for which NIST/NVLAP accreditation is not available (non-WS/WP), laboratories shall obtain PT samples for the purposes of NELAC accreditation from a provider who is accredited by an American National Standards Institute/Registrar Accreditation Board (ANSI/RAB)-accredited registrar or equivalent PTPA or has provided evidence to the laboratory of applying to an ANSI/RAB-accredited registrar or equivalent PTOB/PTPA for the compounds/matrices offered.

For fields of testing for which PT samples are not available from either a NELAP PTOB/PTPA (e.g. NIST) or an ANSI/RAB-accredited registrar or equivalent PT provider, a Primary Accrediting Authority may accept PT results from non-accredited PT providers so laboratories shall check with their primary accrediting authority for accepted PT providers. Question and answer to #6, NELAC PT FAQs (06/18/02).

85. **Subject:** Laboratory enrollment in proficiency testing program – required level of participation (subsection 500 A 1)

**Commenter:** VAMWA, VA AWWA/WWEA LPC, Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The section states that to be initially certified, a laboratory shall participate in two single-blind, single-concentration PT studies, where available, per year. For the initial certification, the two studies in the previous 2 years should be sufficient. Having to do an additional study prior to initial certification is not necessary.

**Commenter:** VAMWA, VA AWWA/WWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The regulation states that: “For a laboratory seeking to obtain initial certification, the most recent three rounds attempted shall have occurred within 18 months of the laboratory’s application date.” Since laboratories currently perform blind PT samples no more frequently than once a year (typically only the required DMR-QA studies), the number of analyses necessary for submittal with the application will be enormous. For example, if the laboratory seeks certification for arsenic analysis by method 206.2 (wastewater samples) and method 7060A analyses after a 3050 digestion (landfill groundwater samples) and method 7060A after a 3050B digestion (503 biosolids) it will be required to perform 8 additional arsenic PT analyses. PT analytical costs will most likely increase by anywhere from 300 to 800%, maybe even more when one considers that the DMR-QA studies do not typically include all parameters.

**Response:** 1 VAC 30-45-70 F 1 o requires the application to include “the results of the three most recent proficiency test studies.” 1 VAC 30-45-520 B 1 requires a laboratory to “successfully complete two PT studies for each requested PT field of testing within the most recent three rounds attempted.” 1 VAC 30-45-520 B 3 requires that “the most recent three rounds attempted shall have occurred within 18 months of the laboratory’s application date.” The additional round allows the laboratory to meet the requirement for two of the three rounds to be successful. The program requires two PT studies per year for each PT field of testing because the on-site assessment occurs only once out of every two years. The PT testing provides a measure of proficiency when the on-site is not done. DGS-DCLS believes that for the initial submittal the results of three PT studies are important. No change has been made to the regulations based on this comment.

86. **Subject:** Laboratory enrollment in proficiency testing program – required level of participation (subsection 500 A 1)

**Commenter:** VAMWA, VA AWWA/WWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, UOSA; Amherst County Service Authority; Chesterfield County Utilities Department; City of Danville Utilities Department; City of Fredericksburg; County of Henrico Department of Public Utilities; Town of Onancock; Rivanna Water & Sewer Authority; City of Roanoke Public Utilities; and County of Spotsylvania Utilities Department.

**Text:** We support the concept of proficiency testing (PT), but continue to object to the requirement of semi-annual testing. In these proposals DCLS provides no justification for the burden and expense of semi-annual testing rather than the current annual testing. Analysis of one PT sample a year is sufficient to monitor laboratory performance. Laboratories should be required to maintain the same frequency as the current DMR-QA studies and the current regulations for Drinking Water Certification.

We do not understand why the proposed regulations place a higher priority on proficiency testing in air, wastewater and waste-discharge laboratories than this testing at *drinking* water laboratories, which obviously have very direct and significant human health importance. We request the same frequency for proficiency testing here as EPA and Virginia have determined to be appropriate for drinking water systems – annual testing. This strikes a better balance between double-checking performance versus cost and burden on laboratories.

**Commenter:** Dominion

**Text:** The proposed regulation requires at least two single-blind, single-concentration proficiency testing (PT) studies per year. Our position is that an additional PT sample per year is unnecessary, and will only increase the lab costs in time and materials. One PT study per year should be sufficient. We would also like to be able to use the annual EPA DMR studies for applicable parameters. Additionally, we would like to see a provision for a single-blind, two-concentration PT study to be an option to replace one of the PTs. Laboratories that hold certification in other states, such as West Virginia, are required to perform a single-blind, two concentration PT study annually.

**Response:** The program requires two PT studies per year for each PT field of testing because the on-site assessment occurs only once out of every two years. The PT testing provides a measure of proficiency when the on-site is not done. These studies need to be blind to the laboratory as well as to the analyst. With regard to the drinking water certification requirements for PT studies, those requirements may be changing to two instead of one proficiency test. No change has been made to the regulations based on this comment.

87. **Subject:** Laboratory enrollment in proficiency testing program – required level of participation (subsection 500 A 3)

**Commenter:** VAMWA, VA AWWA/WWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, UOSA, and DEQ WATER

**Text:** The frequency of the PT studies should be the same for all programs. Allowing DGS-DCLS to establish the frequency by program could cause unjustified greater financial burden to the laboratories performing work for some programs.

**Response:** 1 VAC 30-45-500 A 3 has been deleted. Instead, the specific exception allowed by NELAC has been added to the language of Article 3. That exception is for environmental toxicology and comes from Appendix F to Chapter 2 of the 2003 NELAC Standards.

88. **Subject:** Laboratory enrollment in proficiency testing program – required level of participation (subsection 500 A 3)

**Commenter:** VAMWA, VA AWWA/WWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** Must insert the words “where available” following “per year” because 2 PT samples per year are not currently available for all fields of testing. Toxicity testing is one example. This comment also applies to 30-45-520 B 1-3 and 5. Further, the text must be changed to approve different frequencies for a given method and analyte rather than program because PT is currently administered according to method and analyte.

**Response:** See response to issues 84 and 87. The field of certification has been revised to align with the current NELAC approach: matrix, technology/method, and analyte/analyte group. The PT field of testing follows this approach.

89. **Subject:** Laboratory enrollment in proficiency testing program – requesting certification (subsection 500 B 2)

**Commenter:** VAMWA, VA AWWA/WWEA LPC, Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The section states, “For all fields of testing for which PT samples are not available, the laboratory shall ensure the reliability of its testing procedures by maintaining a quality system that meets all applicable requirements....” This statement is pointless. It appears that the DGS-DCLS implies that for those tests where PTs are available, the laboratory does not need to maintain a quality system that meets all applicable requirements.

**Response:** Proficiency tests (PTs) provide a measure of laboratory and analyst proficiency. On-site assessment also measures the ability of the laboratory and the analysts in the laboratory to perform their work completely and accurately. When PTs are not available, the only measure available is the review of the laboratory and the laboratory’s analysts. There is no implication that proficiency tests are a substitute for on-site assessment. No change has been made to the regulation based on this comment.

90. **Subject:** Proficiency testing. Reporting results. (subsection 500 C 3)

**Commenter:** DEQ WATER, VA AWWA/WWEA LPC, VAMWA, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** Allowing a single PT to apply to “all certified methods within that matrix that a laboratory employs for an analyte” is inappropriate. It will provide no useful information to assess laboratory performance of other methods for which the lab may be certified.

As proposed, a laboratory would be allowed to analyze one PT (i.e. for CWA, nonpotable water, Copper) using a single (i.e. colorimetric) method. Based on that result, the laboratory would obtain certification for analysis of copper in non-potable water under the CWA using any other available method, such as: GFAA, FLAA, ICP and ICP-MS. These are totally different, complex instrumental methods and each of them utilizes different instrumentation. The single PT result cannot be indicative of the laboratory’s ability to perform those multiple, complex methods. This approach is inconsistent with 1 VAC 30-45-50 C, which states that certification shall be granted for specific technology and methods.

**Response:** 1 VAC 30-45-500 C 3 has been deleted for the reasons cited.

91. **Subject:** Requirements for laboratory testing of PT study samples. (section 510 B)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, UOSA, and DEQ WATER

**Text:** The section states: “. . .all PT samples are managed, analyzed and reported in the same manner as real environmental samples utilizing the same staff, methods as used for routine analysis of that analyte, procedures, equipment, facilities and frequency of analysis.” The “frequency of analysis” requirement is not appropriate in this sentence. The frequency of PT samples is specified in the regulations.

**Response:** 1 VAC 30-45-510 B has been revised for the reason cited. Language has also been added to further specify that the handling of PT samples should reflect normal practice.

92. **Subject:** Requirements for laboratory testing of PT study samples. Maintenance of records. (section 510 D)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** There is no specific guidance on how the PT results should be reported. Electronic reporting of PT results should be acceptable. Language needs to be added to allow laboratories to report PT data electronically, and keep hard copies on file, where possible.

**Response:** PT results should be reported as allowed by the PT provider. The regulations do not need to address this issue. Because it is not addressed, laboratories have the flexibility to report in any way that is workable for the PT provider. 1 VAC 30-45-510 D requires maintenance of electronic records so there is no restriction on the records to be kept with regard to whether these are hard copies or electronic copies. No change has been made to the regulation based on this comment.

93. **Subject:** PT criteria for laboratory certification (subsection 520 B 1)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** Losing accreditation for a parameter when a laboratory fails 2 out of 3 PT analyses is unnecessarily burdensome. For example, a laboratory could fail a PT analysis for a parameter on one event because of a transcription error, pass the second one, and then “fail” the next by exceeding a control limit (limits are often somewhat questionable), therefore losing their accreditation status. This

does not appear reasonable, fair and responsible. PT results are just one indicator of laboratory performance and should not be the sole reason for loss of certification status for a given parameter. The regulatory authority should follow up on such instances to determine if de-certification is necessary as well as to allow the laboratory a chance to address such outliers. The laboratory should also be allowed to arrange for analysis of two additional PT samples.

**Response:** While a laboratory may be denied certification if it fails to successfully compete two PT studies for each of the most recent three rounds attempted, there is a process in place to discuss the basis for the denial. A laboratory may discuss the problem it encountered during the PT study with DGS-DCLS prior to receiving a notice that its certification will be denied. It can again, once the notice is received, discuss the problem with DGS-DCLS. Finally, the laboratory may ask for an informal fact finding within the administrative remedies of the *Virginia Administrative Process Act*. No change has been made to the regulations based on this comment.

94. **Subject:** PT criteria for laboratory certification (subsections 520 B 4 and C 2)

**Commenter:** DEQ WATER

**Text:** For successive PTs, the waiting period should be 15 calendar days instead of 30 days between the closing date of one study to the shipment date of another study. The 30 day requirement is more stringent than the NELAC standard.

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** It is not necessary to perform supplemental PT studies at least 30 days apart. This barrier could create unnecessary hardship and disruption in the laboratory operations. Laboratories should be allowed to repeat PT testing as soon as possible.

This requirement is more stringent than the NELAC standard (2.7.2) which requires a waiting period of 15 calendar days (between the closing date of one study to the shipment date of another study).

**Response:** The suggested change has been made to 1 VAC 30-45-520 B 4 and C 2 for the reasons cited.

95. **Subject:** PT criteria for laboratory certification. (subsection 520 E 2)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The text here and throughout the regulation continues to confuse program, matrix, and technology as determinants for PT. The current PT program is defined by technology, method, and analyte.

**Response:** 1 VAC 30-45-520 E 2 has been corrected to reflect the structural change to PT field of testing by matrix, technology/method and analyte/analyte group.

96. **Subject:** PT criteria for laboratory certification. (subsection 520 F 1)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** DGS-DCLS should not have an authority to specify which months the laboratories are required to perform PT samples. Not all PT providers have PT tests available at the same time. By enforcing a set schedule, DGS-DCLS would limit the number of providers a laboratory can use. It may also conflict with a “peak” in analytical work due to season, or other issues, therefore creating an unnecessary hardship and additional costs to the laboratories.

**Commenter:** Dominion

**Text:** The proposed regulation provides that DGS-DCLS may specify which months the lab is required to participate in PT study programs. We are opposed to this requirement simply because our workload is cyclical in nature and some times during the year are better suited for analyzing and reporting proficiency samples. It would be helpful if the regulation allowed for coordination of timing between DGS-DCLS and the laboratories involved to avoid disruption of lab schedules and workload.

**Response:** 1 VAC 30-45-520 F has been revised to allow laboratories to schedule their own PT studies.

#### **Quality System (Article 4)**

97. **Subject:** Quality system (subsection 600 B)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The section states: “The quality system shall be appropriate to the type of testing...some of the requirements of this article may not apply to every laboratory subject to this chapter. When in doubt ...consult DGS-DCLS.” Either all of the requirements in the chapter should apply to all laboratories or if this statement is included to cover laboratories that conduct “simple test procedures,” the sections in the document that do not apply to these laboratories should be explicitly identified. This is an example of compromising implementation of the quality system, while at the same time the regulations rely too heavily on PT samples.

**Response:** In general, all the requirements of Article 4 apply to all the laboratories covered by 1 VAC 30-45. The language in 1 VAC 30-45-600 B has been edited, leaving in the first sentence but removing the other two sentences.

98. **Subject:** Quality system (subsection 600 C)

**Commenter:** DEQ WATER

**Text:** “...If it is not clear which requirements are more stringent, the ~~standard~~ **requirements** from the method or regulation ~~is~~ **are** to be followed.”

The intent remains the same, however, this verbiage will be more easily understood.

**Response:** The sentence could be clearer and a change has been made.

99. **Subject:** Quality system (subsection 600 D)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** This section simply states which parts of the quality system are management sections and which sections are technical. Since this section does not provide any relevant information, it should be deleted.

**Response:** Any information that helps the reader work through a lot of information is useful. No change has been made to the regulation based on this comment.

100. **Subject:** Quality manual (subsection 610 A 2)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The regulation requires that the quality manual be maintained “current”, but a standard has not been provided to define what this means. Therefore this regulation requirement is not auditable or enforceable and must be removed unless greater detail is provided.

**Response:** The provision has the standard. The dictionary definition of “current” is “belonging to the present time” or “most recent [issue].” No change has been made to the regulation based on this comment.

101. **Subject:** Quality manual (subsection 610 B)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The description of the Quality Manual elements should be condensed and consolidated with subsequent sections, such as the Quality Manual outline. This will improve text flow and make it easier for the users to understand and implement. Currently, the rest of the document, from section 1 VAC 30-45-620 onward does not follow any logical order.

**Response:** This suggestion was helpful. The list now follows the outline of Article 4 in a more logical fashion.

102. **Subject:** Quality manual (subsection 610 B 1 e)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** Section 1 VAC 30-45-610 B. 1. e. requires signatures of three people approving the Quality Manual. Therefore it should not be necessary for the “top management” to sign a “quality policy statement” which is already a part of the approved and signed Quality Manual. Note also, that the regulation requires the signatures of the responsible official, lab manager and quality assurance officer on the “Certification of Compliance” that is a part of the application (1 VAC 30-45-70). How many signatures is enough? This is an example of needless redundancy.

**Response:** The requirement for the quality policy statement to be signed by top management has been deleted. The signatures required to be included on the title page of the quality manual are sufficient. The requirement for the quality policy statement has been expanded to define what the objectives and commitment mean.

103. **Subject:** Quality manual (subsection 610 B 3)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** Must define “top management” relative to definitions provided in the regulation

**Response:** See the response to the previous comment.

104. **Subject:** Quality manual (subsection 610 B 7)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** 1 VAC 30-45-610 B., the elements of the Quality Manual uses a term: “document control system.” Section 1 VAC 30-45-630 refers to a “record system.” 1 VAC 30-45-640 A., discusses a “record keeping system.” 1 VAC 30-45-650 D. refers to a “record management system.” These sections all appear to refer to the same subject. If there is a difference it should be defined. The document should have a single section that discusses the necessary elements in a “record system.” The document needs to be rewritten in consistent and precise language to avoid potential confusion and misinterpretation by laboratory personnel and DGS-DCLS inspectors.

**Response:** The element in the list for the quality manual talks about records in a general way. 1 VAC 30-45-630 discusses records generally. 1 VAC 30-45-640 discusses the system for keeping records. 1 VAC 30-45-650 discusses the management and storage of records. Finally 1 VAC 30-45-660 specifies the records required to be kept. These are related but distinct topics. No change has been made based on this comment.

105. **Subject:** Quality manual (subsection 610 B 12)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The regulation discusses in subsection B 12 “Reference to ...verification test procedures used.” In subsection B 16 it discusses “References to verification practices” again and provides some examples. It’s unclear why verification practices are addressed twice. If there are indeed differences and distinct meanings between these two sections, then the regulation should be rewritten with the appropriate delineation.

**Response:** Subdivision B 12 does appear to repeat what is already listed in subdivisions B 15 and B 16. Subdivision B 12 has been deleted.

106. **Subject:** Quality manual (subsection 610 C 1)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The text requires the QA officer to review the QA program, manual and related documentation when a change in the laboratory “may significantly affect” the QA program. This language is far too vague to audit and enforce and must either include specifics or be removed from the regulation.

**Response:** Not all language in the regulation is meant to be audited and enforced. The language in 1 VAC 30-45-610 C 1 has been edited to clearly state that the QA officer shall review the quality manual when any change in the laboratory occurs that affects the QA program.

107. **Subject:** Recordkeeping system and design (section 640 B)

**Commenter:** DEQ WATER

**Text:** “The records shall include the identity of personnel involved in sampling, *sample preservation*, sample receipt, preparation, calibration or testing.”

Sample preservation is usually performed by the sampler, but it may occur in the laboratory. Therefore, the person performing the sample preservation must be identified.

**Response:** The change as requested has been made for the reasons cited.

108. **Subject:** Quality manual (subsection 640 H)(also 1 VAC 30-45-650 C & 1 VAC 30-45-730K)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** All three sections deal with computers and electronic records. Three separate, essentially redundant sections are not needed. These sections should be consolidated.

**Response:** These sections are not redundant. 1 VAC 30-45-640 H is part of the requirements for recordkeeping and design. This subsection brings in the requirements for computer and electronic data records by referring to those requirements as they appear in 1 VAC 30-45-650 C and 1 VAC 30-45-730 K. 1 VAC 30-45-650 C specifies how records stored on electronic media and on computers should be kept or backed up. 1 VAC 30-45-730 K specifies procedures for testing and documenting the adequacy of computer software; protecting the integrity of data entry, storage, transmission and processing; maintenance of computers and automated equipment; and security issues. The references in 1 VAC 30-45-640 H ensure that all the computer and electronic record requirements can be easily found. No change to the regulation has been made based on this comment.

109. **Subject:** Required records. Sample handling. (subsection 660 A 1)

**Commenter:** DEQ WATER

**Text:** “A record of *sampling information* and all procedures to which a sample is subjected while in the possession of the laboratory...”

Without the addition of a requirement for sampling information (time and date of collection, type of sample - composite or grab, type of container, sampling point and preservation) the laboratory procedures become meaningless. While actual sampling is not covered in this regulation, the information associated with it must be retained by the laboratory in order for the sample to be valid for regulatory purposes.

Section 1 VAC 30-45-730 D 1 requires that for methods associated with permit compliance must “...include(ing) applicable quality assurance requirements, and sample preservation, container, storage, and holding time requirements.”

**Response:** Language was added to 1 VAC 30-45-660 A 1 in response to this comment.

110. **Subject:** Required records. Sample handling. (subsection 660 A 2)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The sentence refers to the receipt and retention of “test items.” It is unclear what is a “test item.” Is it a sample? If yes, this is already addressed in the preceding section. If no, it should be defined what a “test item” is and how it differs from a sample. “Test item” is not mentioned elsewhere in the regulation.

**Response:** The language of 1 VAC 30-45-660 A 2 was revised in response to this comment.

111. **Subject:** Required records. Laboratory support activities. Analytical records. (subsections 660 B 1 and 660 C)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The language in these two sections in several cases seems to identify the same type of records. It's unclear what is a “Laboratory Support Activity” in Section B. Many of these items deal with “Analytical Records,” which are discussed in section C. For example, under B.1. it refers to “...data output records (chromatograms, strip charts, and other instrument response readout records).” These records are more appropriately labeled analytical records in section C. In fact, in the first sentence in section C., the regulations refer specifically to “strip charts.”

**Response:** While the listed items appear to be the same, there is a difference in the general type of item that should be kept. 1 VAC 30-45-660 B 1 discusses “original raw data ... for calibrations, samples and quality control measures.” 1 VAC 30-45-660 C discusses “essential information associated with analytical documents.” No change has been made to the regulation based on this comment.

112. **Subject:** Required records. Administrative records. (subsections 660 D 2)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** Initial Demonstration of Capability for each analyst is not applicable for many tests and laboratories where several analysts contribute to completion of one test. The concept of work cells must be included in this regulation. Many laboratories use work cells for streamlining work and to increase efficiency.

**Response:** The addition of “work cells” has been made to 1 VAC 30-45-660 D 2 and to the requirements and procedures for demonstration of capability.

113. **Subject:** Audits. Internal audits (subsections 670 A 4)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The section refers to “small laboratories.” A small laboratory is not defined elsewhere in the document. If this is the same as a laboratory that conducts “simple tests” it should be clarified.

**Response:** The requirement does not need to be restricted to small laboratories. The provision has been edited accordingly.

114. **Subject:** Audits (subsections 670 A and B)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** Part A. (Internal Audits), states: “The laboratory shall arrange for annual internal audits to verify that its operations continue to comply with ... quality system.” The next sentence states that this is the responsibility of the quality assurance officer. Part B. (Managerial Review), says: “The laboratory management shall conduct a review, at least annually of its quality system ...” Is it really the intention of this regulation that two separate audits be conducted of the laboratory’s quality system, one by the quality assurance officer and one by the lab management?

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** Prescribing annual internal audits removes the flexibility that a laboratory should have in running its operation. The section should be modified to read: “Internal audits should be performed at a defined frequency using appropriate personnel and in such detail as necessary to generate acceptable data quality and integrity. The audit procedures and reports shall be documented.”

**Response:** DGS-DCLS believes that an annual internal audit and an annual managerial review are necessary. The defined frequency of one year for this audit and review is not excessive. No change has been made to the regulation based on these comments.

115. **Subject:** Audits. Managerial review. (subsection 670 B 1)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The text states that laboratory management shall conduct a review of the quality system “to ensure its continuing suitability and effectiveness,” but standards defining “suitability” and “effectiveness” are not provided. This language is far too vague to audit or enforce, therefore it must be removed and replaced with specifics defining the referenced terms.

**Response:** These terms are general but have specific meanings. Is the quality system suitable (“adapted to a use or purpose”) for the tests the laboratory needs to run and the operation it needs to support? Is it effective (does it produce the desired effect – consistently accurate and reproducible data)? The laboratory develops the procedure for the review. The procedure is not specified in the regulations. No change has been made to the regulation based on this comment.

116. **Subject:** Audits. Performance audits. (subsection 670 D)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County, Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** This section is unnecessary. Most of the examples in the section are QC elements that are listed in test methods, mentioned a second time in 1 VAC 30-45-750 (Essential QC procedures), or included as part of the performance-testing program in Article 3. This needless language should be removed. Additionally, the text must be changed because a laboratory can not “ensure the quality of results” without Data Quality Objectives (DQO), and DQOs are not required nor defined by the regulation. Quality can only be defined by DQOs, the current language is far too vague.

**Response:** 1 VAC 30-45-670 D has been deleted. All but one of the specific examples have been moved to the section on essential quality control procedures.

117. **Subject:** Outside support services and supplies (subsection 690 A)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The text requires laboratories to use outside support services and supplies that are of “adequate quality to sustain confidence in the laboratory’s tests”. Nowhere in this regulation is quality defined quantitatively to be adequate, therefore the regulation is not enforceable or auditable. Only DQOs can be used to define “adequate quality”, and the regulation does not include DQOs. Either specific requirement must be listed, or the language must be removed.

**Response:** Specific language has been substituted for the general language used in the proposal.

118. **Subject:** Complaints (subsection 700)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** Protocol for handling complaints may not be applicable for a laboratory that performs only simple tests for its own plant.

**Response:** This protocol can be simple. There ought to be a standard way to document and deal with complaints. If no complaints occur, then the one-time effort of creating the protocol will be all that needs to be done. No change to the regulation has been made based on this comment.

119. **Subject:** Environment and work areas (subsection 710)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The second sentence addressing laboratory environment and work area, reads “Laboratories may meet the requirements of subsections 1 through 8...” If subsections 1 through 8 are optional, they should be deleted from the document. Only mandatory requirements should be listed. Discretionary instructions only confuse laboratory personnel and laboratory inspectors alike. These optional ideas can be communicated using other methods.

**Response:** The eight listed requirements were not meant to be optional. The phrase “as appropriate” indicates that these requirements may not apply in all instances. The sentence was revised to replace “may” with “shall.”

120. **Subject:** Environment and work areas (subsection 710 4)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** There are no criteria to determine “when the activities in the testing areas are incompatible”. A condition for “effective separation between testing areas” is vague and lacks definition.

**Response:** Revisions to 1 VAC 30-45-710 4 have been made that should make this provision clearer.

121. **Subject:** Equipment and reference materials. Equipment shown to be defective. (section 720 C)

**Commenter:** DEQ AIR

**Text:** “Any item of the equipment ....or has been shown by verification or otherwise to be defective shall be taken *immediately* out of service, *clearly identified as being out of service and, wherever possible, stored ....*”

Without this additional wording lab may continue to have defective equipment in service until they can determine an alternative solution.

**Response:** The recommended change has been made to 1 VAC 30-45-720 C.

122. **Subject:** Equipment and reference materials. Records. (section 720 E)

**Commenter:** DEQ AIR

**Text:** The records ~~may~~ *shall* include...

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The sentence pertaining to equipment records states: “The records may include.” It’s unclear whether or not the 9 items listed in this statement are mandatory. If the list is optional as indicated by the word “may”, then it should not be included in the regulation. Optional or suggested items/practices should be relayed in a different manner.

**Response:** The verb “may” has been replaced with “shall.” The use of “may” was unintentional.

### **Test Methods and Standard Operating Procedures (1 VAC 30-45-730)**

123. **Subject:** Standard operating procedures and Laboratory Methods Manuals (subsection 730 B & C)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** Section B. discusses “ Standard Operating Procedures” and includes the following statement: “Laboratories shall maintain SOPs that accurately reflect all phases of current laboratory activities ... and all test methods.” In the very next section (Laboratory methods manuals), it states: “The laboratory shall have and maintain an in-house manual or manuals for each certified analyte or test method.” Both sections refer to tests methods. It’s unclear why the regulation discusses test-method manuals in two sections, when one section is sufficient.

**Response:** Subdivision C discusses test methods in detail; subdivision B discusses test methods in the context of standard operating procedures. In the latter test methods are one of several items discussed. No change to the regulation has been made based on this comment.

124. **Subject:** Standard operating procedures (subsection 730 B 2)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The regulation refers to an “approving authority”, but no definition is provided. It is unclear as to which members of the quality system represent the approving authority.

**Response:** The commenter is correct. This term is ambiguous. A revision has been made to clarify the meaning.

125. **Subject:** Laboratory methods manual (subsection 730 C 2)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** Subsections: l, m, r, s, t - should be combined in l as: l. Quality control, including calibration and standardization, data assessment and acceptance criteria for quality control measures, corrective actions for out-of-control data, and contingencies for handling out-of-control data. Subsections q and u should be combined as q. Pollution prevention and Waste management.

**Response:** Each laboratory may organize its method manual as it sees fit. The organization the commenter suggests may be used or not. The requirement here is the laboratory must include the listed items in its method manual. No change has been made to the regulation based on this comment.

126. **Subject:** Demonstration of capability (subsection 730 E 3)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** It is not clear why the regulation sets a cut off date of July 1999 for not requiring an initial demonstration of capability. If it was originally based on the VA regulation going into effect in 1999, the date should be updated to the current projected implementation date.

**Response:** This requirement, taken from the NELAC standards, grandfathers the requirement for demonstration of capability when the method has been used for that long and the analyst performing the method and instrument type have not changed since that time. No change has been made to the regulation based on this comment.

127. **Subject:** Demonstration of capability (subsection 730 E 5)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The work cell concept needs to be included in the requirement for a demonstration of capability. The demonstration of capability may not need to be repeated every time one person in a work cell changes. If all QC requirements are met, this should be sufficient to show the quality of data is acceptable.

**Response:** While the standard has not been changed, a provision has been added to incorporate the concept of work cells in the regulation.

128. **Subject:** Procedures for demonstration of capability (subsection 730 F)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The procedure for demonstration of capability was written specifically with chemical analyses in mind but does not address biological tests. No language has been provided to address biological methods.

**Response:** Revisions have been made to 1 VAC 30-45-730 F that should resolve this issue.

129. **Subject:** Procedure for demonstration of capability (subsection 730 F 1 a)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** This section states, "A quality control (QC) sample shall be obtained from an outside source. If not available, the QC sample may be prepared by the laboratory using stock standards that are prepared independently from those used in instrument calibration." It is unclear what is a "QC sample from an outside source". If it means a certified reference material from a NIST-certified QC/PT provider it creates another significant financial burden on the laboratories, at the same time providing a windfall for QC sample providers. Allowing labs to prepare QC samples from secondary source standards (as mentioned in the second sentence) should be acceptable whether or not a manufacturer sells a QC sample for a particular parameter.

**Response:** 1 VAC 30-45-730 F 1 a has been revised to allow the laboratory to purchase or to prepare its own QC sample.

130. **Subject:** Requirement for the demonstration of capability certification statement (subsection 730 G)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The certification document for each test for each analyst is another example of the excessively prescriptive nature of the program and the overly burdensome and unnecessary documentation requirements. This section should be removed. Demonstration of capability must mirror the criteria used in the PT program to allow matching of PT results with this demonstration.

**Response:** The certification statement is done once for each method that the analyst performs. 1 VAC 30-45-730 E 1 states the requirement as "prior to acceptance and institution of any test method." No change to the regulation has been made based on this comment.

131. **Subject:** Certification statement (subsection 730 G)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The statement: "A copy of the certification statement shall be retained in the personnel records of each affected employee." should be changed to read: "A copy of the certification statement shall be retained in the laboratory records of each affected employee."

**Response:** The reference to "personnel records" is more explicit than the suggested change to "laboratory records." No change has been made to the regulation based on this comment.

132. **Subject:** Certification statement – examples. (section 730 G)

**Commenter:** DEQ WATER

**Text:** "(examples: barium by 200.7, trace metals by ~~6010~~ **6010B**, benzene by ~~8021~~ **8021B**, etc.)"

Methods 6010B and 8021B are the most recent promulgated versions (1996) of these methods and the only versions allowed for compliance reporting.

**Response:** The requested revision has been made for the reason cited.

133. **Subject:** Certification statement (subsection 730 G 5)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The section states: "All raw data. . .have been retained at the facility, and . . . available for review by authorized assessors." In many organizations the personnel records are not retained in the laboratory and would not be readily available for review. The language change should clarify the point of the information being organized and available for review.

**Response:** The certification statement needs to be available for the on-site assessment. When the personnel records are held elsewhere they will need to be available to the on-site assessment team for other reasons as well as to see the certification statement. No change to the regulation has been made based on this comment.

134. **Subject:** Data verification (subsection 730 I)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** This section should be incorporated into section 30-45-730 C. 2, Laboratory methods manuals.

**Response:** The requirements of 1 VAC 30-45-730 I are additional requirements. These requirements could be added to the method manual but this subsection should not simply listed as part of the list in subdivision C 2. No change to the regulation has been made based on this comment.

135. **Subject:** Documentation and labeling of standards and reagents. (subsection 730 J 1)

**Commenter:** DEQ WATER

**Text:** "The laboratory shall retain records for all standards, reagents, **reference materials** and media including the manufacturer/vendor, the manufacturer's Certificate of Analysis or purity (if **supplied available**)..."

"Reference materials" should be included because they may be used for calibration or calibration verification.

"If supplied" implies that if it isn't provided with the shipment, the lab isn't required to request it. Some manufacturers only supply the COA upon request. COA's should be retained by the labs as it provides information for traceability, sensitivity, and appropriateness of use in a given method.

**Response:** 1 VAC 30-45-703 J 1 has been revised for the reason cited.

136. **Subject:** Computers and electronic data related requirements (subsection 730 K 1)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The statement: "All requirements of this article are complied with" is unnecessary and should be deleted.

**Response:** 1 VAC 30-45-703 K 1 has been revised for the reason cited.

137. **Subject:** Computers and electronic data related requirements (subsection 730 K 2)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The meaning of "...focus point of quality assurance and quality control" is unclear. Should be either clarified or deleted.

**Response:** 1 VAC 30-45-730 K 2 has been revised to clarify the provision's meaning.

#### **Measurement traceability and calibration (1 VAC 30-45-740)**

138. **Subject:** General requirements (section 740 A)

**Commenter:** DEQ AIR

**Text:** "...or both before being put into service. ~~and on a continuing basis.~~ *Equipment shall be checked or calibrated before use.*

Statement obtained from July 12, 2002 NELAC Standards Chapter 5 - Quality System Standard Section 5.5.5.2 <http://epa.gov/ttn/nelac/standard/chapter5.pdf>

**Response:** The comparable NELAC citation is 5.5.6.1. The basis for the proposed language was the NELAC language as written in 1999. These NELAC provisions have undergone considerable editing since that time. Subsection 740 A has been revised; the revised language is that used in the 2003 NELAC standards at 5.5.6.1. In addition, subsections 740 B and C have also been revised to reflect the clearer language in the 2003 NELAC standards at 5.5.6.2 and 5.5.6.3.

139. **Subject:** Reference standards (subsection 740 C 3)

**Commenter:** DEQ WATER

**Text:** "Reference materials shall be traceable *to appropriate measurement standards.*"

By not defining what the reference materials must be traceable to, makes this section of the regulation unauditible.

**Response:** 1 VAC 30-45-740 C 3 has been revised for the reason cited. Also see response to issue 138.

140. **Subject:** Reference standards and calibration (subsection 740 C 3 and D 1 b)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** In section C. 3., the regulation states: “Where possible, traceability shall be to national or international standards of measurement, or to national or international standard reference materials.” However, in section D.1.b., it limits traceability as follows, “All support equipment shall be calibrated...using NIST traceable references when available...” Are international standards acceptable in lieu of national standards or only when a national (i.e. NIST) standard does not exist? The acceptability and definition of international standards must be clarified. (See also the definition of “traceability” in section 1 VAC 30-45-40)

**Response:** Subsection 740 C has been revised. Also see response to issue 138.

141. **Subject:** Calibration – Support equipment (subsection 740 D 1 b)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The section states: “All support equipment shall be calibrated ...over the entire range of use.” “Over the entire range” is too vague and could be interpreted too many ways. Should be replaced as follows: “...according to instrument manufacturer instructions or to standard accepted practices.”

**Response:** The phrase “over the entire range of use” is clear especially when read with the following sentence. This next sentence states that “the results of such calibration shall be within the specifications required of the application for which this equipment is used.” No change to the regulation has been made based on this comment.

142. **Subject:** Calibration – Support equipment (subsection 740 D 1 e)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The section requires quarterly verification of mechanical volumetric dispensing devices. It is not clear what is the justification behind a quarterly frequency, or is there information available to support a quarterly frequency as necessary. Brinkman Instruments (manufacturer of Eppendorf pipettes) recommends a verification frequency of every 6 months.

**Response:** The frequency required is that required by NELAC. DGS-DCLS uses NELAC as a basis for specific requirements because the NELAC standards are consensus standards developed by the states over time. A number of changes to these standards have been made over the past few years since this particular requirement first appeared. However this requirement has not changed in that time. No change to the regulation has been made based on this comment

143. **Subject:** Calibration – Instrument calibration (subsection 740 D 2)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The entire section on instrument calibration is redundant. Analytical SOPs based on approved reference methods discuss calibration requirements. The entire section should be eliminated.

**Response:** This section provides requirements where methods do not. Where methods do provide these requirements, the provisions of subdivision D 2 a state that the most stringent of the requirements of this chapter or the method's requirements must be met. No change to the regulation has been made based on this comment.

144. **Subject:** Calibration – Instrument calibration (subsections 740 D 2 b (4) and D 3 c (1))

**Commenter:** VAMWA, VA AWWA/WWEA LPC, Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority, Fairfax County Water Authority, Hanover County Department of Public Utilities, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The regulation specifically exempts laboratories that conduct simple tests from meeting the requirements in these two subsections. It appears that these are the only exemptions in Article 4. Quality Systems for labs that conduct simple tests. If not, the regulation should explicitly identify the requirements that do not apply.

**Response:** The statements the commenters cites are not exemptions. They are statements of fact: simple test procedures do not require instruments that are to be calibrated. The statements are included to assist those laboratories only performing simple test procedures. No change to the regulation has been made based on this comment.

145. **Subject:** Calibration – Instrument calibration (subsection 740 D 2 b 3)

**Commenter:** DEQ WATER

**Text:** "Sample results shall be quantitated from the initial...not be quantitated from any continuing instrument calibration verification ***unless otherwise required by regulation, method, or program.***"

NELAC Section 5.5.5.2.2.1.c allows this exception. The Virginia regulation should allow the same exception.

**Response:** 1 VAC 30-45-740 D 2 b 3 has been revised for the reason cited.

146. **Subject:** Calibration – Instrument calibration (subsection 740 D 2 b 5)

**Commenter:** DEQ WATER

**Text:** Many EPA approved methods contain no criteria for acceptance of calibration curves. For this reason, DEQ established the criterion of 0.995 or greater for the calibration coefficient (DEQ's Water Division Guidance Memorandum No. 98-2007) unless a different criterion is included in the method being used. This same criterion is given in *Standard Methods 20<sup>th</sup> ed.* Part 1020B.10.b. A similar criterion should be established for this regulation rather than allowing the labs to select their own.

**Response:** 1 VAC 30-45-740 D 2 b 5 has been revised for the reason cited.

147. **Subject:** Calibration – Instrument calibration (subsection 740 D 2 c (2)(b))

**Commenter:** DEQ WATER

**Text:** "A continuing instrument calibration check shall be repeated at the beginning and end of each analytical batch. The concentrations of the calibration verification shall be varied within the established calibration range. ***Over time, all concentrations of calibration standards shall be used for verification.*** If an internal standard is used, only..."

All concentrations of the calibration curve need to be verified. This is needed to help ensure that the calibration range is appropriate for the laboratory's system of analysis.

**Response:** 1 VAC 30-45-740 D 2 c (2)(b) has been revised to add the sentence suggested by this comment for the reason cited.

148. **Subject:** Calibration – Instrument calibration (subsection 740 D 2 c (2)(b))

**Commenter:** UOSA

**Text:** "The concentrations of the calibration verification shall be varied within the established calibration range." What is the purpose of varying this concentration? All this does is increase the difficulty in conducting the analysis and likely increase analyst errors and reduce data quality.

**Response:** See the text of the comment from DEQ WATER in issue 147. No change to the regulation has been made based on this comment.

149. **Subject:** Calibration – Instrument calibration (subsection 740 D 2 c (2) (d))

**Commenter:** DEQ WATER

**Text:** "Criteria for the acceptance of a continuing instrument calibration verification shall be established, e.g., **percent recovery** or relative percent difference."

"Percent recovery" is the term that is commonly used to compare the difference between the known concentration of a sample and the concentration reading from the instrument when based on a linear regression. The majority of laboratories will be more familiar with this term.

**Response:** The suggested change has been made to 1 VAC 30-45-740 D 2 c (2) (d) for the reason cited.

150. **Subject:** Essential quality control procedures. (subsection 750 B 1, 2 & 3)

**Commenter:** DEQ WATER

**Text:** The essential quality control procedures given in these sections are extremely vague. By stating that written protocols for on-going QC must exist without stipulating how and with what frequency the QC must be demonstrated, the auditors' hands will be tied. They will have to adhere to a strict interpretation of the regulation and only minimal QC can be required. For example: a lab that runs a method blank twice a year and finds no apparent contamination will have demonstrated that the negative control requirement on an on-going basis has been met for that method. The newer EPA methods require that a method blank be prepared with each preparation batch and that it undergo the same preparation steps as the samples. For these methods this section is adequate, but for other methods it is grossly lacking.

Methods for Chemical Analysis of Water and Wastes (MCAWW) contains the EPA approved inorganic chemical methods used by the majority of wastewater laboratories. It was written in 1979 and the last revisions were in 1983. Required quality control procedures in these methods are nearly non-existent. This lack of QC calls into question the quality of compliance data and is one of the reasons lab certification is needed in Virginia.

NELAC Chapter 5, Appendix D should be added to this chapter with the exception of D.3.1.b.1. This section requires each batch of media to be tested with a pure culture. It would not be appropriate for wastewater treatment plants to maintain pure cultures of *E. coli*. Suggested language is "Each pre-prepared, ready-to-use lot of medium (including chromofluorogenic reagent) and each batch of medium

prepared in the laboratory shall be tested and demonstrate a positive response. This shall be done prior to first use of the medium.”

**Response:** The requirements of Appendix D of the 2003 NELAC Chapter 5 have been added to 1 VAC 30-45 from 1 VAC 30-45-760 through 1 VAC 30-45-829. The suggested language substitute for D.3.1.b.1 has been made.

151. **Subject:** Sample receipt protocols. (subsection 760 3)

**Commenter:** DEQ AIR

**Text:** *All documentation, such as memos or transmittal forms, that is transmitted to the laboratory by the sample transmitter shall be retained.*

Addition of new language.

Statement obtained from July 12, 2002 NELAC Standards Chapter 5 - Quality System Standard Section 5.5.8.3.1(e) <http://epa.gov/ttn/nelac/standard/chapter5.pdf>

*A complete chain of custody record form, if utilized, shall be maintained.*

Addition of new language.

Statement obtained from July 12, 2002 NELAC Standards Chapter 5 - Quality System Standard Section 5.5.8.3.1(f) <http://epa.gov/ttn/nelac/standard/chapter5.pdf>

**Response:** Rather than change 1 VAC 30-45-760, additions have been made to the requirements for the sampling records that should be retained in 1 VAC 30-45-640 B.

152. **Subject:** Sample acceptance policy. (subsection 760 2)

**Commenter:** DEQ WATER

**Text:** “Sample acceptance policy...The policy shall ensure that only properly obtained samples **with appropriate sampling records (see 1 VAC 30-45-640 B)** are analyzed and that samples...”

Mentioning the sampling records in this section provides continuity and will assist labs in adhering to the standards.

**Response:** The suggested change has been made for the reason cited.

153. **Subject:** Sample receipt protocols. (subsection 760 3 a)

**Commenter:** DEQ AIR

**Text:** Under Sample Receipt Protocols, need to add following language: **System laboratories shall utilize a permanent chronological record such as a logbook or electronic database to document receipt of all containers. This sample receipt log should record as a minimum the following information: client/project name, date and time of laboratory receipt, unique laboratory ID code and signature or initials of the person making the entries.**

Addition of new language.

Statement obtained from July 12, 2002 NELAC Standards Chapter 5 - Quality System Standard Section 5.5.8.3.1(d) <http://epa.gov/ttn/nelac/standard/chapter5.pdf>

This addition will necessitate a definition of “System laboratory” being added. A possible definition is “a non-commercial lab that analyzes samples from more than one facility.”

**Response:** The suggested change has been made not to subdivision 760 3 a but to subdivision 760 1. The definition is useful in more than this context and has been added to 1 VAC 30-45-40.

### **SPECIFIC COMMENTS: 1 VAC 30, CHAPTER 46**

#### **Purpose (1 VAC 30-46-10) and Standards (Part II, Section 200)**

154. **Subject:** NELAC Standards.

**Commenter:** DEQ WATER

**Text:** "...Commercial environmental laboratories are accredited under the standards of the National Environmental laboratory Accreditation Conference as approved in 2002."

Chapters 1 (Glossary), 2 (PT's) and 6 (Accrediting Authorities) of the 2003 NELAC Standards became effective July 1, 2003. Regulation should reflect currently effective NELAC Standards.

**Commenter:** LAVA, Coastal Bioanalysts, Inc., Aquatech Environmental Services, Inc.

**Text:** Based on effective date being January 1, 2005 applications would be due at that time 2003 standards will be the current NELAP standard. We would urge DCLS to consider the 2003 standards in completing this regulation.

**Commenter:** VAMWA, VA AWWA/WWEA LPC, VAMWA, VA AWWA/WWEA LPC; Addison-Evans Water Production & Laboratory Facility, Chesterfield County; Augusta County Service Authority; Fairfax County Water Authority, Water Quality Laboratory; HRSD; Hanover County Department of Public Utilities; Town of Round Hill Utility Department; and UOSA.

**Text:** We are concerned that the Chapter 46 regulations will not always be current with the national NELAC standards. The proposed regulations themselves are based on the 2002 edition of the NELAC standards, which will be obsolete in July 2005. To maintain its status as an accrediting authority under NELAC, DCLS must keep Chapter 46 current with NELAC standards. If DCLS intends for "commercial" laboratories to pay higher fees and comply with NELAC in exchange for the ability to claim NELAC status in the marketplace, there must be a timely process for keeping ever-changing NELAC standards current in state regulations

By incorporating the NELAC 2002 standard by reference the regulation puts limitations on the future development to the program. Laboratories will be unable to implement improvements to their quality system that will be introduced into future versions of the NELAC standards. This is particularly important considering lack of stability and maturity in NELAC standards, which are still experimental and undergo significant changes each year.

**Response:** DGS-DCLS sent the proposed regulations to executive review in early fall 2002. The regulations emerged from executive review in late 2003. No change could be made to the regulations during this time and until after the agency received public comments. The regulations have been revised to incorporate the 2003 NELAC standards, rather than the 2002. The 2003 NELAC Standards will become effective on July 1, 2005. NELAP recognizes that the States have limits on their legal ability to quickly incorporate any technical document by reference. Therefore, NELAP decided to have a policy whereby the standards would not become effective, for the most part, until two years after they had been voted on. These two years allow most states to carry out a rulemaking to change the standards under which the state operates. DGS-DCLS will have to undergo a rulemaking to incorporate a later standard. The only other method by which NELAC standards could more readily be incorporated into 1 VAC 30-46 would be if the governing statute, §2.2-1105, was changed to allow automatic incorporation of revised NELAC standards.

**Applicability (1 VAC 30-46-30)**

155. **Subject:** Maintenance of DCLS' accrediting authority (subsection B 1) and timing of DCLS' obtaining accrediting authority (subsection B 2)

**Commenter:** VAMWA, VA AWWA/WWEA LPC, Fairfax County Water Authority, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** In order to accredit laboratories in VA under the NELAC program, the DGS-DCLS must obtain the NELAP Accrediting Authority (AA) status and actively maintain this status for the duration of the program. There is no provision for DGS-DCLS to maintain the AA status after they obtain an initial accreditation, prior to the implementation of 1 VAC 30-46.

In order to maintain accreditation DGS-DCLS will be required to submit a renewal application every 2 years to the EPA NELAC Accrediting Authority. To renew accreditation DGS-DCLS laboratory must comply with the most recent version of the approved standard. If DGS-DCLS will comply with new standard, this will result in the DGS-DCLS laboratory using a different standard than will be required for the commercial laboratories to meet.

If DGS-DCLS does not meet the requirements of NELAC to maintain their status as a NELAC Accrediting Authority (AA), they would not be able to administer NELAC accreditation. Commercial laboratories will gain nothing by holding 1VAC 30-46 accreditation but they will have to pay excessive fees.

DCLS plans to become an AA one year after this chapter becomes effective, depending on the timeline, this could happen when NELAC 2003 is effective, not 2002 and DCLS could not become an AA. DCLS makes no provision as to what will happen if they are unable to become an AA within the time frame they have set forth, or if NELAC is no longer in existence.

Because of the discrepancy between the date when applications are due from laboratories and the date at which DGS-DCLS must become an AA, laboratories may potentially waste time and money submitting application materials. Errors that may exist in the application process may have to be corrected later, as a result of NELAP approving DGS-DCLS as an AA.

**Response:** DGS-DCLS shall apply to become an accrediting authority (AA) and expects to attain that accreditation within one year following the effective date of 1 VAC 30-46. The DGS-DCLS application must meet the requirements of Chapter 6 of the 2003 NELAC Standards in order that the agency be recognized as the primary accrediting authority for Virginia. Every three years, DGS-DCLS will have to renew its AA status. DGS-DCLS must also meet the 2003 NELAC standards to become an accredited NELAC laboratory. DGS-DCLS plans to apply for AA status prior to the effective date of 1 VAC 30-46. DGS-DCLS expects to be approved. However the agency may need to submit revised materials to be approved. This circumstance should occur before any applications are received under this chapter.

**Definitions (1 VAC 30-46-40)**

156. **Subject:** Definition of "accreditation"

**Commenter:** VAMWA, VA AWWA/WWEA LPC, Fairfax County Water Authority, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** Accreditation is defined as "the term used as a substitute for the term "certification". There is however no definition for certification in chapter 46. Accreditation is a major element of this chapter, and a complete definition must be included.

**Response:** The term "accreditation" has been more completely defined. The term now is defined as NELAC defines it.

157. **Subject:** Definition of “accrediting authority”

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Fairfax County Water Authority, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The “accrediting authority” definition should be expanded to “...under NELAC and follows and meets all NELAC standards.”

**Response:** The term “accrediting authority” is the same as that used by NELAC. A body or state agency cannot become an accrediting authority unless it follows and meets all NELAC standards.

Process to Apply and Obtain Accreditation (1 VAC 30-46-70)

158. **Subject:** Accreditation for current NELAP-accredited laboratories

**Commenter:** Aquatech Environmental Services, Inc.

**Text:** Since our renewal is January 31, 2005 and we are required to pay all fees to the accrediting state 3 months prior to renewal, what will be the accreditation (Interim?) offered to Current NELAP holders by the State of Virginia while the program takes off. This needs to be addressed.

**Response:** Current NELAP-accredited laboratories that wish to apply for accreditation during the initial accreditation period will have to wait while all applications under this chapter are determined to be complete. See 1 VAC 30-46-70 J 3 and H. No change has been made to the regulation based on this comment.

159. **Subject:** Final determination on accreditation. (subsection J 2)

**Commenter:** DEQ AIR

**Text:** “...within nine months from the time an ~~application is determined to be complete~~ **a completed application is first received from the laboratory.**

New wording is obtained from July 12, 2002 NELAC Standards Chapter 6 - Accrediting Authority Section 6.3.3.1(e) [<http://epa.gov/ttn/nelac/standard/chapter6.pdf>].

**Response:** This is the wording used in NELAC (now 6.3.2.1 (e) of the 2003 Standards). The suggested change has been made.

160. **Subject:** Final determination on accreditation (section J 5)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Fairfax County Water Authority, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The regulation should make clear that comments and recommendations are not requirements for laboratories to follow; the laboratory may choose not to follow them without compromising certification.

**Response:** By definition, recommendations and comments are not requirements. The wording of the last sentence in subdivision J 5 is misleading. The on-site assessment report will have a section on findings and a separate section with comments and recommendations. Subdivision J 5 has been revised to delete this sentence. The on-site assessment provisions of the NELAC standards include the details of what is in the on-site assessment report.

161. **Subject:** Grant of accreditation (section K 1)[citation from comments]

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Fairfax County Water Authority, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** Text suggests that “a” lab manager be designated for general laboratory oversight. However laboratories may have more than one laboratory manager, as recognized by NELAC. The text must be changed to allow for more than one laboratory manager, technical director, etc. for each laboratory. See also 1 VAC 30-46-70 L.3, and 1 VAC 30-46-120.

**Response:** See response to issue 72. The comment cites the use of the term “technical director” in 1 VAC 30-46. The comment language is addressed in issue 72. No change to 1 VAC 30-46 has been made based on this comment. The NELAC standards provide that other laboratory managers may be employed.

162. **Subject:** Grant of accreditation. (subsection K 6)

**Commenter:** DEQ WATER

**Text:** “Accreditation shall expire ~~two~~ **one** years after the date on which accreditation is granted.”

NELAC 2002 Standards, Section 4.2 states “...the period of accreditation within fields of accreditation ...shall be 12 months...” Laboratories are allowed to renew their certification annually with an on-site inspection required every two years.

**Response:** The commenter is correct that 4.2 of the 2002 NELAC Standards, and the same citation from the 2003 standards, states that the period of accreditation within fields of accreditation shall be 12 months. However not all of the sentence in 4.2 was included in the comment. Section 4.2 states: “For a laboratory in good standing, the period for accreditation within fields of accreditation for methods or analytes shall be 12 months and will be considered to be ongoing once a laboratory has been accredited for that field of accreditation method or analyte within a field of accreditation.”

DGS-DCLS does not believe that the intent of the standard was to require laboratories to reapply completely for accreditation every 12 months. The regulations for all the NELAP Accrediting Authorities (AA) specify that the accreditation shall last for only 12 months. However the process to renew that accreditation varies across the spectrum of the AA requirements. Revisions have been made to 1 VAC 30-46-70 C, G, H and K. The new renewal scheme provides that a complete application with fees will occur every two years following the initial date of accreditation. The on-site assessment will occur during this review period. For the other years, the laboratory will be accredited if it does the following. The laboratory has to have maintained compliance with 1 VAC 30-46. It has to submit a signed Certificate of Compliance to that effect. Finally the laboratory must have successfully performed the applicable proficiency tests available for its Fields of Accreditation during the previous year. The application is the same as the list in 1 VAC 30-46-70 F 1, without the quality manual. Fees will be required only for the renewal year when the on-site accreditation is performed.

163. **Subject:** Denial of accreditation (section L)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Fairfax County Water Authority, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** There must be a mechanism in place for laboratories to appeal a denial of accreditation by DGS-DCLS in case there is a controversy. Currently NELAC has such a mechanism in place, but none would be available in Virginia if NELAC were to dissolve or DGS-DCLS would not maintain their status as NELAP AA.

**Response:** See response to issue 65. NELAC does not have a “mechanism in place for laboratories to appeal a denial of accreditation.” NELAC states that “a laboratory is always entitled to the right of due process.” NELAC continues by saying “[d]ue process rights are delineated in the appropriate state laws and regulations of the accrediting authorities. Since these laws and regulations may vary from state to state, laboratories seeking accreditation are encouraged to become familiar with the specific laws and regulations governing due process for each of the accrediting authorities of interest.” Section 4.7 of the 2003 NELAC Standards. NELAC sets out provisions for suspension, in 4.4.2 of the 2003 Standards. However, DGS-DCLS cannot take advantage of these provisions because the statute governing the program, §2.2-1105, is not sufficiently specific in its enforcement provisions to allow suspension. The statute would need revising to provide this basis for suspension. In any case, it is Virginia law that determines what enforcement and appeal provisions pertain to this program and not the NELAC standards.

### **Maintaining Accreditation (1 VAC 30-46-80)**

164. **Subject:** Quality systems (section B)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Fairfax County Water Authority, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The terms “assure consistency” and “promote” are used to describe requirements of the quality system. These terms are far too vague to be auditable, therefore enforcement will be problematic and inconsistent. These terms must be removed from the text. Further, this section requires that the quality system is “appropriate” to the type, range and volume of testing in the lab. This term is also far too vague to audit or enforce and must be removed.

**Response:** The terms “assure consistency” and “promote” are not to be used to audit. The requirements of Part II are the standards and will be used to audit the laboratories. The phrase “appropriate to the type, range and volume of testing” is inappropriate and has been deleted.

Appeal Procedures (1 VAC 30-46-110)

165. **Subject:** Appeal procedures provided by NELAC

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Fairfax County Water Authority, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** This language only provides for the Virginia-specific APA process for appeals, the language must address and recognize the appeals process provided by NELAP as one that DGS-DCLS will recognize and abide by.

**Response:** See response to Issue 163.

### **Fees (1 VAC 30-46-150)**

166. **Subject:** Costs of accrediting out-of-state laboratories

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Fairfax County Water Authority, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** Under the current regulation out-of-state laboratories applying for the accreditation in Virginia will be charged the same fees as the laboratories located in the State. There is no provision for out-of-state laboratories to pay additional travel and per diem expenses for on-site inspections. There is no reason why the Virginia laboratories or the Virginia taxpayers should have to foot the bill for on-site inspections

conducted by DGS-DCLS elsewhere in the country. The regulation should be modified to address this issue.

**Commenter:** LAVA, Aquatech Environmental Services, Inc.

**Text:** There is no provision in the regulation to charge per diem or travel expenses for out of state labs that want to use Virginia as their primary accrediting authority. Presumably the cost to audit these labs would be normalized across all the in state labs, which is unacceptable to LAVA. Other accrediting authorities charge these fees for out of state laboratories.

**Response:** A provision has been added to both 1 VAC 30-45 and –46 requiring out-of-state laboratories to pay reasonable travel costs for on-site assessments. These costs could be substantial and should not be paid by laboratories other than those out-of-state laboratories seeking accreditation or certification in Virginia.

167. **Subject:** Fee refund.

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Fairfax County Water Authority, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** Section A 2 must be modified to include a refund of fees to laboratories if DGS-DCLS is not able to meet the regulation.

**Response:** Section 2.2-1105 requires that environmental laboratories shall be certified in Virginia. Regardless of what type of program is in place, this certification must occur unless the law is repealed. The environmental laboratories covered by §2.2-1105 will pay a fee as required by the statute to pay for their portion of the cost of the program. No change to the regulation has been made based on this comment.

168. **Subject:** Fees for small laboratories

**Commenter:** LAVA, Coastal Bioanalysts, Inc., VAMWA, VA AWWA/VWEA LPC, Fairfax County Water Authority, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The fees are disproportionately high for small laboratories. Because of the administrative requirements of the NELAC standards, the relative costs of instituting and maintaining the program are already higher for small laboratories. The fee structure should not also place an unfair burden on these businesses.

To the best of our knowledge the proposed auditors for this program will be trained and sanctioned in NELAC accreditation process and will administer both Chapter 45 and Chapter 46 audits. The state personnel cost of auditing should therefore be the same whether the lab is Chapter 45 or 46 compliant. The fees for the programs should be more equitable in this regard. The time it takes to perform the audits should not be much different for either chapter since Chapter 45 is based on the NELAC standards and the QA programs are very similar. The following scenario explains the inequity in the fee system proposed for small commercial laboratories.

For example, a small commercial lab with only a few employees, and accredited for BOD and bacteriology only, would pay \$2700 compared with the maximum fee of \$4200 for a large, full service lab accredited for all test categories. Based on DCLS' own cost estimates, this means the small lab would require 80 hours of effort to accredit whereas the large lab would require only an additional 40 hours of effort; this is an obviously unrealistic discrepancy. It seems that in the case of a small laboratory with a few categories, reviewing the application and associated documents, conducting the on-site assessment and preparing an evaluation report should take no more than 40 hours of effort. Noteworthy is the maximum fee for a comparable non-commercial lab performing only these "simple" tests: \$400!

**Commenter:** Aquatech Environmental Services, Inc.

**Text:** Aquatech Environmental Services, Inc. (AES) is a NELAP-accredited laboratory for the services of Toxicology Testing in both Aquatic and Sediment Toxicology, as well as, Hazardous Materials WET testing. Our accreditation was initiated at the inception of the NELAP program through the state of California with secondary accreditation through Florida. AES are a small laboratory (only 5 employees). This laboratory as a matter of principal has endured the burden and expense of this program. We believe strongly in what this program is trying to achieve. After having participated in this program for the last 5 years and providing services across the country as a result of such participation I have recorded the following issues relating to AES and its future as a laboratory accredited in the state of Virginia.

The fee basis is one of our main concerns. Having participated in state programs which run their NELAP two different ways I would like to go on record saying that a unified program which requires ALL laboratories, without exception (who report information that is used by state regulators to evaluate our waters, soils, etc.) to participate in the program. Unilateral participation places all analysts in a professional profile. It reduces the incidence of bias in analyses and reduces the fees to a level which all may participate. Florida requires all reporting facilities to participate, thus reducing the overall fee for PRIMARY ACCREDITATION (including fields) for me to \$800.00, plus fees for traveling for inspections. The choice for them as a secondary accrediting agency is \$500.00. California on the other hand has a dual accreditation program. The fees for just my field of accreditation run Primary \$ 6,400.00, plus audit expenses or \$5,400.00 for Secondary. They have been working on this fee structure with a promise of reduction for YEARS- AES is about to withdraw from the state after servicing it for 8 years.

Since we are in the State of Virginia we would of course have to participate with Virginia as a PRIMARY. The structure of Florida's fee and participation base, like that of NY, makes sense to us and would be the choice way to continue participation in the program in Virginia. Please consider this STRONGLY, as our choice to remain in Virginia is dependent on it.

The goal by EPA was to format an accreditation that would be participated in by all states. AES still has states that are unwilling to participate or acknowledge this program, which makes the validity of such a programs solidarity questionable. North Carolina and Arizona (at a minimum) require additional auditing and fees subsequent to such audits.

**Commenter:** Joiner Micro Laboratories, Inc.

**Text:** The Virginia Environmental Laboratory Accreditation Regulation (1 VAC 30 Chapter 45 and Chapter 46) defines a two-tier system of standards that separate environmental laboratories into two categories. The categories are non-commercial (Chapter 45) and commercial (Chapter 46). As the owner of a commercial laboratory, I have concerns about the significant inequities in this program between commercial and non-commercial environmental laboratories. My two main concerns are the "simple test" sub-category and the fees.

*Non-commercial laboratories are given a "simple test" sub-category, which reduces their regulation requirements and fees. Commercial laboratories are not given this status. Joiner Micro Laboratories is a small commercial laboratory that only analyzes "simple tests". Joiner Micro Laboratories and other small commercial laboratories will be at an economic disadvantage without the "simple test" sub-category option.*

*One economic disadvantage is the fees applied to commercial labs in comparison to the non-commercial fees. A non-commercial lab performing "simple tests" would pay a base fee of \$400 to DCLS for certification. A commercial lab performing "simple tests" would pay a base fee of \$2100 to DCLS. A \$1700 difference seems extremely unfair and not indicative of the extra expense it may cost the regulatory agency to conduct the on-site audit and to administer the program. Remember, a lab*

*analyzing “simple tests”, whether non-commercial or commercial, is doing the same testing. The base fee for laboratories performing “simple tests” should not be different.*

The “simple test” category should be available to all environmental laboratories. If the addition of this category were necessary for non-commercial environmental laboratories – why wouldn’t it be applicable to commercial laboratories too?

**Commenter:** Environmental Systems Services, Ltd. (ESS)

**Text:** My specific comment concerns the proposed fee structure for commercial vs. non-commercial laboratories, and the particular situation that exists within the structure of ESS. In addition to the environmental laboratory in Culpeper, ESS has laboratories in three other locations, two of which are out of state and concerned almost entirely with the testing of milk and other dairy products. A small laboratory in Bedford focuses primarily on food microbiology testing. However, the technicians at that facility assist my laboratory by performing the simple tests of pH and fecal coliform bacteria on the wastewater samples of some of my clients. The additional testing of BOD, TSS, ammonia, TKN, etc. is handled here in Culpeper.

As proposed, the two-year fee for the Bedford Lab to become an accredited facility would be \$2,700 (\$2,100 base fee, plus \$300 for the category of Bacteriology, and \$300 for the category of Physical Parameters). The two-year charge for a non-commercial laboratory performing the same testing would be only \$400. In part, I can understand the DCLS position to have the commercial laboratories assist in funding this program. However, this fee discrepancy is unacceptable to us. It places an undue burden on the Bedford facility, and any other commercial laboratory whose analyses are limited to the simple tests. The base fee for commercial labs should be lowered, while the separate category fees could be raised.

I ask that you seriously consider this aspect of the proposed fee structure, and work toward a more equitable plan.

**Commenter:** LAVA

**Text:** The base fee for laboratories places an undue burden on a small commercial laboratory that only performs the simple tests or is focused on only a few categories. It would be more equitable to raise the “al la carte” fees on the categories and lower the base fee. The base fee covers the costs of the program that should be the same for either Chapter 45 or 46, such as application and administrative fees. These costs should not be different for any participating laboratory. The difference in the audit and the costs should be through the “al la Carte” menu for the test categories. Chapter 46 fees for each category should be higher than the categories for Chapter 45 and that would be equitable. We want to reiterate that the base fee for all participating laboratories should be the same.

**Response:** The fees for both commercial and noncommercial laboratories have been reassessed in response to these comments. The base fees and maximum fees have been altered so that they are now equivalent for commercial and noncommercial laboratories, with the exception of the simple test procedure laboratories. The base fees are lower for the commercial laboratories and about the same for noncommercial laboratories. The fees charged for the simple test procedure laboratories are low because these noncommercial laboratories will undoubtedly have to spend more time and resources to meet the requirements of 1 VAC 30-45 than any small commercial laboratory would. A small commercial laboratory should have the components of a good QA/QC system in place.

## **Standards (Part II)**

169. **Subject:** Standards for accreditation (section 210)

**Commenter:** VAMWA

**Text:** This section fails to reference all appendices of the NELAC standards as well as Chapter 6, Accrediting Authority, as requirements of this regulation. These are critical components of an accreditation program and cannot be selectively omitted. These appendices and this chapter of the NELAC standards must be included in this regulation. Chapter 46 has also selectively avoided adoption of other critical parts of the NELAC standards including PT program purpose (program must be affordable); PT goals (generation of data quality required by DEQ); PT fields of testing; requirements for PT providers; and denial, suspension and revocation of accreditation (no regulation proposed requiring DCLS to operate within NELAC standard).

**Response:** It is not appropriate to incorporate all of the NELAC standards. Some standards pertain to requirements for groups other than the laboratories covered by 1 VAC 30-46 or to DGS-DCLS, such as 2.3, the requirements for PT providers under Chapter 2 of NELAC. However, laboratories are required to obtain PT samples from these providers under 2.4.1, which is incorporated by reference. Changes have been made to Part II of 1 VAC 30-46 to replace the 2002 NELAC standards with the 2003 standards. Some of these changes reflect changes made to the NELAC standards. In addition, in reviewing the incorporated NELAC standards, some changes have been made based on this comment. Where the NELAC standards include requirements that conflict with Virginia law, those requirements can not be included in 1 VAC 30-46. A provision has been added to Article 2 to make this clear. See response to issue 163.

170. **Subject:** Standards for accreditation – quality systems (section 210 D 2 a)

**Commenter:** VAMWA, VA AWWA/VWEA LPC, Fairfax County Water Authority, HRSD, Town of Round Hill Utility Department, and UOSA

**Text:** The language must remove the words “to ensure” quality of data because this regulation does not contain Data Quality Objectives (DQOs), nor does the NELAC standards. This regulation will only document quality, it cannot ensure quality.

**Response:** The regulation cannot ensure quality. Laboratories accredited under the quality assurance and quality control protocols required by Chapter 5 of the NELAC standards, along with the other requirements for accreditation are able to provide data of a consistent and high standard. No change has been made to the regulation based on this comment.

## **PUBLIC TESTIMONY RECEIVED, SEPTEMBER 20 THROUGH OCTOBER 20, 2004**

### **GENERAL COMMENTS**

171. **Subject:** General comments

**Commenter:** Virginia Department of Environmental Quality (DEQ)

**Text:** The major points covered in the Virginia Department of Environmental Quality comments are as follows:

Additional requirements are needed for the appropriate handling of electronic files. The quality control procedures given in Chapter 45 require the use of pure cultures of microorganisms, which could pose a potential health hazard for wastewater treatment facilities. Whole Effluent Toxicity Testing laboratory proficiency test requirements should not be limited to the Discharge Monitoring Report Quality Assurance Studies (DMRQA). Inclusion of taxonomic identification of algae, benthic macroinvertebrates, macrophytes, vertebrates and zooplankton as a “field test and measurement”.

DEQ continues to support the proposed regulations.

**Response:** DCLS appreciates DEQ's support for the proposed regulation. The specific DEQ comments are addressed below.

172. **Subject:** Procedural Issues

**Commenter:** Augusta County Service Authority (ACSA) and Hampton Roads Sanitation District (HRSD)

**Text:** The following text is identical to that submitted by the two commenters; the comments were filed separately.

ACSA and HRSD were troubled that DCLS would choose to not extend the [second] public comment period for the above-referenced regulations. While the APA does recommend a 30-day comment period, the omission of providing a copy of the amendments to the *Virginia Register* delayed review of the document and significantly shortened the amount of time available to develop comments for submittal. These regulations will impact every environmental laboratory (both large and small) in Virginia and therefore, should be afforded the highest level of scrutiny.

ACSA and HRSD were also extremely disappointed and disheartened to find that the majority opinion of the commenters was ignored by DCLS. Specifically, the fact that DCLS has decided to move forward with a two-tiered certification program despite concerns raised by many commenters, including the Department of Planning and Budget. Furthermore, DCLS has placed additional requirements on the noncommercial laboratories without providing a rationale for increasing the burdens on the smaller municipalities. Your letter of October 12 denying a comment period extension referenced the Governor's Executive Order (21) in setting the review guidelines for regulations by the state agencies. ACSA and HRSD would like to add that the Governor's Executive Order (21) also states that regulations shall be "designed to achieve their intended objective in the most cost-effective manner. Regulatory development shall be based on the best reasonably available scientific, economic, and other information concerning the need for, and *consequences of* (emphasis added) the intended regulation." (Executive Order 21 Sections C. and D. page 2)

ACSA and HRSD question whether the guidelines of the Governor's Executive Order (21) have been diligently followed during this rulemaking process. ACSA and HRSD are submitting for the second time (HRSD: and third time in some cases) their comments on the latest proposal for public comment regarding the proposed regulations for environmental laboratories certification program.

ACSA and HRSD have attempted to participate in the various stages of the regulatory process leading up to the publication of these regulations without adequate recognition of its comments. Our initial comments on the proposed regulations were submitted in April 2004; however, our most important comments were not adequately addressed. DCLS' second proposal reflects changes made to the proposed regulations based partially upon the comments received after the initial publication on February 9, 2004.

**Response:** On October 8, 2004, the Virginia Association of Municipal Wastewater Agencies (VAMWA) submitted a request for an extension of the second public comment opportunity provided on proposed regulations. The commenters requested the 30-day public comment period be extended to 60 days. The opportunity for public comment was published in the *Virginia Register* on September 20, 2004 in a general notice. On the same day, September 20, 2004, DCLS sent all those who commented during the initial 60-day public comment period (including these two commenters) a copy of the revised regulations and a copy of the general notice. DCLS also sent the revised regulations to anyone else the agency thought would be interested. On September 22, 2004, DCLS sent the same organizations and individuals a copy of the summary and response to comments received during the initial public comment period. The commenters had as much time to review the regulations as they would have if the revised regulations had been published in the *Register* directly. Agencies may choose how to provide an opportunity for public comment if the opportunity is in addition to that required by the Administrative Process Act.

In its October 12, 2004, response to VAMWA regarding the request for an extension of public comment, DCLS stated:

We agree that the revisions are substantive. This is why we are providing the additional 30-day public comment period. The *Virginia Administrative Process Act* (§2.2-4000 *et seq.*) [APA] requires an initial 60-day public comment period for proposed regulations. The APA generally provides for an additional 30-day public comment period if an agency makes substantive changes to proposed regulations when promulgating the regulations in final. The agency may provide this opportunity for public comment or be asked to do so during executive branch review of the final regulations. As stated in the general notice published on September 20<sup>th</sup>, “DCLS is providing this additional opportunity for public comment because some of the changes made to the proposed regulations are substantial.”

With regard to the comments on both the “two-tiered certification program” and the “additional requirements on the noncommercial laboratories,” please see the response to issue 176 below.

The commenters also question whether the requirements of Executive Order 21 were carried out. The commenters wonder whether the agency focused adequately on the consequences for those affected by the regulations. The agency did so. There is a difference between extraordinary consequences and those consequences due to a change that comes about because of new programmatic requirements. DGS-DCLS believes that the quality control requirements added to the last proposal are not extraordinary but indeed requirements that the laboratories must meet now or will have to in the future. Please see the response to issue 176 below for an expanded discussion of this issue.

In addition, the commenters state that as submitted in April 2004, their “most important comments were not adequately addressed.” The commenters do not make it clear what they mean by this statement. All comments submitted during the initial 60-day public comment period were addressed in the *Summary and Response to Public Testimony* provided to the commenters. However changes were made when the suggested change appeared to be appropriate relative to the purpose and goals of the program. If the suggested change was not appropriate, it was not made.

173. **Subject:** Decertification and Reapplication Requirements

**Commenter:** Augusta County Service Authority; Hampton Roads Sanitation District; Hanover County Department of Public Utilities; Laboratory Practices Joint Committee, Virginia Section of the American Water Works Association (VAWWA)/Virginia Water Environment Association (VWEA)[LPC]; Upper Occoquan Sewage Authority (UOSA); and Virginia Association of Municipal Wastewater Agencies (VAMWA).

**Text:** The following text is either identical to or closely representative of the comments on this issue.

VAMWA is strongly opposed to the decertification and reapplication provisions in the proposed regulations because these provisions are unnecessary for environmental protection and are punitive to the point that VAMWA simply cannot accept them. (See 1-VAC 30-45-100; 1 VAC 30-45-70 M).

The regulations as currently drafted would mandate that any laboratory where one employee submitted one piece of false data would be decertified. VAMWA members have strict policies against falsification by an employee. The employment of any person who falsifies laboratory data is in almost all cases terminated. As currently drafted, this provision provides no discretion for DCLS to evaluate the circumstances and determine whether decertification is appropriate and, instead, mandates that the laboratory be decertified. This would be so even if there were some mitigating circumstances or the laboratory owner could show that the alleged falsification occurred in spite of proper precautions and a history of good compliance. Thus, a laboratory could be decertified despite long-standing compliance due to an allegation that one decision had been made regarding one piece of data by one employee.

At a minimum, VAMWA strongly believes that DCLS should maintain the discretion over decertification decisions to prevent unjust decertification rather than being compelled by its own regulations to take mandatory decertification actions. VAMWA suggests that this could be accomplished by amending 1 VAC 30-45-100(A) to state that DCLS “may” decertify a laboratory rather than “shall” decertify a laboratory on certain conditions. This amendment would still be consistent with § 2.2-1105(E) of the Virginia Code because the use of the word “found” in the statute suggests that DCLS have some role in reviewing and assessing the alleged conduct. Further, the statute address decertification in the present tense. This suggests that once a laboratory fully deals with an employee guilty of falsifying data (e.g., terminates employment), there is no ongoing falsifying and therefore decertification is not mandatory.

VAMWA also suggests that the language of 1 VAC 30-45-100 be amended to clarify what is meant by the use of the term “laboratory owner or an employee.” VAMWA believes that “employee” should be removed from the regulations as not necessary and potentially confusing. The statute only provides that actions should be taken against “laboratories” found falsifying data, not against “employees” found falsifying data. Next, the term “laboratory” needs to be defined in a way so that the actions or one possibly misbehaving employee cannot automatically be imputed to the laboratory as a whole.

VAMWA has similar objections to 1 VAC 30-45-80 M, which prohibits a lab from reapplying for certification until six months after denial. Rather than idling public facilities and workers, DCLS regulations should encourage the facility to quickly address any deficiencies, meet the standards for certification, and return to serving the public as soon as possible. The six-month waiting period is punitive; serves no legitimate environmental purpose, and, in VAMWA’s opinion, must be removed.

**Commenter:** MeadWestvaco

**Text:** The presently proposed decertification and reapplication requirements are too prescriptive. DCLS must have the capability to decertify labs but it also needs to have the discretion to evaluate the need to decertify on a case-by-case basis.

The prohibition of a lab to reapply for six months after application denial serves no purpose.

**Commenter:** UOSA

**Text:** The proposed six month waiting period for laboratories that were denied certification will have serious economical and social implications on government laboratories. We recommend that the regulation include language that precludes the need for reapplying after denial except when absolutely necessary (applicant negligence, for example).

**Response:** The commenters present three issues. First, the commenters are opposed to the provisions for decertification where an employee may have committed fraud because they believe the provision “provides no discretion for DCLS to evaluate the circumstances and [to] determine whether decertification is appropriate.” Second, the commenters take issue with the use of the term “laboratory owner or employee” in the decertification requirements. This language also appears in the provisions concerning denial of certification. Third, the commenters believe that six months is too long a period to wait to reapply for certification if certification has been denied.

With regard to the second issue, DCLS agrees that the provisions using the term “laboratory owner or employee” should be revised. The statute at § 2.2-1105 E states “[i]n addition to any other penalty provided by law, laboratories found to be falsifying any data or providing false information to support certification shall be decertified or denied certification.” The statute does not specify the laboratory’s employees or the laboratory’s management. In strict accordance with § 2.2-1105 E, the regulation has been revised to substitute the term “laboratory” for the phrase “laboratory owner or employee.” In addition, these commenters point out that § 2.2-1105 E uses the phrase “found to be falsifying any data or providing false information.” After rereading 1 VAC 30-45-70 L 1 and 1 VAC 30-45-100, DGS-DCLS

has modified these provisions so they reflect the statute's language. Comparable provisions in 1 VAC 30-46 have also been revised.

With regard to the first issue, DCLS must follow the requirements of the *Virginia Administrative Process Act* (APA) in order to decertify a laboratory. Like any other instance that would trigger decertification, if DCLS has a basis to believe that fraud has been committed, the agency must notify the laboratory of this belief. This notification must clearly set out the issues associated with the cause for decertifying the laboratory. DCLS has revised the appeal provisions in both 1 VAC 30-45 and 1 VAC 30-46. These revisions reflect the process that DCLS must follow. The provisions now state that DCLS will notify a laboratory when the agency "believes it has grounds to deny certification or to decertify" a laboratory. The notice will provide a detailed explanation of the basis for the notice. The provisions include language encouraging a laboratory receiving such a notice to engage in informal discussions on the issue immediately after receiving the notice. These informal discussions may well lead to a resolution of the issue. If the informal discussions do not resolve the issue, an informal fact finding under Virginia's *Administrative Process Act* is held. At the end of this fact finding, the DCLS director will make a case decision on the issue. This case decision may then be appealed. While a determination or case decision is being made, the laboratory retains its certification and indeed does so until all its appeal opportunities are carried out.

DCLS has made a revision to 1 VAC 30-45-70 G 5 that is related to this discussion. Subdivision G 5 addresses what happens when a laboratory does not respond in a timely fashion to a request for additional information. The revision deletes the language stating that DCLS "may deny" this application and substitutes language stating that DCLS "may return the incomplete application" informing the laboratory that the application cannot be processed. The laboratory may then reapply.

With regard to the third issue, DCLS believes that a six-month time period is appropriate. DCLS may deny an application for any number of reasons.

The issue of falsification discussed under issue one is one reason. As discussed above, if DCLS has a basis to believe that a laboratory has falsified data or provided false information with its application, then DCLS will notify the laboratory of this belief. DCLS and the laboratory will then discuss the issues that form the basis for the belief that falsification occurred. DCLS and the lab may resolve these issues. In that case, DCLS and the lab would continue with the application process. If DCLS and the lab cannot resolve these issue, the process outlined in Virginia's *Administrative Process Act* takes place. The application process stops until a case decision is made and appeals that may be taken from this decision are completed. If the case decision or the appeals are successful for the laboratory, the application process continues. If not, the laboratory will have to wait six months to reapply.

The other reasons given in 1 VAC 30-45 that may cause DCLS to deny certification have to do with whether the laboratory:

- meets the certification standards;
- pays the required fees;
- is responsive to findings of deficiencies; or
- provides additional information on time.

DCLS will have worked with the laboratory on the application process in each of these circumstances. DCLS will determine that an application is incomplete if it does not contain fees or enough information to process the application. If DCLS determines an application is incomplete and asks for additional information, the laboratory must provide the information in a timely fashion. If the application is complete and the process begins, DCLS must find that the laboratory meets the certification standards. If during the on-site assessment DCLS finds deficiencies, the laboratory must provide a plan for corrective action in a timely fashion for the certification process to continue.

If the laboratory cannot work through this application process within the time frame provided, then DCLS believes it is important for the laboratory to take the time to organize itself so that it can be certified. DCLS will have worked closely with the laboratory to resolve deficiencies and spent considerable time doing so.

It is important to note that this issue of when laboratories are allowed to reapply once their application is denied has been discussed at some length early on during the development of the NELAC standards. It is also been discussed at some length with regard to other national certification programs. These national programs provide that after an application is denied a laboratory must wait six months before reapplying. It is also important to contrast this six-month waiting period with the language for reapplication after decertification. The regulation, at 1 VAC 30-45-100 E, states “[a]fter correcting the reason or cause for decertification under 1 VAC 30-45-100 A or B, the laboratory owner may reapply for certification.” The key phrase is “after correcting the reason or cause for decertification.” When DCLS has denied certification to a laboratory, DCLS will have worked extensively with the laboratory to help them resolve the problem that holds up certification. The laboratory will have had an opportunity to correct the issue. If the laboratory will not make the correction or is not timely in its response to DCLS, then it is clear to DCLS that the laboratory does not want to make a serious effort to become certified. This is why the regulation calls for a six-month time before the laboratory may reapply.

With regard to the third issue, no change to the regulation has been made.

174. **Subject:** Interim Certification

**Commenter:** Augusta County Service Authority, Hampton Roads Sanitation District, Hanover County Department of Public Utilities, LPC, and VAMWA.

**Text:** The following text is either identical to or closely representative of the comments on this issue.

VAMWA objects to the change in 1 VAC 30-45-70 H (3) (Process to apply and obtain certification – grant of interim certification pending final determination on application). Initially, the regulation stated that interim certification would expire “when DCG DCLS issues a final determination on certification.” The new proposed provision states that interim status “shall not exceed twelve months.”

VAMWA is concerned that the certification process may not be completed in twelve months. To obtain a final certification, an onsite assessment “shall be performed” and there is no required time in which DCLS must perform the assessment. Therefore, if DCLS fails to complete its on-site assessment of the laboratory in twelve months, the laboratory will be forced to either reapply (and possibly pay the application costs a second time) or be forced to hire a third-party assessor. A laboratory should never lose certification because DCLS did not address its responsibilities in a timely manner, and VAMWA believes this provision should remain the way it was originally proposed on February 9, 2004.

Federal and state agencies administratively continue permits when the agency, though no fault of the permittee, is unable to complete the application process. That is exactly the approach under DEQ’s VPDES permit regulations, and it is appropriate. We were shocked that DEQ proposed a different approach in this regulation by requesting in its earlier comments that DCLS have interim certification expire after 12 months. It is arbitrary for DCLS to abandon that approach here and transfer the risk to the regulated laboratories of any potential non-performance or tardiness by DCLS in its certification duties. It is equally arbitrary for DEQ to propose that approach here when its own regulations provide to the contrary in similar situations. DCLS should provide for interim certification to continue in place when DCLS has not completed this permitting process.

**Commenter:** UOSA

**Text:** According to the latest draft for Chapter 45, following the laboratory’s submission of an initial complete application, DCLS will limit interim certification to 12 months. However, to obtain a final

certification, an onsite assessment shall be performed. We recommend that the regulations include the proper timeframe commitment for DCLS to complete its on-site assessments of the laboratory in 12 months. Failure to include a required timeframe for the assessment will most likely result in the laboratory having to either reapply (pay the application costs a second time) or hire a third-party assessor. Please note that based on the proposed regulation, certification expires two years after the date on which certification is granted and DCLS is not required to complete action on a laboratory's application within nine months during the "initial certification period." We urge you to include a reasonable timeframe for completion of the laboratory assessments by DCLS to protect the integrity of the program.

**Commenter:** MeadWestvaco

**Text:** Interim certification should only expire when DCLS completes the formal certification process.

**Commenter:** Augusta County Service Authority, Hanover County Department of Public Utilities, UOSA, and VAMWA

**Text:** Interim certification should be extended to at least 24 months (the normal certification period). If limited to 12 months and DCLS fails to fulfill its responsibilities to complete the review of an application or more likely is unable to conduct an on-site audit, the laboratory will either lose certification status or be forced (i.e. penalized) to hire a 3<sup>rd</sup> party on-site assessor. Essentially in this case, these labs will be paying the on-site inspection fee twice: once to DCLS (which is part of the initial application fee) and a second time to a 3<sup>rd</sup> party inspection team. The laboratory community should not have to bear this hidden financial burden for poor program implementation and planning by DCLS.

**Response:** DGS-DCLS has revised 1 VAC 30-45-70 H 3. The language reads now as it did when proposed in February 2004.

DEQ in its earlier comments on this issue (see Issue 47 above) stated that 12 months "should be adequate time for DCLS to conduct an on-site inspection and grant or deny certification. The on-site inspection is the most crucial part of the certification process in determining if the procedures being performed in the lab are meeting regulatory requirements. Allowing an interim accreditation status to exist indefinitely would greatly weaken the certification program." DEQ also noted that "at 4.5.1, the NELAC standards (2002) require that interim accreditation status should not exceed 12 months."

The 2003 NELAC standards at 4.5.1 also require that interim accreditation status not exceed 12 months. DGS-DCLS will not change the comparable provision at 1 VAC 30-46-70 H 3; this provision needs to remain so that DCLS will meet NELAP requirements. The agency may do so in 1 VAC 30-45, however. DGS-DCLS agrees that 12 months is adequate time to conduct an on-site inspection and grant or deny certification. DGS-DCLS also agrees that because any delay would be caused by the agency, the applicant laboratory should not be penalized.

175. **Subject:** Application for Certification

**Commenter:** Augusta County Service Authority, Hampton Roads Sanitation District, Hanover County Department of Public Utilities, LPC, and VAMWA.

**Text:** The following text is either identical to or closely representative of the comments on this issue.

The provisions of 1 VAC 30-45-70 do not provide a time requirement for DCLS to notify a laboratory that its application is complete. Consequently, a laboratory could wait an extended period of time to hear from DCLS as to whether its certification application is incomplete, find out that it is not complete, and be in jeopardy of not meeting the regulation by the time the program is established. Laboratories need to know that if they submit an application, DCLS will review it promptly so that if any deficiencies are present, they can be corrected and re-submitted before the application deadline. This is simply good practice, and it has been implemented for years in the VPDES permit program. For example, DEQ assesses

completeness of VPDES applications within fourteen days of receiving the application. See VPDES Permit Manual II-15. Fourteen days is also an appropriate length of time for DCLS to review applications. There is no excuse not to provide a similar approach and level of service here.

**Commenter:** UOSA

**Text:** In the proposed regulations there is no time requirement for DCLS to notify a laboratory that its application is complete during the initial certification period. Other regulatory programs under the Clean Air Act and the Clean Water Act require that permit applications be assessed by regulation in an established timeframe, for example, 14 days of receipt. We believe that a 60-90 day requirement is reasonable and attainable and recommend inclusion of a notification of application status in both regulations. Establishing a time frame for notifying the applicant of the status of the application ensures continuity of the laboratory certification process and opens lines of communication between regulators and the regulated community.

**Commenter:** MeadWestvaco

**Text:** DCLS should have a time limit on its requirement to notify labs that their certifications are complete.

**Response:** Setting a limit on the time needed to do completeness determinations during the initial certification period of this new program is difficult. DGS-DCLS agrees that the completeness determinations need to be done in a reasonable amount of time. Determining what is reasonable is the problem and why no limit was set. However to respond to the commenters' concern that review of applications would be delayed, the provisions of 1 VAC 30-45-70 G have been revised to set a time of 90 days for completeness determinations to be done during the initial certification period. This should be more than adequate time to carry out completeness determinations.

176. **Subject:** Addition of Quality Control Requirements for Specific Types of Testing; Should The Dual Regulation Approach Continue?

**Commenter:** Augusta County Service Authority, Hampton Roads Sanitation District, Hanover County Department of Public Utilities, LPC, UOSA, and VAMWA

**Text:** The following text is either identical to or closely representative of the comments on this issue.

When this issue first arose, VAMWA supported a dual program approach, one for "commercial" laboratories and another for "noncommercial" laboratories. VAMWA believed that two separate programs were better than one combined mandatory NELAC-based program, which VAMWA believed would be inappropriate and unnecessary for municipal laboratories. DCLS agreed to adopt a two-program approach and established Chapter 45 for non-commercial laboratories, which provided for more flexibility and was less prescriptive.

However, the most current revision of the standards for Chapter 45 has been expanded to the point that major differences between Chapter 45 and 46 have been all but eliminated. DCLS added well over sixty pages of new requirements to Chapter 45 since the last draft, which increased the length of the regulation by over 70 percent. Yet DCLS still claims to have a "two-tiered" regulation which is not as burdensome as the NELAC standards. DCLS has essentially included most of the NELAC standard into the noncommercial regulation, resulting in a regulation that is represented by DCLS as not being NELAC-based but in reality is NELAC-based. Accordingly, the two tiers in the laboratory accreditation regulation no longer exist.

According to the DCLS response to comments, almost all of the commenters now support one regulation for Virginia, and advocate one regulation that is more like the February 2004 draft of 1 VAC 30-45, which would be acceptable to small and large laboratories. As the Department of Planning and Budget

suggests, simplicity in the program will enhance enforcement and compliance, there will be much more consistency in standards and performance across laboratories, the cost to laboratories (and the public) will be lower if the program is simpler, and implementation of the program will be easier and hence less expensive. DCLS states that one of its tasks “is to help laboratories understand the program and what is needed.” This task will be much simpler and cost effective if there is only one regulation for all laboratories in Virginia.

Thus, based on the fact that the dual program approach as now proposed no longer has the benefits of the two-tiered approach that VAMWA first supported, VAMWA now requests that DCLS return to a one-program system similar to the first draft of 1 VAC 30-45.

**Commenter:** MeadWestvaco

**Text:** Originally I understood there would be two different lab certification programs. One would be a NELAC-based program for commercial labs and the second would be a less stringent DCLS-based program that would apply to the noncommercial labs. It now appears that the two certification programs are NELAC-based. Recognizing the significant differences between commercial and non-commercial labs, I do not believe it is necessary or cost effective for every lab in Virginia to have to meet a NELAC certification.

**Response:**

Why the quality control requirements were added to 1 VAC 30-45.

The specific quality control requirements for specific types of laboratory analysis from Appendix D of the 2003 NELAC standards were added to Article 4, Quality System, of 1 VAC 30-45. The addition of these specific quality controls does not eliminate the differences between the 1 VAC 30-45 and 1 VAC 30-46. These additional requirements ensure that any 1 VAC 30-45 laboratory carries out the same quality control when performing the same test method as another 1 VAC 30-45 laboratory. These requirements provide a consistent standard for laboratories to meet.

These quality control requirements were added to the revised regulations as a result of a comment from DEQ that the initially proposed quality control requirements were inadequate. The pertinent text of DEQ’s comments from issue 150 above is printed below:

The essential quality control procedures given in these sections are extremely vague. By stating that written protocols for on-going QC must exist without stipulating how and with what frequency the QC must be demonstrated, the auditors’ hands will be tied. They will have to adhere to a strict interpretation of the regulation and only minimal QC can be required. For example: a lab that runs a method blank twice a year and finds no apparent contamination will have demonstrated that the negative control requirement on an on-going basis has been met for that method. The newer EPA methods require that a method blank be prepared with each preparation batch and that it undergoes the same preparation steps as the samples. For these methods this section is adequate, but for other methods it is grossly lacking.

*Methods for Chemical Analysis of Water and Wastes (MCAWW)* contains the EPA-approved inorganic chemical methods used by the majority of wastewater laboratories. It was written in 1979 and the last revisions were in 1983. Required quality control procedures in these methods are nearly non-existent. This lack of QC calls into question the quality of compliance data and is one of the reasons lab certification is needed in Virginia.

DEQ states the quality control requirements that were proposed first were quite general and insufficient to audit quality control at the laboratories covered by Chapter 45. For example, one of these general quality control requirements was to have detailed written protocols for “positive and negative controls to monitor tests such as blanks, spikes, reference toxicants.” Specific quality controls for specific types of testing were not provided.

Requiring laboratories in Chapter 45 to meet specific quality controls provides that all laboratories meet the same quality control standards for the same test methods. DCLS could require that the laboratories each meet those quality control requirements set out in the methods the laboratories perform. However that would mean that some laboratories or laboratories performing some tests would have no quality controls to perform. The consequence would be limited understanding of whether these laboratories were performing the tests accurately.

Three of the seven categories of quality control requirements that have been added to 1 VAC 30-45 pertain to most laboratories. These three are general requirements in 1 VAC 30-45-760 (three and a half pages), chemical testing requirements in 1 VAC 30-45-770 through –775 (eleven pages), and microbiology testing requirements in 1 VAC 30-45-790 through –798 (slightly less than eight pages). The other categories, toxicity testing, radiochemical testing, air testing, and asbestos testing, affect a limited number of the laboratories covered by 1 VAC 30-45.

In addition, EPA, on April 6, 2004, proposed revising 40 CFR 136 in part to eliminate old EPA test methods that do not include quality controls (69 *Fed. Reg.* 18,166-18,226 (2004)). If EPA's proposed revisions to 40 CFR 136 become final, these old methods that do not have quality control requirements will be replaced with methods that do.

#### Do These Changes Constitute a Sufficient Reason to Change from a Dual to a Single Regulation?

The specific quality control measures added to the second proposed 1 VAC 30-45 expand on the general requirements proposed initially. In making the general requirements specific, every laboratory must meet the same standards as all other laboratories under 1 VAC 30-45 performing the same testing. This change provides equity for the laboratories. The laboratories under the initial proposal would have developed quality control measures. The second proposal sets out the specific quality control measures that all the 1 VAC 30-45 laboratories must meet. These additional provisions do increase the length of the regulation but this is not a reason to eliminate 1 VAC 30-46.

The commenters cite the suggestion of the Department of Planning and Budget (DPB) to have only one program regulation. However, DPB suggested that 1 VAC 30-45 be the required regulation for all Virginia laboratories and that 1 VAC 30-46 be a voluntary program for those laboratories wanting to become NELAP-accredited. There are problems with this approach. First, this suggestion, as explained in Issues 4 through 7 above, calls for two programs. Second, this suggestion is in opposition to the agreement reached during the *ad hoc* group process that laboratories providing service to others in Virginia should meet the NELAC standards, and that all other laboratories meet a Virginia set of standards whatever these standards might be. Third, DGS-DCLS believes the correct policy if there is to be one program, is a program based on the NELAC standards. This approach, as the commenters note, was not feasible or agreeable. This is why there are two sets of standards.

#### Support for a Single Rather Than a Dual Program

Many commenters addressed this issue. Some preferred a two-tiered system. Others indicated that if DCLS chose to adopt only one tier, the standards should be the standards of Chapter 45. Others, like the present commenters stated that Chapter 45 should be the only mandatory regulation but that DCLS could choose to implement a voluntary Chapter 46 or NELAC program. Agencies have a responsibility to respond thoughtfully to public comments but they do not have a responsibility to treat comments as a vote on the changes proposed. During rulemakings, agencies try to balance the interests of the parties affected by the rulemaking with the intent and goals of the statute that forms the basis for the regulations under development. See the detailed DCLS response given under issues 4 through 7 above.

177. **Subject:** Applicability of Regulations to State University Research Laboratories

**Commenter:** Thomas J. Grizzard, Professor of Civil and Environmental Engineering, Virginia Tech, and Director, Occoquan Watershed Monitoring Laboratory

**Text:** I am writing to express my concern over the lack of an explicit identification of the status of state college and university research laboratories in the draft Virginia Environmental Laboratory Certification Regulation (1-VAC-30-45/46). These facilities are organized under their parent universities, and therefore, are sub-units of state agencies. The text of Chapter 45 states that the provisions of the chapter are applicable to local and federal government owned and/or operated laboratories. However, the same definitions found in 1-VAC-30-45-40 do not explicitly include state agency laboratories and state university laboratories. This omission seems to imply that either (1) the regulation does not apply to state laboratory facilities, or (2) state laboratory facilities are covered as “commercial” enterprises under the provisions of Chapter 46. It does not seem logical to me that the latter case could have been the intent of the draft regulation. Why would local and federal laboratories be included in Chapter 45, but state laboratories in Chapter 46?

The intent of the regulation should be made more clear. The Applicability paragraph found in (1 VAC 30-45-30) should either identify or exclude state laboratories (both agency and university) from the provisions of the regulation. If the intent of the regulation was to include state laboratories, then it is clear that they should be placed under Chapter 45.

Resolution of this apparent omission is important because a large number of state-supported university laboratories are involved in leading edge research on a variety of environmental problems of critical importance to the Commonwealth. These facilities conduct basic and applied research for the purpose of understanding and solving environmental problems and for training future generations of engineers and scientists.

Data produced by such facilities are often transmitted to the Virginia Department of Environmental Quality (DEQ) and other state agencies in a variety of ways. Generally speaking, data produced by state university research laboratories are not for the purpose of regulatory compliance reporting, but as stated above, are the results of scientific studies and investigations. Such investigations are often commissioned by federal and state agencies, but are of fundamental interest to other agencies such as the Department of Environmental Quality (DEQ).

Because of the fundamental differences in the activity and mission of most university laboratories, most of my colleagues and I have been under the assumption that the Environmental Laboratory Certification Regulation would not generally apply to academic institutions. In addition, because most university laboratories do not have traditional regulatory compliance reporting requirements, most administrators have been only vaguely aware of the regulation development. In general, this has resulted in the development of the regulation not being closely followed in the academic community. In hindsight, this might have been addressed by the inclusion of some university laboratory representatives in some of the stakeholder groups involved in the regulation development. While this might have been done, I am not aware of it.

Recently, some information has come to my attention that leads me to conclude that scientists and engineers at state academic institutions do have a fundamental interest in the progress of the regulation. One of the senior scientists on the staff of the Occoquan Watershed Monitoring Laboratory (OWML) of the Virginia Tech Civil and Environmental Engineering Department recently attended the Chesapeake Bay Program Analytical Methods and Quality Assurance Workgroup (AMQAW) meeting on 30 September, 2004. At that meeting, an employee of DEQ informed the attendees that university research laboratories conducting work for the Chesapeake Bay Program (CBP) and reporting data to DEQ will be required to comply with either Chapter 45 or 46 of the proposed Environmental Laboratory Certification Regulation, 1 VAC 30. At the same meeting, an employee of the Division of Consolidated Laboratory Services indicated that university laboratories would fall under the definitions of Commercial Environmental Laboratories in Chapter 46.

After the meeting, my staff and I have conducted a review of the draft regulations, and have concluded that there is inadequate definition of the role(s) played by state university research laboratories in providing environmental monitoring data to DEQ and other state agencies. These laboratories represent a

unique resource for the Commonwealth that is clearly necessary for solving our environmental problems, and equally clearly, not appropriately assigned to the status of “commercial” laboratories in Chapter 46.

Most of the affected laboratories at state universities in Virginia generally do not analyze environmental samples for regulatory compliance purposes, nor do they compete with commercial laboratories for routine analytical work. Such facilities are principally involved in non-routine research and development activities. From my knowledge of the water sector, representative activities would include fundamental research on physical, chemical, and biological processes in a variety of aquatic ecosystems, as well as development of prevention, mitigation, and treatment technologies to address a wide range of natural and anthropogenic impacts on water quality.

Many of these laboratories are at the forefront in the development of new analytical methods, the refinement of detection limits, and generally produce high quality data that exceeds the minimums established by regulatory programs. Research laboratories must also have the flexibility to pursue new results along unanticipated paths of inquiry. Such flexibility requires the ability to modify analyses and procedures for specialized applications, perhaps in ways that do not fit into existing regulatory definitions, but are nevertheless carried out with standard research levels of QA/QC. In fact, many analytical methods that have found their way into approved test methods under 40 CFR Part 136.3 were originally developed in exactly this way.

I might go on with this argument for many more pages, but the fundamental issue is whether research laboratories established and operated under the government of the Commonwealth of Virginia should be treated in the regulations as commercial enterprises under the regulations of 1-VAC-30-46. A basic aspect of the mission(s) of these laboratories and their parent agencies is that they have been established for the expressed purpose of pursuing research in support of the public good. It seems to me that a disservice is done to them and their many dedicated employees to imply that they are commercial enterprises like any other.

**Response:** There are three issues presented by this commenter. First, are state college and university research laboratories covered by the regulations in 1 VAC 30-45 and 1 VAC 30-46? The environmental laboratory certification statute says that “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.*)” must be certified under the program being developed. Section 2.2-1105 A of the *Code of Virginia*. The statute further says at subsection B: “Once the certification program has been established, laboratory certification shall be required before any tests, analyses, measurements or monitoring performed by a laboratory after the effective date of such program may be used for the purposes of” the air, waste or water laws of Virginia. The regulation lays out the scope of the program in more detail. 1 VAC 30-45 applies to owners of noncommercial laboratories and 1 VAC 30-46 applies to owners of commercial laboratories. A noncommercial laboratory generally is one that performs environmental analysis solely for the owner of the laboratory. A commercial laboratory is one where environmental analysis is performed for another person. A person is a legal term defined in the regulation as “an individual, corporation, partnership, association, company, business, trust, joint venture or other legal entity.” The definition of noncommercial laboratory contains a list where performing analysis for another person would be considered noncommercial. The definition of environmental analysis sets out what kind of environmental analysis the program will cover and what kind it will not. DCLS has proposed eliminating sampling, field testing and measurement, and taxonomic identification of samples. The definition of environmental analysis also includes an explanation of the phrase “used for the purposes of” which appears in the statute at Section 2.2-1105 B (see above). This explanation is as follows: “For the purposes of these regulations, any test, analysis, measurement, or monitoring required pursuant to the regulations promulgated under these three laws, or by any permit or order issued under the authority of any of these laws or regulations is ‘used for the purposes’ of these laws.”

If a state university research laboratory performs environmental analysis that is required to be submitted under Virginia’s environmental laws or regulations or used to make decisions under those regulations or

laws, this laboratory must be certified under the program before it can submit data to the Department of Environmental Quality.

Second, is the research that state college and university laboratories conduct covered by the program? If the data obtained from the research is not required to be reported or is not used to make a decision by DEQ, then the laboratory carrying out the research does not need to be certified. The research that state college and university laboratories perform is beneficial to Virginia. It is understood that these laboratories generally develop their own quality assurance and quality control procedures for such research. The key in this instance is how the data obtained from the research will be used.

Third, if a state-owned college or university laboratory was performing environmental analysis that is required to be reported or is used to made a decision by DEQ, would this laboratory be a noncommercial or a commercial laboratory? If DEQ or another state agency hired the laboratory, then DCLS would interpret its status as noncommercial because the State of Virginia owns both the laboratory and the agency. If a private individual or company hired the laboratory to perform the analysis and the data is provided to DEQ, then DCLS would interpret the laboratory's status as being commercial.

178. **Subject:** Soil Testing at Virginia Tech

**Commenter:** Department of Crop & Soil Environmental Sciences and the Virginia Tech Soil Testing Laboratory

**Text:** With this letter we are providing written comments regarding the *Draft Proposed Regulations 1 VAC 30-45 (Certification for Noncommercial Environmental Laboratories)* and *1 VAC 30-46 (Certification for Commercial Environmental Laboratories)* that were recently published in the *Virginia Register of Regulations* (Vol. 21, Issue 1, Sept. 20, 2004). . In the following we are providing some follow-up comments regarding DEQ's response to the written comments submitted in April 2004 by the Virginia Tech Soil Testing Laboratory and the Virginia Tech Department of Crop and Soil Environmental Sciences.

1. Contrary to DEQ assertion in the face of evidence to the contrary, the Virginia Tech soil testing lab does not receive any money from DCR to conduct routine soil testing and nutrient recommendations. DEQ is confused, and must be referring to funds DCR provides for out-of-state analyses of manure and plant tissue, which we do not conduct in our laboratory. We receive no funds from commercial producers and currently have no means of generating funds from commercial producers to provide testing or nutrient recommendations.
2. NELAC, for all its good features in water testing, does not at any point in the documentation address routine soil testing nor the appropriate standards required for this type of testing. We laid this evidence out very clearly for DEQ in our previous comments. As far as we are aware, NELAC has never been implemented, proven effective, tested, or even proposed as a suitable certification standard for routine soil testing. One NELAC certified lab of which we are aware does not attempt to apply this protocol for its soil testing operations, for obvious scientifically valid reasons. Instead of considering the scientific evidence, DEQ has chosen to simply ignore the facts and recommend a "one size fits all" system. We ask again: Is NELAC an appropriate tool for routine soil testing. Our answer remains - NO. DEQ has not responded in good faith to our concerns.
3. In spite of DEQ's opinion, we maintain that we are under no obligation to provide any data to DEQ or DCR. Our clientele is the person submitting a soil sample, and our mission is to provide the best available recommendation on nutrient applications within suitable agronomic limitations. What that clientele chooses to do with that recommendation, or claims the recommendations may represent, is beyond our control.

**Response:** See Issue 14 above for the referenced discussion on soil testing. The following are in response to the three paragraphs of comments above.

1. DCLS regrets its misunderstanding about the funds provided by DCR for some soil testing. DCLS was under the impression that the soils laboratory at Virginia Tech was the recipient of some of these funds.

2. The NELAC standards apply not just to water but to air and waste methods as well. However if the quality controls and quality assurance requirements of the NELAC standards are inappropriate for the testing of soils Virginia Tech does, Virginia Tech and DCLS may work together to devise an appropriate set of criteria. To do so, the regulations provide that a lab may apply for a variance (see 1 VAC 30-45-140 and 1 VAC 30-46-160).

3. Virginia Tech is correct that it is under no obligation to provide any data to DEQ or DCR. Virginia Tech is also correct that its clientele is the person submitting the soil sample. However, the farmers or other persons who are submitting the data they receive from Virginia Tech are doing so because they are required to submit the data. Therefore, these clients must get their analyses done at a laboratory that has been certified under 1 VAC 30-45 or 1 VAC 30-46 once the environmental laboratory certification program is established (within three years of the effective date of the regulations). Virginia Tech will have to decide whether it wishes to continue providing the analysis of soil it does if that analysis is to be reported to DEQ under 9 VAC 25-191, 9 VAC 25-192 or 9 VAC 25-630.

179. **Subject:** Certification of Taxonomic Identification and Enumeration of Biological Organisms

**Commenter:** Frederick Hoffman, DEQ

**Text:** I have the following comments regarding the DCLS lab certification program.

It is unclear whether taxonomic identification and enumeration of biological organisms is going to be part of the program. Of particular interest to DEQ is planktonic organisms and benthic macroinvertebrates used by several DEQ environmental testing programs. Some taxonomic enumeration and identification is clearly included (i.e. bacteriology) and no "environmental test, analyses, measurement or monitoring" is clearly excluded except field sampling procedures and field analyses (ch 46 pg. 4). In fact the inclusion of "Benthic Assessment" as a test category (chapter 46, page 35) suggests the possibility of benthic community taxonomy and enumeration is to be part of the program.

If it is not the intent to include anything except bacteriology test as part of this program at this time then I suggest:

1) Add language that specifically excludes taxonomic identification and enumeration of biological organisms (with the exception of bacteriological) and/or

2) Delete the test category of "Benthic Assessment", or at least add clarifying language as to what this means. It is unclear what the test category of "benthic assessment" means since the definition given for the word assessment is: "'Assessment" means the evaluation process used to measure or establish the performance, effectiveness, and conformance of an organization and its systems or both to defined criteria." (chapter 46, pg 3).

I look forward to some clarification of the intent in regards to biological taxonomy and enumeration.

**Commenter:** Daniel M. Dauer, Old Dominion University [these comments were originally sent to F. Hoffman, DEQ, and then passed on to DCLS]

**Text:** Obviously further clarification is necessary before even beginning to assess the attached documents [the proposed regulations]. There are two primary problems: (1) the definition of a commercial or noncommercial laboratory and (2) the application of these documents to organismal labs.

Definition of Commercial Environmental Laboratory

It is clear to me that the ODU labs do not fall under any of the listed types of noncommercial laboratory. The commercial laboratory definition might apply by the following tortuous application of the definitions in the documents.

“Commercial environmental laboratory” means an environmental laboratory where environmental analysis is performed for another person.”

“Person” means an individual, corporation, partnership, association, company, business, trust, joint venture or other legal entity.”

“Legal entity” means an entity, other than a natural person, who has sufficient existence in legal contemplation that it can function legally, be sued or sue and make decisions through agents as in the case of corporations.”

I guess that the “legal entity” (a.k.a. “person”) is VA DEQ. However, if ODU is a state institution and VADEQ is a state institution analyses are NOT being performed for another person. In addition, our labs are not consistent with commonly accepted definitions and uses of the term commercial - “Of, relating to, or being goods, often unrefined, produced and distributed in large quantities for use by industry. Having profit as a chief aim.”

Application to biological labs

For the biological labs my best guess is that by the greatest stretch of the imagination that less than 5% of this document can be construed as having any application to the analyses performed in organismal type labs. For example the primary function of the biological programs’ laboratory analysis is the accurate taxonomic identification of collected organisms. The word taxonomy, or any variant of it, does not appear in any of the documents. The word identification, as applied to taxonomy, is also not used. How can we possibly comply with a document that has no obvious application to our programs?

Necessary Further Clarification

Assuming that we must proceed with compliance with this document what is essential before any further efforts are taken is accomplishing two tasks. (1) A person knowledgeable of the origin and intent of the document and who also understands plankton and benthic monitoring programs must go through this document and delete all sections that irrelevant to biological labs. (2) For the undeleted sections, modify the text and procedures so there is an obvious and direct application to our procedures that we can understand.

**Response:** See issue 193 and related issues 190 and 202 below. DCLS has decided not to include taxonomic identification of samples in its laboratory certification program. The reason for this decision lies in the approach taken by other states on this type of analysis. DCLS gives Florida as the example. Florida has a program for taxonomic identification of benthic organisms. Florida is also a NELAP accrediting authority. Florida does not include taxonomic identification of benthic organisms in its NELAC program; its taxonomic identification efforts are carried out separately. While Florida and several other coastal states have programs for taxonomic identification, these programs vary considerably in their methods, equipment, and quality assurance and quality control. The states bordering the Chesapeake Bay approach benthic assessment differently. Furthermore, there has been no effort made by those performing these assessments to establish a national approach to taxonomic identification of benthic samples. Therefore, DCLS concluded that there are no readily agreed-upon standards to certify laboratories for benthic assessment.

180. **Subject:** Citizen monitoring groups

**Commenter:** Friends of the Powhatan Creek Watershed

**Text:** The Friends of the Powhatan Creek Watershed is a non-profit, 501(c)(3) organization formed in 1999 by interested citizens to promote stewardship of natural resources in the Powhatan Creek Watershed in James City County. Since forming, FOPCW has managed a volunteer-based water quality monitoring program within the Watershed. As part of this effort, the FOPCW maintains a small laboratory for off-site water sample analysis.

While the FOPCW welcomes the additional technical assistance that an accreditation process could provide, as a small, voluntary organization, FOPCW has neither the resources for the proposed fees nor the need for accreditation. A commercial laboratory has the ability to pass the cost of accreditation on to customers, since accreditation has value to commercial customers. However, under the proposed regulations, most local government, college, university and volunteer organization facilities would bear the substantial cost themselves with little real benefit.

This proposed regulation adds an additional layer of cost for volunteer water quality monitoring organizations. Volunteer organizations must already develop and implement quality assurance plans in order for data to be used in the Department of Environmental Quality water quality assessments. Laboratory procedures are included in these plans.

We urge the Division of Consolidated Laboratory Services to exempt non-profit, volunteer water quality monitoring organizations from this regulation or greatly reduce the biennial fees to less than \$200.

**Commenter:** Charles Newton (Stanley, VA): Friends of the Shenandoah River (FOSR)

**Text:** Please accept these comments on the proposed adoption of National Environmental Laboratory Accreditation Conference (NELAC) standards for all environmental laboratories that do business in Virginia.

Please amend Chapter 45 of the proposal to allow that fees be waived for non-profit water monitoring organizations.

The Friends of the Shenandoah River (FOSR) have just completed VA-DEQ certification of our laboratory for the following water quality tests: ammonia, nitrogen, phosphorus, turbidity, pH, dissolved oxygen and temperature. The VA-DEQ and VA-DCR are going to need to rely on the quality water data produced by our laboratory for the measuring the effectiveness of Virginia Tributary Strategies and Total Maximum Daily Load Implementation Plans. The proposed fees would make it very difficult for the Friends of the Shenandoah River to afford to maintain the laboratory accreditation. I believe the FOSR would have no trouble meeting the NELAC standards for producing quality data on water quality throughout the 3,000 square mile Shenandoah River Watershed.

Please find some way to avoid having to charge non-profit organizations like the FOSR large fees to get their laboratories accredited.

**Commenter:** Meryl Christiansen, Executive Vice President: Friends of the Shenandoah River (FOSR)

**Text:** The Friends of the Shenandoah River (FOSR) has conducted a water quality monitoring program for over a decade. Samples are collected at two week intervals by a cadre of over seventy-five volunteers at over 150 sites throughout the seven counties of the watershed. The samples are tested for D.O., pH, turbidity, ammonia, nitrite-nitrate, orthophosphate, and coliform. The data bank spans over ten years for the entire watershed and is available on the FOSR website.

Several years past our QA/QC protocols were reviewed and approved by U.S. EPA and the Commonwealth Department of Conservation and Recreation. Very recently the Department of Environmental Quality reviewed the FOSR program, including refereed samples, and approved the data for DEQ use in their 305d report to Congress and EPA. The data will be useful for DCR for Tributary Strategy and TMDL work.

FOSR data is used by local soil and water conservation units, both USDA and Commonwealth to guide expenditure of agricultural best management practice funding. The U.S. Geologic Service is using FOSR data in a minimum in-stream flow study. James Madison University is utilizing the water quality data and GPS overlay to relate land use, industry, weather, etc., impact on water quality. The information is presented on their Water Window Web Site. FOSR does not want data to be used for governmental enforcement but only to identify sources of pollution for verification by government agencies.

Thus, it follows that FOSR strongly supports a Commonwealth laboratory certification program. Such action will validate all manner of laboratory data. However we do think that the fee schedule should be lower or non-existent for citizen groups. For example, an Assemblyman remarked that the FOSR monitoring program would cost the Commonwealth five million dollars annually to duplicate. Please go easy on citizen groups. Grant funds are difficult to find!

**Commenter:** David Buckalew, Longwood University

**Text:** I have assayed streamwater samples for fecal coliforms and strep for the past 5 years as a microbiologist, prof, and research mentor at Longwood University. Much of the work began with grant monies received obtained with Katie Register, Director of Clean VA Waterways here on our campus. I/we have monthly bacterial data on ~ 24 different sampling locations for most of this period. Since last summer, I have been working through the details of a QA/QC plan for bacterial assessment for DEQ consideration and use. In the last 6 months, I have solidified a QA/QC or SOP plan for using Colilert defined substrate analyses pursuant to the same goal - to have our data accepted by VA DEQ for their use.

I am contacting the folks at DEQ to hear what they think, but do you feel this new proposal will affect this activity? I/we certainly cannot afford the proposed fee for a registered lab - nor could we afford to send our water samples to DCLS for bacterial screening.

Hopefully, this proposal will not receive much support as it threatens to take citizen volunteer groups out of the picture.....is this proposal something state agencies want to support? It appears to me to be a regressive plan and counterproductive to environmental advocacy.

In the long run, I don't think any bit of legislation will turn away those truly interested in environmental surveillance and protection, but I cannot see how this will stimulate positive relations between citizens' groups and the various state regulatory agencies (e.g., VA DEQ, VDH, etc).

**Commenter:** Alliance for the Chesapeake Bay: Kent Mountford, Cove Corporation

**Text:** I have been a volunteer water quality monitor for the Alliance for Chesapeake Bay since 1985, and have maintained a water quality monitoring data base on my own since 1975, just about 30 years of my forty-year career as an estuarine ecologist.

While Senior Scientist with the US-EPA Chesapeake Bay Program (until 2000), I was one of the founders of the current Chesapeake -wide volunteer monitoring network and a contributor to and Federal Agency funder for the underlying quality assurance program which continues for this data base today.

I am fully aware of and strongly support good quality assurance and clear data objectives for water quality monitoring in the Commonwealth of Virginia, but it is vital NOT to impose unrealistic or costly additional requirements on volunteer programs designed to involve citizens in the work for an improved Bay and tributaries. They should be excluded from fees or difficult certification.

As a former full-time Environmental Scientist and Quality Assurance Officer for the District of Columbia (1980-84) I am painfully aware of the difficulties in ensuring that money invested by Government results in data collections meeting the required data objectives. Support by DCLS for volunteer monitoring efforts

and help in assuring adequate data is most important, rather than imposition of costs or irritating requirements atop the already difficult task of getting people involved in bettering their environment.

Thank you for helping assure the continuation and encouragement of volunteer monitoring in this region.

**Commenter:** Stacey F. Moulds, Senior Program Coordinator: Alliance for the Chesapeake Bay

**Text:** Based on our interpretation, the proposed regulation has the possibility of detrimentally affecting any citizen group that collects samples to be analyzed offsite (i.e. not for field measured parameters such as DO, pH, temperature, salinity and water clarity). In talking with the Department of Environmental Quality, it appears that biological identification for items such as plants, fish, and macroinvertebrates will be exempted because there are no national standards for these parameters by NELAC.

The Alliance for the Chesapeake Bay proposes that the fee for certification be waived or greatly reduced for citizen groups that are performing lab analyses as a volunteer-type activity but are submitting their results to a State agency.

Secondly, it is our opinion that this certification requirement is repetitive and unnecessarily demanding for citizen groups to have to go through further certification by DCLS for lab accreditation who have already received approval for their quality assurance measures as required by the DEQ.

Thirdly, the regulation should exempt biological identification for items such as macroinvertebrates, fish, algae and other plants from certification by DCLS.

**Commenter:** Stacey T. Brown: Virginia Save Our Streams

**Text:** Comments on 1 VAC 30 Chapter 45 Certification for Noncommercial Environmental Laboratories

1. There are several citizen groups in Virginia that utilize their own lab for analysis of water quality samples from streams (for general information purposes). The Department of Environmental Quality will use this data for their water quality assessments in accordance with the Federal 305(b) program provided that the citizen group collects and uses laboratory measures that comply with a quality assurance plan. The fee structure as outlined in this chapter will be cost prohibitive for these citizen groups to obtain certification for their small labs. In addition, requiring citizen groups to obtain certification as outlined in 1 VAC 30 Chapter 45 AND comply with the Virginia Department of Environmental Quality's requirement for a quality assurance program plan is duplicative in nature and overly burdensome on citizen groups. As such, citizen organizations with their own labs for analyzing general water quality data should either be exempt from this regulation (preferable) or be exempt from the fees associated with obtaining certification.

2. Biological measures such as benthic macroinvertebrate monitoring, fish tissue, algae assays, etc where there are no NELAC standards should also be exempt from this regulation.

**Commenter:** John Murphy: StreamWatch

**Text:** Although I have not read the proposed regulation, it is my understanding that citizen environmental monitoring groups may be required to obtain laboratory certification in order for their data to be incorporated into DEQ assessments. Lab certification could put citizen groups "out of business." Is this desirable to you?

Monitoring groups like Virginia Save Our Streams are required to have EPA quality-assurance plans. This is sufficient, given the mission of citizen organizations, which is to help provide wider monitoring coverage, alert the "professionals" to potential problems, and provide data to *help* move the assessment process forward.

**Response:** See issue 179 for a discussion of certification for taxonomic identification of samples. There are two other issues raised by these commenters. First, there is concern that a citizen monitoring group laboratory would have to establish a quality assurance/quality control plan and have it approved by DEQ as well as meet the environmental laboratory certification program standards. Any laboratory meeting the environmental laboratory certification program standards would only have to meet those standards. DEQ is having these laboratories develop and adhere to QA/QC plans to ensure that their analyses are done consistently and accurately. The environmental laboratory certification program's purpose is the same. Neither DCLS nor DEQ would desire or find such duplicative efforts appropriate. Second, the commenters are concerned about the cost of fees and ask that their fees be limited. DCLS understands that seven laboratories run by citizen monitoring groups are providing data to DEQ at this time. Of these seven laboratories, four analyze samples for *E. coli*. Their fee, assessed every other year (biennially), would be \$475 under the proposed program. Three other laboratories perform various inorganic and organic tests. The fees for these laboratories are either \$2075 or \$3050, again due every other year. While DCLS understands that funds are especially scarce for these volunteer laboratories, it would be inequitable to ask the other laboratories covered by the program to pay while these three laboratories pay considerably less. No change has been made to the regulation based on these comments.

181. **Subject:** Accrediting Authority (AA)

**Commenter:** Augusta County Service Authority, Hampton Roads Sanitation District, Hanover County Department of Public Utilities, LPC, and VAMWA.

**Text:** The following text is either identical to or closely representative of the comments on this issue.

In response to comments, DCLS states it will become a NELAC AA before the VELAP program goes into effect, and acknowledges they may have problems with their initial application, but offers no course of action if they are unable to meet the requirements of an AA in a timely manner.

DCLS has not included any language in the regulation to address what happens to commercial laboratories or those that chose to meet NELAC standards if DCLS does not achieve NELAC AA status, if it loses NELAC AA status, or NELAC ceases to exist. If commercial laboratories lose their primary AA, they are no longer accredited under NELAC and therefore do not meet the regulation. The regulation does not even address the fact that it is highly probable that DCLS will be holding laboratories to NELAC standards long before they meet the standards themselves; this should be a requirement in the regulation. Finally, DCLS has no intention of refunding fees if they fail to attain AA status or lose AA status, even though laboratories are paying for that accreditation. VAMWA recommends that language be inserted that defaults such laboratories to a requirement to meet the Chapter 45 regulation if DCLS does not achieve AA status within one year of the effective date of the regulation or immediately if it either fails to maintain AA status or the NELAP dissolves.

**Response:** A representative of the NELAP review team gave DCLS a current review time of three to six months to review an application from a state applying to be a NELAP accrediting authority. DCLS will submit its application prior to the effective date for the program's regulations. DCLS has three years in which to become approved as an accrediting authority. During that time, DCLS will also be reviewed to ensure that it meets the NELAC standards. DCLS believes this time is adequate to attain NELAP accrediting status. Part of the NELAP review is an audit of the on-site assessment of a laboratory. The commenters assume failure on the part of DCLS and on the part of NELAC. There is no reason to assume failure and to build that assumption into the regulation. If failure occurs, there are legal and regulatory mechanisms that DCLS can use to take care of the laboratories covered by 1 VAC 30-46. No change has been made to the regulation based on this comment.

182. **Subject:** Commercial vs. Non-Commercial

**Commenter:** Augusta County Service Authority, Hampton Roads Sanitation District, Hanover County Department of Public Utilities, LPC, and VAMWA.

**Text:** The following text is either identical to or closely representative of the comments on this issue.

DCLS essentially ignored the comment requesting that the regulation be modified to recognize local government laboratories that perform analyses for other local governments, on a non-profit, cost reimbursement basis when those analyses pertain to the purpose for which the authority was created, as noncommercial laboratories. Although such laboratories may conduct analyses for entities outside of their authority's borders, the current regulation does not recognize these laboratories as noncommercial. The definition of commercial laboratories is inadequate without addressing this scenario.

**Response:** See issue 27 above for the discussion on this issue. DCLS believes the response to this issue as previously raised is appropriate.

183. **Subject:** Standards of quality

**Commenter:** Augusta County Service Authority, Hampton Roads Sanitation District, Hanover County Department of Public Utilities, LPC, and VAMWA.

**Text:** The following text is either identical to or closely representative of the comments on this issue.

VAMWA reiterates that this regulation does not set "minimum standards of quality" as intended by the JLARC report and will not provide data of a "high" standard. Even DCLS states in its response to comments that the "regulation cannot ensure quality." Standards of quality are established through DQIs (data quality indicators) and MQOs (measurement quality objectives). See EPA DQO guidance documents. These data qualifiers are absent from the regulation and therefore standards of quality have not been set through this regulation.

**Response:** The statute governing the environmental laboratory certification program (§2.2-1105) states the purpose of the program: "to ensure that laboratories provide accurate and consistent tests, analyses, measurements and monitoring so that the goals and requirements of" the air, waste and water laws of Virginia "may be met." The General Assembly set up the certification program to accomplish this goal. The certification program was by statute to include minimum criteria for laboratories performing environmental analyses in, for example, laboratory procedures, analytical quality control and quality assurance, supervisory and personnel requirements, and performance evaluations. The General Assembly believes that by certifying or accrediting laboratories to the standards set out in the program, the data provided by these laboratories may be of a consistent and accurate quality.

184. **Subject:** Costs of the program

**Commenter:** Augusta County Service Authority, Hampton Roads Sanitation District, Hanover County Department of Public Utilities, LPC, UOSA, and VAMWA.

**Text:** The following text is either identical to or closely representative of the comments on this issue.

The economic impact of the program has not been assessed adequately in light of (over 30%) increase in certification fees and increases in the internal compliance costs, due to increased QC requirements in Chapter 45. Those costs would most seriously affect smaller laboratories. VAMWA believes that in light of the substantial changes to the proposed regulations, the Virginia Department of Planning and Budget should conduct an additional review of these proposed regulations.

**Response:** The base fees for 1 VAC 30-45 laboratories did not change in the second proposal. The maximum fees and the test category fees did change. The maximum fees for simple test procedure laboratories were increased from \$400 to \$600, an increase of 50%. The maximum fees for general environmental laboratories were increased from \$3800 to \$5200, an increase of 36.8%. The test category fees were increased and the percentage increases vary as well as the numeric increases. It is

important to remember that these fees are paid every two years. Simple test procedure laboratories that pay the maximum fee must budget for \$300 per year.

Small or large, the increase in fees for 1 VAC 30-45 general environmental laboratories is the increase in the test category fees. The maximum fees will affect very few laboratories. For a typical general environmental laboratory, the fee should be \$2825; the initial proposed fee was \$2600 (a percentage increase of 8.65%). This includes the base fee of \$1700, a fee of \$375 for BOD, a fee of \$375 for physical tests (the tests for solids), and a fee of \$375 for fewer than 4 inorganic test methods (ammonia). There are approximately 300 VPDES permittees that report on bacteriological testing (an additional \$375). This would increase the two-year fee to \$3200. As initially proposed, the fee was \$2900. The percentage increase is 10.34%.

See issue 168 above on the changes to the fees made in the second proposal. In addition, the structure of certification changed from program, method and analyte to matrix, technology/method and analyte/analyte group. DCLS modified the test category for chemistry metals to account for the structural change. The change to chemistry metals was to revise the category of "chemistry metals, fewer than four methods" to "chemistry metals, one-two methods" and "chemistry metals, four or more methods" to "chemistry metals, more than two methods." There are six technologies common to metals methods. Typically wastewater treatment plants perform a maximum of two of these technologies/methods.

DCLS submitted the proposal package to DPB in the fall of 2002 for review. The proposal package was not approved to go out to public comment until late December 2003. No changes to the proposed regulations could be made until after the Feb. 9 – Apr. 9, 2004, public comment period. Because there had been this two-year hiatus, DCLS decided to review and update the program cost estimates. The result of the review showed increases in the estimates of both labor and non-labor costs and the need to increase the fees. Along with the comments received from small commercial laboratories, the approach to charging fees was reviewed and the modifications made that were proposed in the second round.

It is important to remember that once these regulations become final, the fees cannot be changed unless DCLS proposes the changes in a rulemaking. The base fees as proposed are estimated to pay for 48% of the program costs every two years. The test category fees will need to make up 52% of the program costs.

The next step in the rulemaking process is a second review by DPB.

185. **Subject:** Cost of database

**Commenter:** Augusta County Service Authority, Hampton Roads Sanitation District, Hanover County Department of Public Utilities, LPC, and VAMWA.

**Text:** The following text is either identical to or closely representative of the comments on this issue.

DCLS acknowledges that a database to track certification/accreditation does not exist and that they will have to do this to implement the regulation. However, the cost of this effort has not been addressed in the cost of the program or the fees to be charged to laboratories. EPA spent well over a million dollars to establish a database, and the State of New York spent \$750,000 on their database that is not more complicated than the one required by Virginia. After the database is established, it must then be maintained. The average fee for lab accreditation/certification rose by over 30% since the last draft of this regulation, and it still does not address all costs associated with the program. We are concerned that the cost of the program appears not to be adequately presented.

**Commenter:** UOSA

**Text:** We are uncertain that DCLS has accounted for the cost of developing and maintaining a certification database. It is critical to fully assess the cost of certification as early as possible in the

process for laboratories to plan for them as accurately as possible. An assessment of cost and benefits of a single versus a dual certification standard is also critical to steer this program in the right direction.

**Response:** The commenters assume that DCLS plans to create a rather complex database. DCLS will need to develop a database from available software such as Microsoft Access. In general, the cost of the program is derived from the cost of hiring and employing twelve staff members for the various activities of the program. The cost of the program includes both labor and non-labor components to the extent that DCLS can preplan the program activities. See issue 184 above on the increase in fees.

186. **Subject:** Program applicability

**Commenter:** Augusta County Service Authority, Hampton Roads Sanitation District, Hanover County Department of Public Utilities, LPC, UOSA, and VAMWA.

**Text:** The following text is either identical to or closely representative of the comments on this issue.

Based on the DCLS response to comments, VAMWA is of the understanding that any laboratory that generates data used to support regulations must meet these regulations. VAMWA strongly supports this position. If this understanding is incorrect, DCLS must make changes to the regulation ensuring that all laboratories providing data to support activities in support of the referenced federal regulations must meet the proposed Virginia regulations in the same manner as any commercial or government laboratory.

**Response:** Any laboratory that generates data used to support regulations must meet the requirements of 1 VAC 30-45 or 1 VAC 30-46. The governing statute, §2.2-1105, at subsection B states that “once the certification program has been established, laboratory certification shall be required before any tests, analyses, measurements or monitoring performed by a laboratory may be used for the purposes of Chapter 13 (§10.1-1300 et seq.) of Title 10.1, the Virginia Waste Management Act, and the State Water Control Board.” The definition of “environmental analysis,” found in both 1 VAC 30-45 and 1 VAC 30-46, elaborates on the meaning of the phrase “used for the purposes of.” This phrase means “any test, analysis, measurement, or monitoring required pursuant to the regulations promulgated under these three laws, or by any permit or order issued under the authority of any of these laws or regulations.” There are exceptions listed to the definition of “environmental analysis.” These exceptions of course would not be considered environmental analysis for the purposes of 1 VAC 30-45 or 1 VAC 30-46.

187. **Subject:** Assessor training

**Commenter:** Augusta County Service Authority, Hanover County Department of Public Utilities, and VAMWA

**Text:** DCLS indicates in their comment that assessors will be trained as required by the NELAC 2003 standards and that this will be adequate for inspecting labs applying for certification under 1 VAC 45. This is not sufficient because inspectors need to have documented training proving that they fully understand the differences between the two programs. If only trained to understand the requirements under 1 VAC 46, inspectors may impose additional requirements on labs applying for certification under 1 VAC 45.

**Commenter:** UOSA

**Text:** In the response to comments, DCLS states that it will meet all NELAC requirements for Assessor training for both Chapters 45 and 46, as specified in NELAC Chapter 4, but makes no references of the technical training requirements outlined in the appendices. We believe that in the response to this second round of comments the appendices should also be referenced.

We would like to express concern on the lack of specificity of both Chapters 45 and 46 in the requirement that assessors be proficient in identifying the differences between Chapter 45 and Chapter 46

assessments. If assessors do not understand the differences between these two chapters, there is the potential for assessors to impose Chapter 46 elements for laboratories certified by Chapter 45. Note that establishing a single certification program for all laboratories in Virginia will eliminate this type of complication in the training of assessors. We again recommend the use of a single certification program for all Virginia laboratories based on the first draft of Chapter 45.

**Response:** DCLS agrees that the training for on-site assessors needs to include full understanding of the differences between the standards in 1 VAC 30-45 and 1 VAC 30-46. With regard to the technical training requirements outlined in the appendices to Chapter 3 of the 2003 NELAC standards, DCLS has incorporated these requirements by reference into 1 VAC 30-46 (see 1 VAC 30-46-210 B). No change has been made to the regulation based on these comments.

188. **Subject:** Clear and concise regulation

**Commenter:** UOSA

**Text:** We continue to urge the Division of Consolidated Laboratory Services (DCLS) to streamline the rules by removing redundant sections and language. A streamlined rule will reduce misinterpretation of the requirements by assessors and laboratory personnel alike, and help laboratories in the proper implementation of the rule.

**Response:** DCLS has endeavored to make the regulation clear and concise. What may seem to be streamlining to others may not be to DCLS. No change has been made to the regulation based on this comment.

189. **Subject:** Technical Advisory Committee

**Commenter:** UOSA

**Text:** DCLS response to the comments on the first draft regulations states that it would be acceptable to call for an “ad hoc voluntary committee” to act on an “as needed” basis, but cites cost constraints as a hurdle for establishing a Technical Advisory Committee. We recommend that the language in the regulation be modified to include a voluntary standing committee instead of an ad hoc voluntary committee.

**Commenter:** Augusta County Service Authority, Hanover County Department of Public Utilities, and VAMWA

**Text:** The appeals process does not make mention of a TAC, which has been requested through previous comments. A technical advisory committee is necessary to provide assistance on technical issues and should serve to minimize the need to employ the appeals process by having the committee recommend appropriate measures.

**Response:** The appeals process is governed by Virginia’s *Administrative Process Act*. See the response to issue 9 above. No change has been made to the regulation based on this comment.

### **SPECIFIC COMMENTS: 1 VAC 30, CHAPTER 45**

#### **Definitions (1 VAC 30-45-40)**

190. **Subject:** Additional definitions [also 1 VAC 30-46-40]

**Commenter:** DEQ

**Text:** The following terms should be added to the definitions in this section:

Algae - Simple single-celled, colonial, or multi-celled, mostly aquatic plants, containing chlorophyll and lacking roots, stems and leaves that are either suspended in water (phytoplankton) or attached to rocks and other substrates (periphyton).

Benthic Macroinvertebrates - bottom dwelling animals without backbones that live at least part of their life cycles within or upon available substrates within a body of water.

Macrophytes - any aquatic or terrestrial plant species that can be identified and observed with the eye, unaided by magnification.

Zooplankton - Microscopic animals that float freely with voluntary movement in a body of water.

**Response:** These definitions are pertinent to issue 193 below. These definitions have been added to 1 VAC 30-45-40.

191. **Subject:** Definitions for “annual” and “quarterly”

**Commenter:** Augusta County Service Authority, Hanover County Department of Public Utilities, UOSA, and VAMWA

**Text:** Since there are many requirements in the regulation tied to a quarterly and annual frequency add definitions for these two terms. Recommend “annual” means “occurring or happening once in a calendar year or a specifically defined 12-month period” and “quarterly” means “occurring once in a specifically defined three-month period, such as January through March, April through June, July through September, and October through December.”

**Response:** The terms “annual” and “quarterly” are common terms that are defined in standard dictionaries. Language has been added to 1 VAC 30-45-40 and 1 VAC 30-46-40 stating that terms not defined in these sections on definitions have the “meaning commonly ascribed to them by recognized authorities,” for example, standard dictionaries. DGS-DCLS has added this additional language to prevent confusion over the meaning of specific terms.

192. **Subject:** Definition of “aliquot”

**Commenter:** Augusta County Service Authority, Hanover County Department of Public Utilities, and VAMWA

**Text:** The modified definition that includes the word “measured” may give the impression that the quantity of the subsample must be known exactly, which is not the case.

Recommend changing the definition to one of the following:

“A subsample of a material or chemical substance that is analyzed in order to determine its properties.”  
Oxford English Dictionary: “a portion of a larger whole, especially a sample taken for chemical analysis or other treatment.”

**Response:** The definition of “aliquot” has been modified to remove the term “measured.” It now reads as follows: “Aliquot” means a portion of a sample taken for analysis. This change is equivalent to those suggested by the commenter.

193. **Subject:** Definition of “environmental analysis” [also 1 VAC 30-46-40]

**Commenter:** Augusta County Service Authority, Hanover County Department of Public Utilities, and VAMWA

**Text:** "Tissue" must be added to the list of media in (1) and (2), same for Chapter 46.

**Commenter:** DEQ

**Text:** "Environmental analysis...The term shall not include the following:

Sampling of ~~air~~, water, **solid and chemical materials**, ~~soil, sediments~~, **tissue**, or ~~waste~~-air and emissions-

Field testing and measurement of ~~air~~, water, **solid and chemical materials**, ~~soil, sediments~~, **tissue**, or ~~waste~~ air and emissions, except when performed..."

**Taxonomic identification of samples for which there is no national accreditation standard such as algae, benthic macroinvertebrates, macrophytes, vertebrates and zooplankton.**

Use of the field of certification matrices provides consistency and helps to ensure that all sampling and field testing are excluded from this definition.

Addition of item #3 (taxonomic identification) eliminates an analytical/measurement segment for which a national accreditation standard does not exist. This is the same rationale that was used to eliminate sampling and field testing and measurement. Once national accreditation standards are developed for these items, they should be included in the certification program.

**Response:** DCLS has made the suggested changes to the definition of "environmental analysis."

Changing "air, water, soil, sediments, or waste" to "water, solid and chemical materials, biological tissue, or air and emissions" ensures consistency with the definition of the term "matrix."

Taxonomic identification of samples is not included in any other environmental certification program as far as DGS-DCLS understands. There is no national standard for such identification although quality assurance and quality control standards exist. However there is no agreement nationally on these standards. Until such agreement exists, DGS-DCLS will not include this type of testing in its certification program.

For related matters, see issues 190 and 202.

194. **Subject:** Definition of "non-aqueous liquid" and "solids," subcategories of quality system matrix within the definition of "matrix"

**Commenter:** Augusta County Service Authority, Hanover County Department of Public Utilities, UOSA, and VAMWA

**Text:** The definition of solids and non-aqueous liquid include the phrase: "...15% settleable solids."

Recommend changing to "...**approximately** 15% settleable solids." Leaving it as written implies that the laboratory must exactly know the percent settleable solids. This is typically a guideline for labs to use. Note also, that the regulation does not specify a method for determining settleable solids in these type samples.

**Response:** The quality system matrix type "non-aqueous liquid" is defined as "any organic liquid with less than 15% settleable solids." The quality system matrix type "solids" is defined as including "soils, sediments, sludges, and other matrices with more than 15% settleable solids." These matrix types are by definition used "for purposes of batch and quality control requirement determinations." In neither case does the definition require an exact determination of 15%. Rather the definition indicates that 15% is the breaking point between whether a matrix is a non-aqueous liquid or a solid. Furthermore, wastewater treatment plants performing sludge analyses need to determine the exact percentage of solids. Finally, the regulation would not direct the laboratory to a specific method for determining solids. Rather it defines various matrix types for batch and quality control requirement determinations. No change has been made to the regulation based on this comment.

195. **Subject:** Definition of owner

**Commenter:** Solite Corporation/Giant Resource Recovery (Solite)

**Text:** The extensive changes in the treatment of "owners" and "operators" have resulted in internal inconsistencies. The 1 VAC 30-45-10 definition of owner now defines "operators" as owners. Accordingly when 1 VAC 30-45-70 says that "All owners" must apply for certification it necessarily requires both the owner and the operator to apply, because the operator is an "owner." But then 1 VAC 30-45-70 goes on to provide that an operator may submit an application for "the owner." Since an operator by definition is "the owner", this makes no sense.

"Owner" should be defined simply as the person or entity that actually controls the laboratory. There is no reason the rule should apply to an owner who is simply a passive landlord, when another entity controls the lab and is actually the one seeking the certification. The purpose of the rule is to regulate laboratory testing, not real estate or buildings, and the applicant should be the entity that is doing the testing. If holders of title to the land are required to apply, 1 VAC 30-45-70 should at least allow the operator to submit an application "instead of" rather than "for" the owner.

**Response:** The change made to the definition of the term "owner" was made to provide clarification and was based on comments made during the first public comment period. The previous version of the definition allowed the term "owner" and the term "operator" to be interchangeable. However, the definition already included the idea that the "operator" or "owner" could operate the laboratory. The provisions directed at the "owner" also included the "operator." This was redundant. The change made to the regulation eliminated this redundancy. The regulation currently addresses those instances when the "owner" and the "operator" are different legal entities. Otherwise the terms are interchangeable. This revision further made it clear that the "owner" of the laboratory was the responsible party. Previously there was some confusion about this because of the redundant use of the term "operator." No change has been made to the regulation based on this comment.

196. **Subject:** Definition of quality assurance officer

**Commenter:** DEQ

**Text:** "Quality Assurance Officer means...Where staffing is limited, the quality assurance officer may also be the ~~technical director~~ **laboratory manager**."

1 VAC 30-45-200 is entitled "Laboratory manager". Replacing the term 'technical director' with 'laboratory manager' will provide consistency.

**Response:** The use of "technical director" was an editorial error. This error has been fixed.

197. **Subject:** Definition of simple test procedure

**Commenter:** Solite

**Text:** The definition of "Simple Test Procedure" should be revised in accordance with the comment included in our April 7, 2004 submittal. The tests procedures identified by Solite/GRR are in fact simple test procedures whose methods are comparable to the procedures included in your proposed definition. The GRR lab facility in Arvonnia is also small in terms of the physical size, extent of instrumentation and number of personnel relative to a commercial laboratory.

**Response:** See issue 33 above. The response to issue 33 still pertains. In further response, it was not DCLS' intent to review each test method to determine if it fits the requirements for simple test procedures. The intent was to add tests when it was clear that the tests were simple and that these additions would

provide relief with regard to fees for a large number of laboratories. No change has been made to the regulation based on this comment.

### **Process to Apply (1 VAC 30-45-70)**

198. **Subject:** On-site assessment (subdivision I 2 a)

**Commenter:** Augusta County Service Authority, Hanover County Department of Public Utilities, and VAMWA

**Text:** There are no criteria included for how DCLS will approve third party assessors. VAC 30-45 is not supposed to be a NELAC accreditation, it is supposed to be a VELAP certification. NELAC does not provide assessor training, but outlines what must be included in Assessor training for NELAC On-Site assessments for NELAC.

In addition, it is unclear where a lab would find a 3<sup>rd</sup> party on-site inspector to conduct inspections under the 1 VAC 45 since this is unique to Virginia?

**Response:** Subdivision 1 VAC 30-45-70 I 2 a has been revised to delete the phrase “NELAC-trained.” DCLS intends to use NELAC-trained third-party on-site assessors. DCLS will need to ensure that the third-party assessors it lists as acceptable are trained to fully understand the differences between 1 VAC 30-45 and 1 VAC 30-46.

199. **Subject:** Renewal period (subdivision K 4)

**Commenter:** MeadWestvaco

**Text:** The need for certification renewals for non-commercial labs every two years should be reviewed. I believe longer certification periods should be considered, especially for smaller labs, labs conducting simple routine testing, labs whose testing requirements do not [vary] significantly, etc.

**Response:** 1 VAC 30-45-120 allows a laboratory to apply for an exemption from the requirements of the regulation. Laboratories that perform well may get an exemption for up to 24 months. This would allow a limited extension of a laboratory’s certification status. The two-year renewal period currently set by 1 VAC 30-45 is a reasonable time for renewal. Once a laboratory is certified initially, the renewal process should be simple, especially if the laboratory performs simple routine testing and the laboratory’s requirements do not vary. No change has been made to the regulation based on this comment.

### **Notifications and changes to certification elements and status (1 VAC 30-45-90)**

200. **Subject:** Change of ownership or location of lab (subdivision C 5)

**Commenter:** Augusta County Service Authority, Hanover County Department of Public Utilities, and VAMWA

**Text:** What are “Laboratory certification numbers?”

**Response:** A laboratory certification number is the identifying number assigned to the laboratory when DCLS grants certification. See 1 VAC 30-45-70 K 2 d. The previous version of this subdivision used the term “laboratory identification number.” The provision has been revised to use “laboratory identification number.”

201. **Subject:** Change of ownership or location of lab and record retention (subsection C 6)

**Commenter:** DEQ

**Text:** When there is a change in ownership, the new owner of the certified laboratory shall keep all records and analyses performed by the previous owner under his scope of certification for a period of three years **or longer if required by other regulations.**

Some DEQ regulations require that records be retained for five years.

**Response:** The change has been made for the reason stated.

### **Fees ( 1 VAC 30-45-130)**

202. **Subject:** Test category fee for benthic assessment (subdivision E 3) [also 1 VAC 30-46-150 E 3]

**Commenter:** DEQ

**Text:** "Benthic assessment"

Currently there is not a national standard available to which benthic assessment can be audited. It is the recommendation of DEQ that inclusion of this type of assessment be delayed until such time as a standard is developed.

**Response:** See issue 193 above. The fee category for benthic assessment has been deleted.

203. **Subject:** Additional fees (subsection F) [also 1 VAC 30-46-150 F]

**Commenter:** Augusta County Service Authority, Hanover County Department of Public Utilities, and VAMWA

**Text:** DCLS does not give any fee structure for additional fees that can be charged. DCLS states they may charge a transfer fee to a laboratory transferring ownership, but lists no criteria defining how they will determine whether or not to charge fees, or how they will be determined.

**Response:** The criteria for charging a fee and the method to be used to charge the fee are both given in 1 VAC 30-45-130 F. The method is set out in 1 VAC 30-45-130 G. The criteria for charging a fee for modifying scope of certification, transfer of ownership, applying for an exemption, and request that multiple non-contiguous laboratory sites be considered as one site are specified in subdivisions F 1 through F 5. No change has been made to the regulation based on this comment.

### **Article 1. Personnel**

204. **Subject:** Laboratory manager - qualifications (subsection 200 B)

**Commenter:** DEQ

**Text:** The following should be added to this section on laboratory manager qualification:

*3. A full-time employee of a drinking water or wastewater treatment facility who holds a valid treatment plant operator's certificate appropriate to the nature and size of such facility shall be deemed to meet the educational and experience requirements serving as the laboratory manager of the certified laboratory devoted exclusively to the examination of environmental samples taken within such facility system and limited to the scope of that facility's regulatory permit.*

*4. A full-time employee of an industrial waste treatment facility with a minimum of one year of experience under supervision in environmental analysis shall be deemed to meet the requirements for serving as the*

*laboratory manager of a certified laboratory devoted exclusively to the examination of environmental samples taken within such facility for the scope of that facility's regulatory permit.*

The laboratory manager in 1 VAC 30-45 has the same general duties as the technical director in NELAC standards. These provisions are allowed for the technical director of NELAP accredited laboratories in NELAC section 4.1.1.2 and therefore should be allowed in Virginia's certification program.

**Response:** DCLS agrees with DEQ that these additional provisions will widen the options available to qualify laboratory managers. These provisions have been added to subsection B.

205. **Subject:** Absence of laboratory manager (section 230)

**Commenter:** DEQ

**Text:** "When a laboratory manager will be absent for a period exceeding 15 consecutive calendar days, the laboratory shall designate ~~another full-time staff member~~ **a qualified replacement** to perform the manager's function."

Requiring the replacement to be a full time staff member may be too burdensome for many facilities.

**Response:** DCLS agrees with DEQ on their comment. The term "a qualified replacement" will be used instead. In this case, to be "qualified" means that the replacement meets the requirements of 1 VAC 30-45-200 B.

## **Article 2. On-Site Assessment**

206. **Subject:** Frequency of on-site assessment (subsection 300 A)

**Commenter:** Augusta County Service Authority, Hanover County Department of Public Utilities, and VAMWA

**Text:** The frequency of on-site assessments for drinking water labs in VA is currently every three years, though new certification is granted annually. An on-site assessment every other year is costly, and not necessary with the PT requirements.

**Response:** DCLS believes that both the semi-annual proficiency testing requirements and the two-year cycle for the on-site assessment are critical to determining whether a laboratory is maintaining the standards of the certification program. No change was made to the regulation based on this comment.

207. **Subject:** Other on-site assessments (subsection 300 B)

**Commenter:** Augusta County Service Authority, Hanover County Department of Public Utilities, and VAMWA

**Text:** DCLS may conduct an on-site assessment when a lab applies to modify its scope of certification, but the current language would allow an on-site assessment for any part of the scope of accreditation if the modification only occurs in one part of the scope. The language must be changed to limit the on-site assessment to only that part of the scope where the modification is requested.

The regulation also refers to other "major" changes that would trigger an on-site assessment. "Major" is too subjective and should be deleted.

**Response:** DCLS agrees that the use of the term "major" in 1 VAC 30-45-300 B 2 is unnecessary and vague and has deleted the term. With regard to the scope of the on-site assessment when a lab applies to modify its scope of certification, DCLS would expect to limit its on-site review to the change requested

by the laboratory. DCLS would expect to limit its on-site review in any of the instances listed in subdivision B 2 to the reasons for the review. DCLS does not believe that specifying this limit in the provision is necessary. No change has been made to the regulation based on this aspect of the comment.

208. **Subject:** Follow-up and reporting procedures. (subsection 390 F)

**Commenter:** DEQ

**Text:** "...DGS-DCLS shall provide written notification to the responsible official and ~~technical director~~ **manager** of the laboratory..."

Because the term "technical director" should be replaced with "manager". The duties of the laboratory manager in 1 VAC 30-45 are similar to the duties of a technical director in 1 VAC 30-46.

**Response:** The use of "technical director" rather than "manager" is an editorial error and has been corrected.

209. **Subject:** Documentation of on-site assessment. Release of report. (subdivision 400 C 2)

**Commenter:** Augusta County Service Authority, Hanover County Department of Public Utilities, and VAMWA

**Text:** This statement is not necessary.

**Response:** While the statement is not necessary, it is not harmful either. No change has been made to the regulation based on this comment.

### **Article 3. Proficiency Testing.**

210. **Subject:** Laboratory enrollment in proficiency testing. (subdivision 500 A 2)

**Commenter:** Augusta County Service Authority, Hanover County Department of Public Utilities, and VAMWA

**Text:** NELAC has employed a PTOB/PTPA to approve PT providers. How does DCLS plan to approve a PT provider, will they become a PTOB/PTPA? This certification is not NELAC Accreditation, therefore a NELAC approved PT provider should not be a requirement.

**Response:** These commenters asked in their comments submitted during the initial public comment period for the changes provided in the second proposal (dated September 20, 2004). See issue 84 above. This comment has been raised previously and answered at great length.

211. **Subject:** PT criteria for laboratory certification. Initial and continuing certification. (subdivision 520 B 5)

**Commenter:** Augusta County Service Authority, Hanover County Department of Public Utilities, UOSA, and VAMWA

**Text:** The section states: "For a laboratory to maintain certification, completion dates of successive proficiency rounds for a given PT field of testing shall be approximately six months apart." The next sentence states "Failure to meet the semiannual schedule is regarded as a failed study."

Failing to meet an equivocal standard ("approximately six months") with such serious consequences is inappropriate. Recommend changing the language as follows:

“For a laboratory to maintain certification, completion dates of successive proficiency rounds for a given PT field of testing shall be **completed twice in a calendar year and occur no more than nine months from the previous performance round** ~~approximately six months apart.~~”

**Response:** The rounds of proficiency testing need to be spaced apart appropriately to show how the laboratory is performing on a regular basis over time. Under the scenario suggested by this comment, one proficiency testing round could be performed in January and another in October. The next year the first round could be performed again in January leaving only two months between the October round and the following January round. The laboratories are allowed to choose when they perform the proficiencies; they just need to do so approximately six months apart. No change has been made to the regulation based on this comment.

212. **Subject:** Special requirements for whole effluent toxicity (WET). (subsection 530 A)

**Commenter:** DEQ

**Text:** “Laboratories seeking certification for ~~WET~~ **aquatic toxicity** testing shall be assessed through on-site assessment and evaluation of ~~EPA Discharge Monitoring Report Quality Assurance (DMRQA) test results when available~~ **proficiency test results.**”

In order to conform to the test categories in 1 VAC 30-45-130, “WET” should be replaced with “aquatic toxicity”.

In Virginia, DMRQA tests MUST be analyzed using exactly the same procedures used for routine compliance monitoring data. The DMRQA studies do not include some of the same analyses as required in VA NPDES permits (temperature and feeding procedures are different). Because of this, a WET testing laboratory may not be required to participate in the WET portion of DMRQA. There are now several aquatic toxicity PT tests available each year that have the potential to include all of DEQ’s permit required parameters. Limiting the PT to DMRQA would be inappropriate because it would potentially exempt PTs for some WET labs.

**Response:** In some cases, the WET portion of the DMRQA study will include all the same analyses as required by a VA NPDES permit. In these cases, the laboratory may use the WET portion of the DMRQA study. If there are differences (temperature and feeding procedures, for example), then the laboratory must perform an aquatic toxicity PT. Section 530 has been revised to add subsection C setting out this requirement.

#### **Article 4. Quality System.**

213. **Subject:** Quality system. (subsection 600 C)

**Commenter:** Augusta County Service Authority, Hanover County Department of Public Utilities, and VAMWA

**Text:** It is unclear as to which requirements must be followed; the method or the standard. The method should be followed, because the QC requirements outlined in this chapter are excessive and are essentially the NELAC quality System requirement.

**Response:** The provisions of subsection 600 C do address the question of whether to follow the method or the standard. The more stringent requirement of (i) 1 VAC 30-45 or of (ii) the mandated test method or regulation is to be followed. If it is unclear which is more stringent, the requirement of the mandated test method or regulation should be followed.

The commenters address the quality control requirements specifically. The language used in 1 VAC 30-45-600 C has been added to 1 VAC 30-45-760 A 1. This additional language helps point out that the quality control requirements in mandated methods or regulations should be followed when it is unclear whether the quality control requirements in Article 4 or those in the mandated test methods or regulations are more stringent.

214. **Subject:** Recordkeeping system and design. (subsection 640 H)

**Commenter:** DEQ

**Text:** "Laboratory shall keep computer and electronic data records in accordance with 1 VAC 30-45-650 C and 1 VAC 30-45-730 K."

This implies that these two sections are the only ones a lab must adhere to where electronic data/records are concerned. They should be required to maintain hardware and software in proper working condition to allow retrieval of data for the record-retention time required in regulation. In addition, the data must be protected against fire, theft, loss, environmental deterioration, vermin and electronic or magnetic sources.

There is an EPA guidance document entitled "2185 - Good Automated Laboratory Practices". It contains the principles and guidance to regulations for ensuring data integrity in automated laboratory operations. DEQ currently requires that permittees must adhere to all sections of "GALP" if they maintain records only in an electronic format. If "GALP" can not be met, a hardcopy of records must be maintained.

**Response:** 1 VAC 30-45-640 H has been revised to include all pertinent provisions concerning computer and electronic data records. This revision includes provisions that cover the concerns specified by DEQ.

215. **Subject:** Subcontracting analytical samples. (subsection 680 A)

**Commenter:** DEQ

**Text:** "Where a laboratory subcontracts any part of the testing covered under this chapter, the testing shall only be subcontracted to a laboratory certified under 1 VAC 30-46 or under another state's NELAP-approved program."

This section implies that a lab that uses another state as their primary accrediting authority would not be required to apply for accreditation with VA as a secondary accrediting authority prior to analyzing VA environmental samples. If NELAP approved laboratories outside of VA are allowed to perform analytical work in VA without paying a fee, it will put VA's commercial laboratories at a disadvantage and DCLS will stand to lose substantial revenue.

**Response:** DCLS had not considered the revenue outcome of 1 VAC 30-45-680 A as proposed. The provision was meant to require subcontractors to meet the requirements of 1 VAC 30-46 or an equivalent program. DEQ has a good point. 1 VAC 30-45-680 A has been revised to delete the phrase "or under another state's NELAP-approved program." The effect of this change is to require subcontractors to obtain reciprocal accreditation under the Virginia program before laboratories meeting the requirements of 1 VAC 30-45 can use these subcontractors' laboratory services.

216. **Subject:** Environment and work areas. (subdivision 710 4)

**Commenter:** Augusta County Service Authority, Hanover County Department of Public Utilities, and VAMWA

**Text:** Cannot be audited in current form. Recommend change to "Measures will be taken to address potential for cross-contamination...".

**Response:** 1 VAC 30-45-710 4 has been revised to make the provision more specific based on this comment.

217. **Subject:** Test methods and standard operating procedures. Demonstration of capability. (subdivision 730 E 6 and F, especially F1)

**Commenter:** Augusta County Service Authority, Hanover County Department of Public Utilities, UOSA, and VAMWA

**Text:** The concept of “Work Cell” and the entire demonstration-of-capability concept need to be better defined. It is a very confusing and misunderstood rule. These questions/scenarios need answers:

*This lone 1 VAC 45 requirement, in its most stringent interpretation, will overload laboratories with paperwork as well as affect personnel resources. Does the expense justify the relatively minor improvement in quality that it may impart. If not well defined, the requirement will lead to considerable confusion when labs attempt to implement and substantial contention when inspectors interpret the requirement differently and then force labs to implement the inspectors’ latest vision of its meaning.*

As the questions and scenarios above illustrate, the DOC concept is poorly defined and can lead to considerable confusion and red tape. In reality, it provides no great added value to a quality system compared to the level of effort labs might need to commit to implement it.

We recommend the following change: Because the requirements in the DOC and work cells are unclear as well as the fact that it would have only a minor impact on data quality, the sections 1 VAC 45 30-45-730 E and F should be removed until such time that the exact requirements are better defined.

**Commenter:** Augusta County Service Authority, Hanover County Department of Public Utilities, and VAMWA

**Text:** The language is confusing; why must the regulation define the details of DOC if it is mandatory in the test method or regulation as currently stated? It would seem that the details of DOC are necessary when they are not defined by the test method or other regulation.

**Response:** DCLS agrees with the commenters that both the proposed language in 1 VAC 30-45-730 E 6 concerning work cells and the language in 1 VAC 30-45-730 F 1 are confusing. DCLS has revised the language in these provisions to make the concepts understandable.

218. **Subject:** Test methods and standard operating procedures. Procedure for demonstration of capability. (subdivision 730 F 1 a)

**Commenter:** DEQ

**Text:** “A quality control sample may be obtained from an outside source or may be prepared by the laboratory using **alternate source** stock standards that are prepared independently from those used in instrument calibration.”

The insertion of “alternate source” helps to clarify the meaning of “independently.”

**Response:** For the reason stated, the suggested revision was made to 1 VAC 30-45-730 F 1 a.

219. **Subject:** Measurement traceability and calibration. Reference standards and reference materials. Reference standards. (subdivision 740 C 1)

**Commenter:** Augusta County Service Authority, Hanover County Department of Public Utilities, and VAMWA

**Text:** The regulation requires reference standards to be calibrated, there is no way to calibrate reference standards used to calibrate instruments. Perhaps the “verification” and “verified” should replace “calibration” and “calibrated”, respectively.

**Response:** DCLS has added a definition of “reference standard” to 1 VAC 30-45-40 to make sure that the meaning of the term “reference standard” is understood. As added to 1 VAC 30-45-40, a reference standard is “a standard, generally of the highest metrological quality available at a given location, from which measurements made at that location are derived.” A reference standard is calibrated by sending the standard back to NIST or to a certified calibration laboratory for calibration.

220. **Subject:** Measurement traceability and calibration. Calibration. Instrument calibration. Continuing instrument calibration verification. (subdivision 740 D 2 c (2)(b))

**Commenter:** Augusta County Service Authority, Hanover County Department of Public Utilities, UOSA, and VAMWA

**Text:** The following two sentences in this section of the regulation should be removed because they impose an excessive and unnecessary burden on laboratories.  
 “The concentration of the calibration verification shall be varied within the established calibration range”  
 and  
 the new requirement: “Over time, all concentrations of calibration standards shall be used for verification.”

The reasons for removing these requirements are as follows:

Many methods allow analysts to verify calibration using check standards at a single concentration. Adding an additional requirement of checking at multiple concentration levels over time provides little return for a great deal of effort. Even the NELAC authors must have recognized this and removed the first sentence above from their 2003 standards!

Because the signal to noise increases as the concentration decreases, the instrument signal observed as the standard concentration level decreases would result in a larger standard deviation (greater variability), which would mean that a control limit would have to be established for each calibration standard that is used as a check standard for every method. If the method required four calibration standards, then four sets of control limits would have to be employed. It would be an enormous and unwarranted undertaking that provides little added improvement in data quality.

**Response:** See issue 147 above for the rationale behind the sentence: “Over time, all concentrations of calibration standards shall be used for verification.” The commenters correctly point out that the 2003 NELAC standards dropped the requirement that states: “The concentration of the calibration verification shall be varied within the established calibration range.” However the authors of 5.5.5.10 c) of the 2003 NELAC standards listed additional conditions for performing continuing instrument calibration verification. DCLS has deleted the two requirements as suggested by the commenters. Instead DCLS is adding the new conditions for performing continuing instrument calibration verification from the 2003 NELAC provisions and editing the proposed subdivision (e) to make it consistent with the 2003 NELAC standards.

221. **Subject:** Quality assurance. Essential quality control procedures. (subsection 750 B)

**Commenter:** Augusta County Service Authority, Hanover County Department of Public Utilities, UOSA, and VAMWA

**Text:** *Since DCLS has decided to incorporate the essential quality control requirements from the 2003 NELAC standards in the Appendix D under Quality Systems, which they have written verbatim into sections 1 VAC 30-45-760 to -829, it is not necessary to repeat the several items listed in section A. (General) and in section B. (Essential Quality Control Procedures). Sections A. and B. discuss quality*

*control requirements in general terms, whereas Section C. discusses specifics. It is confusing to repeat requirements in slightly different ways in multiple sections of the regulation.*

We recommend to DCLS that it delete sections A. and B. because section C. is sufficient.

**Response:** The material in 1 VAC 30-45-750 A gives general direction to the laboratory to include quality control procedures for monitoring the validity of its environmental tests. Examples are given of the type of monitoring to be included. 1 VAC 30-45-750 B specifies that specific quality control principles apply to the laboratory where applicable and directs the laboratory (or reader) to those specific requirements. 1 VAC 30-45-750 C is the first list of these specific quality control principles or requirements. This subsection applies to all laboratories. Each of these sections has a purpose. While repetitive in some ways, this repetition provides emphasis and clarity. No change has been made to the regulation based on this comment.

222. **Subject:** Quality control requirements (section 760)

**Commenter:** Solite

**Text:** The new QA/QC provisions are excessively detailed, and more appropriately belong in guidance rather than in the regulations. On March 23, 2004 GRR provided copies of our on-site laboratory SOP's and QA/QC plans to the DCLS (Hopper to Pearson) which are required to be utilized at the environmental laboratories at the Solite/GRR plant sites. These SOP/QA/QC plans meet the specific requirements for which the underlying DEQ Permit (i.e. RCRA, Clean Air Act) conditions require. Therefore, for the regulatory purposes for which Solite/GRR operates its on-site laboratories and for the purposes which those laboratory analyses are required to be performed, we submit that the QA/QC plans required by our RCRA and Clean Air Act permits are sufficient to ensure the quality and accuracy of the data generated. Accordingly, the specific QA/QC requirements in DEQ Permits should supercede the Quality Assurance (QA/QC) requirements proposed at 1 VAC 30-45.

**Response:** Not all DEQ permits contain quality assurance and quality control requirements. One of the purposes of 1 VAC 30-45 and 1 VAC 30-46, perhaps their main purpose, is to provide a set of quality assurance and quality control requirements or principles that all environmental laboratories need to meet in order to be certified. Solite and GRR when applying for certification under the program will need to assure that their particular SOP and QA/QC plans meet the requirements appropriate to the testing that Solite and GRR carries out under this regulation as well as under the RCRA and Clean Air Act. The specific quality control provisions added to the regulation may not apply to Solite or GRR. It depends on the type of testing that Solite and GRR does. The general quality control requirements in 1 VAC 30-45-750 and 760 do apply. No change has been made to the regulation based on this comment.

223. **Subject:** Quality control requirements. Initial test method evaluation. (subsection 760 B 1 and 2)

**Commenter:** DEQ

**Text:** The terms 'Limit of detection (LOD)' and 'Limit of quantitation (LOQ)' should be added to the definitions in section 40.

NELAC's glossary defines these as:

LOD: an estimate of the minimum amount of a substance that an analytical process can reliably detect. An LOD is analyte-and matrix-specific and may be laboratory-dependent.

LOQ: the minimum levels, concentrations, or quantities of a target variable (e.g., target analyte) that can be reported with a specified degree of confidence.

**Response:** These definitions have been added to 1 VAC 30-45-40 for the reason given by the commenter.

224. **Subject:** Quality control requirements. Initial test method evaluation. (subsection 760 B 3)

**Commenter:** DEQ

**Text:** There are two sections numbered 760 B 3.

**Response:** This editorial error has been fixed.

225. **Subject:** Chemical testing: positive and negative controls. Positive control – method performance. Laboratory control sample (LCS). (subsection 770 B)

**Commenter:** DEQ

**Text:** The term Laboratory Control Sample (LCS) should be added to the definitions in section 40.

NELAC's glossary defines LCS as: Laboratory Control Sample (however named, such as laboratory fortified blank, spiked blank, or QC check sample): a sample matrix, free from the analytes of interest, spiked with verified known amounts of analytes or a material containing known and verified amounts of analytes.

**Response:** This definition has been added to 1 VAC 30-45-40 for the reason given by the commenter.

226. **Subject:** Toxicity testing: positive and negative controls. Positive control. (subdivision 781 A 1 a)

**Commenter:** Augusta County Service Authority, Hanover County Department of Public Utilities, and VAMWA

**Text:** Appendix C is referenced, but it is unknown as to where this appendix is located.

**Response:** This is an editorial error. The reference has been corrected.

227. **Subject:** Toxicity testing: positive and negative controls. Positive control. (subdivision 781 A 1 b and c)

**Commenter:** Augusta County Service Authority, Hanover County Department of Public Utilities, and VAMWA

**Text:** The text refers to "method-specific" criteria, but there can be many criteria that are specific to each method. The language must be changed to "method defined" criteria.

**Response:** DCLS has revised 1 VAC 30-45-781 A 1 b, adding punctuation that was needed for better clarity. The provisions in subdivisions A 1 b and c specify criteria against which the laboratory would evaluate precision or sensitivity, in the case of A 1 b, and endpoints that are point estimates, in the case of A 1 c. In both cases the criteria would either be set out in the test method or the laboratory would derive the criteria to determine validity. If in the test method and not derived by the laboratory, the criteria are specific to the method or method-specific. The suggested substitute has no meaningful difference. No change other than minor editing has been made to the regulation based on this comment.

228. **Subject:** Toxicity testing: positive and negative controls. Positive control. (subdivision 781 A 2 c)

**Commenter:** Augusta County Service Authority, Hanover County Department of Public Utilities, and VAMWA

**Text:** The term “NOAEC” is used as an example endpoint, but 40 CFR Part 136 does not recognize this endpoint, only the NOEC. DEQ has made it clear that only 40 CFR Part 136 is enforceable, therefore the NOAEC must be removed.

**Response:** In 40 CFR Part 136, EPA references the updated EPA acute and chronic test manuals for inclusion as test procedures. Both LC<sub>50</sub> and NOAEC (No Observed Adverse Effect Concentration) statistical procedures are discussed in the acute manual and are acceptable for use. No change has been made to the regulation based on this comment.

229. **Subject:** Toxicity testing: positive and negative controls. Positive control. (subdivision 781 A 4)

**Commenter:** Augusta County Service Authority, Hanover County Department of Public Utilities, and VAMWA

**Text:** The requirement that the reference toxicant identified by the state must be used is more stringent than 40 CFR Part 136, and since the state can only enforce 40 CFR Part 136, this language must be deleted. Additionally, different reference toxicants have different capabilities, pros and cons. DEQ, over the past 10 years, has identified different reference toxicants without regard to the pros and cons of each toxicant. Therefore DEQ’s recommendations have been arbitrary. Arbitrary designation of reference toxicants is unacceptable to the lab community and must not be promoted in this regulation. Every time DEQ changes its mind on which toxicant to use, labs must abandon the data they have spent considerable funds collecting. The requirement in this regulation must mirror that of federal regulation, which allows the lab to select the toxicant that best meets the needs of the lab.

**Response:** In 1 VAC 30-45-781 A 4, no reference toxicant is specified. This specification is left to the permitting authority. The argument the commenters present is an argument with DEQ and not with the certification standards set out here. No change has been made to the regulation based on this comment.

230. **Subject:** Toxicity testing: constant and consistent test conditions. (subdivision 788 I)

**Commenter:** Augusta County Service Authority, Hanover County Department of Public Utilities, and VAMWA

**Text:** The regulation requires that food be sufficient to allow growth and reproduction, but these are not requirements of acute tests. Food for acute tests should only support satisfactory survival in acute tests.

**Response:** 1 VAC 30-45-788 I states “the quality of the food used for testing or culturing shall be sufficient to allow satisfactory survival, growth and reproduction of the test species ... .” The subsection also states that “the laboratory shall have written procedures for the evaluation of food acceptance.” These provisions do not specify acute or chronic tests. The laboratory should write procedures appropriate for the tests it is performing. No change has been made to the regulation based on this comment.

231. **Subject:** Microbiology testing. Positive controls. (subdivision 791 B 2)

**Commenter:** DEQ

**Text:** “Each pre-prepared, ready-to-use lot of medium (including chromofluorogenic reagent) and each batch of medium prepared in the laboratory shall be tested ~~with at least one pure culture of a~~ and demonstrate a known positive reaction response.”

It would not be appropriate for wastewater treatment plants to maintain pure cultures of bacteria. A positive response can easily be demonstrated by inoculating the media with influent.

**Response:** Based on the reason given, 1 VAC 30-45-791 B 2 has been revised as suggested.

232. **Subject:** Microbiology testing. Negative controls. (subsection 791 C)

**Commenter:** DEQ

**Text:** This section should be eliminated for wastewater treatment plants. The media used in approved wastewater methods have been tested extensively to select for the target organism. Resources needed to continue to demonstrate that the media is selective for the target organism could be better spent elsewhere. A positive control suggested above will enable the wastewater treatment plant to demonstrate permit compliance.

**Response:** Based on the reason given, 1 VAC 30-45-791 C has been revised. This subsection now includes a statement providing that the negative controls for microbiology testing do not apply to wastewater treatment plants.

233. **Subject:** Microbiology testing: constant and consistent test conditions. (subdivision 798 B 7 c)

**Commenter:** Augusta County Service Authority, Hanover County Department of Public Utilities, UOSA, and VAMWA

**Text:** Add the following highlighted phrase to this requirement.

“c. Labware that is washed and reused shall be tested for possible presence of residues which may inhibit or promote growth of microorganisms by performing the Inhibitory Residue Test annually, and each time the lab changes the lot of detergent or washing procedures, **or have on file a certificate from the manufacturer verifying that the detergent is free of inhibitory effects.**”

Documentation from the manufacturer certifying that their detergent is free from inhibitory effects should be sufficient to meet this requirement and is currently an accepted practice.

**Response:** The reason for this requirement is that a manufacturer can be wrong and make a certification that is incorrect. This testing requirement is limited to an annual test or when the lot of detergent is changed or when washing procedures are changed. No change has been made to the regulation based on this comment.

234. **Subject:** Sample handling, sample acceptance policy and sample receipt. (section 850 1)

**Commenter:** Augusta County Service Authority, Hanover County Department of Public Utilities, and VAMWA

**Text:** What are “System laboratories”?

**Response:** The term “system laboratory” is defined in 1 VAC 30-45-40 as “a noncommercial laboratory that analyzes samples from multiple facilities having the same owner.”

#### **SPECIFIC COMMENTS: 1 VAC 30, CHAPTER 46**

235. **Subject:** Purpose. (section 10)

**Commenter:** Augusta County Service Authority, Hanover County Department of Public Utilities, and VAMWA

**Text:** DCLS has changed the version of the NELAC standard for laboratories to be accredited under from 2002 to 2003. This does not solve the time line problem, because by the time the program is implemented the current version of the NELAC standard in use may be 2004 or 2005. DCLS will not be a NELAC AA because they will not be accrediting laboratories for the versions of the standard that is in effect.

**Response:** Most states that have the authority to carry out the NELAP program must update the version of the NELAC standards being used by going through a rulemaking process. Each state has a different process. NELAP recognizes that states need time to update legally the version of the NELAC standards being used. So the NELAC conferees added a lag time between the date a set of standards is voted on and the date the standards become effective. In the case of the 2003 standards, the effective date is July 1, 2005. This is true for certain chapters and not for others, however. The following chapters of the 2003 NELAC standards are marked effective July 1, 2003: Constitution and Bylaws, Program Policy and Structure, Proficiency Testing, and Accrediting Authority. The following chapters of the 2003 NELAC standards are marked effective July 1, 2005: On-site Assessment, Accreditation Process, and Quality Systems.

To update the standards in Virginia, DCLS will need to begin a rulemaking once a new set of standards has been approved to incorporate those standards by reference. The time available to incorporate the new standards by reference should be sufficient to keep the standards up to date.

No change has been made to the regulation based on this comment.

236. **Subject:** Establishment of accreditation program. (subsection 20 B)

**Commenter:** Augusta County Service Authority, Hanover County Department of Public Utilities, and VAMWA

**Text:** DCLS has changed the establishment date to 37 months from the effective date of the chapter, but makes no mention of when they will be required to become a NELAC AA. If DCLS does not become a NELAC AA by this time how will laboratories be accredited? Will this require VA labs to obtain accreditation, and therefore pay fees, to another AA?

**Response:** The extension of the establishment date to 37 months was made to allow sufficient time for DCLS to review and determine certification status for all the laboratories DCLS believes are covered by 1 VAC 30-45 and 1 VAC 30-46. DCLS does not anticipate that the full 37 months will be needed for the agency to become a NELAP accrediting authority. DCLS has spoken with a member of the NELAP team that will be reviewing Virginia's application for NELAP accrediting authority status. DCLS was told that the time for review after receipt of the application is four to six months including the on-site assessment of DCLS. This should be sufficient time for DCLS to become approved as an accrediting authority and allows DCLS to correct deficiencies and to reapply if necessary. No change has been made to the regulation based on this comment.

237. **Subject:** Process to apply and obtain accreditation. Timely renewal applications. (subsection 70 C)

**Commenter:** Augusta County Service Authority, Hanover County Department of Public Utilities, and VAMWA

**Text:** DCLS does not include any provision for renewal applications to be based on the latest version of the NELAC standard in use, or what will happen to commercial labs if there are no longer NELAC standards for labs to use. There must be language added to this chapter specifying DCLS will maintain

their status as an AA, including renewal of their application to EPA every three years, and that the most current version will be used to accredit labs

**Response:** See responses to issues 235 and 236 above. This purpose of this regulation is to set accreditation standards for laboratories as required by §2.2-1105 of the *Code of Virginia*. It is unnecessary to include provisions in the regulations that specify DCLS will carry out the program it believes to be good policy for Virginia. What the commenters request, the addition of provisions stating that DCLS will maintain its status as an accrediting authority, including renewing its status, and that it will use the current version of the NELAC standards to accredit labs, is unnecessary. No change has been made to the regulation based on this comment.