

Virginia Administrative Code

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CHAPTER 46

ACCREDITATION FOR COMMERCIAL ENVIRONMENTAL LABORATORIES

Part I General Provisions

1VAC30-46-10. Purpose.

Section 2.2-1105 of the Code of Virginia directs the Division of Consolidated Laboratory Services to establish a program to certify environmental laboratories that perform tests, analyses, measurements or monitoring required pursuant to the Commonwealth's air, waste and water laws and regulations. This chapter sets out the required standards and the process by which owners of commercial environmental laboratories may obtain certification for their laboratories. Certification is referred to as accreditation in this chapter.

Statutory Authority: § 2.2-1105 of the Code of Virginia.

Historical Notes: Derived from Virginia Register Volume 25, Issue 7, eff. January 1, 2009; amended, Virginia Register Volume 32, Issue 1, eff. November 1, 2015.

1VAC30-46-15. Standards for accreditation transition.

A. Commercial environmental laboratories are accredited under the standards of the National Environmental Laboratory Accreditation Conference (NELAC), now The NELAC Institute (TNI).

B. DCLS shall accredit commercial environmental laboratories under the 2003 NELAC Standards as specified by the provisions of this chapter that became effective on January 1, 2009, for the first 10 months following November 1, 2015.

C. DCLS shall accredit commercial environmental laboratories under the 2009 TNI Standards as specified by the provisions of this chapter effective on November 1, 2015, beginning on the first day of the 11th month following November 1, 2015.

Statutory Authority: § 2.2-1105 of the Code of Virginia.

Historical Notes: Derived from Virginia Register Volume 32, Issue 1, eff. November 1, 2015.

1VAC30-46-20. Establishment of accreditation program.

A. Once the accreditation program has been established, laboratory accreditation shall be required before any environmental analyses performed by a commercial environmental laboratory may be used for the purposes of the Virginia Air Pollution Control Law, the Virginia Waste Management Act or the State Water Control Law (§

10.1-1300 et seq., § 10.1-1400 et seq., and § 62.1-44.2 et seq., respectively, of the Code of Virginia).

B. The accreditation program shall be established on January 1, 2012.

Statutory Authority: § 2.2-1105 of the Code of Virginia.

Historical Notes: Derived from Virginia Register Volume 25, Issue 7, eff. January 1, 2009.

1VAC30-46-30. Applicability.

A. General applicability. This chapter applies to the following:

1. Any owner of a commercial environmental laboratory.
2. Any owner of an environmental laboratory holding TNI accreditation from a primary accreditation body who wishes to apply for secondary accreditation under 1VAC30-46-140.

B. Acquiring primary TNI accreditation through this chapter.

1. A commercial environmental laboratory located in Virginia shall obtain primary TNI accreditation in Virginia as long as the fields of accreditation for which the laboratory seeks accreditation are offered by DCLS.
2. DCLS shall not provide primary TNI accreditation for environmental laboratories located in other states that offer TNI accreditation.

C. Voluntary accreditation. Any owner of a noncommercial environmental laboratory may apply for accreditation under this chapter.

D. Drinking water laboratory certification. An owner of a laboratory who must meet the requirements of 1VAC30-41 pertaining to drinking water laboratory certification and either 1VAC30-45 or this chapter may meet those requirements by obtaining accreditation under this chapter.

Statutory Authority: § 2.2-1105 of the Code of Virginia.

Historical Notes: Derived from Virginia Register Volume 25, Issue 7, eff. January 1, 2009; amended, Virginia Register Volume 32, Issue 1, eff. November 1, 2015; Errata, 32:3 VA.R. 447 October 5, 2015.

1VAC30-46-40. Definitions.

A. The definitions contained in the 2009 TNI Standards are incorporated by reference into this section. Some of these definitions are included in this section because the terms are used throughout this chapter.

B. The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

"Acceptance criteria" means specified limits placed on characteristics of an item, process, or service defined in requirement documents.

"Accreditation" means the process by which an agency or organization evaluates and recognizes a laboratory as meeting certain predetermined qualifications or standards, thereby accrediting the laboratory. "Accreditation" is the term used as a substitute for the term "certification" under this chapter.

"Accreditation body" or "AB" means the territorial, state, or federal agency having

responsibility and accountability for environmental laboratory accreditation and which grants accreditation.

"Algae" means simple single-celled, colonial, or multicelled, 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).

"Analyte" means the substance or physical property to be determined in samples examined.

"Analytical method" means a technical procedure for providing analysis of a sample, defined by a body such as the Environmental Protection Agency or the American Society for Testing and Materials, that may not include the sample preparation method.

"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 (i.e., the standards and requirements of laboratory accreditation).

"Assessor" means the person assigned by DCLS to perform, alone or as part of an assessment team, an assessment of an environmental laboratory.

"Authority" means, in the context of a governmental body or local government, an authority created under the provisions of the Virginia Water and Waste Authorities Act, Chapter 51 (§ 15.2-5100 et seq.) of Title 15.2 of the Code of Virginia.

"Benthic macroinvertebrates" means bottom dwelling animals without backbones that live at least part of their life cycles within or upon available substrates within a body of water.

"Commercial environmental laboratory" means an environmental laboratory where environmental analysis is performed for another person.

"Corrective action" means the action taken to eliminate the causes of an existing nonconformity, defect or other undesirable situation in order to prevent recurrence.

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

"Environmental analysis" or "environmental analyses" means any test, analysis, measurement, or monitoring used for the purposes of the Virginia Air Pollution Control Law, the Virginia Waste Management Act or the State Water Control Law (§ 10.1-1300 et seq., § 10.1-1400 et seq., and § 62.1-44.2 et seq., respectively, of the Code of Virginia). 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. The term shall not include the following:

1. Sampling of water, solid and chemical materials, biological tissue, or air and emissions.
2. Field testing and measurement of water, solid and chemical materials, biological tissue, or air and emissions, except when performed in an environmental laboratory rather than at the site where the sample was taken.
3. Taxonomic identification of samples for which there is no national accreditation standard such as algae, benthic macroinvertebrates, macrophytes, vertebrates and zooplankton.

4. Protocols used pursuant to § 10.1-104.2 of the Code of Virginia to determine soil fertility, animal manure nutrient content, or plant tissue nutrient uptake for the purposes of nutrient management.
5. Geochemical and permeability testing for solid waste compliance.
6. Materials specification for air quality compliance when product certifications specify the data required by an air permit such as fuel type, Btu content, sulfur content, or volatile organic chemical (VOC) content.

"Environmental laboratory" or "laboratory" means a facility or a defined area within a facility where environmental analysis is performed. A structure built solely to shelter field personnel and equipment from inclement weather shall not be considered an environmental laboratory.

"Establishment date" means the date set for the accreditation program under this chapter and the certification program under 1VAC30-45 to be established.

"Establishment of accreditation program" or "established program" means that DCLS has completed the initial accreditation of environmental laboratories covered by this chapter and the initial certification of environmental laboratories covered by 1VAC30-45.

"Facility" means something that is built or installed to serve a particular function.

"Field of accreditation" means those matrix, technology/method, and analyte combinations for which DCLS offers accreditation.

"Field of accreditation matrix" means the following when accrediting a laboratory:

1. Drinking water. Any aqueous sample that has been designated a potable or potential potable water source.
2. Nonpotable water. Any aqueous sample excluded from the definition of drinking water matrix. Includes surface water, groundwater, effluents, water treatment chemicals, and TCLP or other extracts.
3. Solid and chemical materials. Includes soils, sediments, sludges, products and byproducts of an industrial process that results in a matrix not previously defined.
4. Biological tissue. Any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origin (i.e., by species).
5. Air and emissions. Whole gas or vapor samples including those contained in flexible or rigid wall containers and the extracted concentrated analytes of interest from a gas or vapor that are collected with a sorbent tube, impinger solution, filter or other device.

"Field of proficiency testing" or "FoPT" means analytes for which a laboratory is required to successfully analyze a PT sample in order to obtain or maintain accreditation, collectively defined as: matrix, technology/method, and analyte.

"Field testing and measurement" means any of the following:

1. Any test for parameters under 40 CFR Part 136 for which the holding time indicated for the sample requires immediate analysis; or
2. Any test defined as a field test in federal regulation.

The following is a limited list of currently recognized field tests or measures that is

not intended to be inclusive: continuous emissions monitoring; online monitoring; flow monitoring; tests for pH, residual chlorine, temperature and dissolved oxygen; and field analysis for soil gas.

"Finding" means an assessment conclusion referenced to a laboratory accreditation standard incorporated by reference or contained in this chapter and supported by objective evidence that identifies a deviation from a laboratory accreditation standard requirement.

"Governmental body" means any department, agency, bureau, authority, or district of the United States government, of the government of the Commonwealth of Virginia, or of any local government within the Commonwealth of Virginia.

"Holding time" means the maximum time that can elapse between two specified activities.

"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.

"Local government" means a municipality (city or town), county, sanitation district, or authority.

"Macrophytes" means any aquatic or terrestrial plant species that can be identified and observed with the eye, unaided by magnification.

"Matrix" means the substrate of a test sample.

"National Environmental Laboratory Accreditation Conference (NELAC)" means a voluntary organization of state and federal environmental officials and interest groups with the primary purpose to establish mutually acceptable standards for accrediting environmental laboratories.

"Noncommercial environmental laboratory" means either of the following:

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. Environmental analysis performed by an environmental laboratory owned by a local government for an owner of a small wastewater treatment system treating domestic sewage at a flow rate of less than or equal to 1,000 gallons per day.
 - b. Environmental analysis performed by an environmental laboratory operated by a corporation as part of a general contract issued by a local government to operate and maintain a wastewater treatment system or a waterworks.
 - c. Environmental analysis performed by an environmental laboratory owned by a corporation 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 by a hazardous waste management permit under 9VAC20-60.
 - d. Environmental analysis performed by an environmental laboratory owned by a Publicly Owned Treatment Works (POTW) for an industrial source of

wastewater under a permit issued by the POTW to the industrial source as part of the requirements of a pretreatment program under Part VII (9VAC25-31-730 et seq.) of 9VAC25-31.

e. Environmental analysis performed by an environmental laboratory owned by a county authority for any municipality within the county's geographic jurisdiction when the environmental analysis pertains solely to the purpose for which the authority was created.

f. Environmental analysis performed by an environmental laboratory owned by an authority or a sanitation district for any participating local government of the authority or sanitation district when the environmental analysis pertains solely to the purpose for which the authority or sanitation district was created.

"Owner" means any person who owns, operates, leases or controls an environmental laboratory.

"Person" means an individual, corporation, partnership, association, company, business, trust, joint venture or other legal entity.

"Physical," for the purposes of fee test categories, means the tests to determine the physical properties of a sample. Tests for solids, turbidity and color are examples of physical tests.

"Pretreatment requirements" means any requirements arising under Part VII (9VAC25-31-730 et seq.) of 9VAC25-31 including the duty to allow or carry out inspections, entry or monitoring activities; any rules, regulations, or orders issued by the owner of a POTW; or any reporting requirements imposed by the owner of a POTW or by the regulations of the State Water Control Board. Pretreatment requirements do not include the requirements of a national pretreatment standard.

"Primary accreditation body" or "primary AB" means the accreditation body responsible for assessing a laboratory's total quality system, on-site assessment, and PT performance tracking for fields of accreditation.

"Proficiency test," "proficiency testing," or "PT" means evaluating a laboratory's performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by an external source.

"Proficiency test sample" or "PT sample" means a sample, the composition of which is unknown to the laboratory and is provided to test whether the laboratory can produce analytical results within specified acceptance criteria.

"Proficiency testing program" or "PT program" means the aggregate of providing rigorously controlled and standardized environmental samples to a laboratory for analysis, reporting of results, statistical evaluation of the results and the collective demographics and results summary of all participating laboratories.

"Publicly Owned Treatment Works" or "POTW" means a treatment works as defined by § 212 of the CWA, which is owned by a state or municipality (as defined by § 502(4) of the CWA). This definition includes any devices and systems used in the storage, treatment, recycling, and reclamation of municipal sewage or industrial wastes of a liquid nature. It also includes sewers, pipes, and other conveyances only if they convey wastewater to a POTW treatment plant. The term also means the municipality as defined in § 502(4) of the CWA, which has jurisdiction over the indirect discharges to

and the discharges from such a treatment works.

"Quality assurance" or "QA" means an integrated system of management activities involving planning, implementation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the client.

"Quality assurance officer" means the person who has responsibility for the quality system and its implementation. Where staffing is limited, the quality assurance officer may also be the technical manager.

"Quality control" or "QC" means the (i) overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer; (ii) operational techniques and activities that are used to fulfill requirements for quality; and (iii) system of activities and checks used to ensure that measurement systems are maintained within prescribed limits, providing protection against "out of control" conditions and ensuring that the results are of acceptable quality.

"Quality manual" means a document stating the management policies, objectives, principles, organizational structure and authority, responsibilities, accountability, and implementation of an agency, organization, or laboratory, to ensure the quality of its product and the utility of its product to its users.

"Quality system" means a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required quality assurance and quality control activities.

"Quality system matrix," for purposes of batch and quality control requirements, means the following:

1. Air and emissions. Whole gas or vapor samples, including those contained in flexible or rigid wall containers and the extracted concentrated analytes of interest from a gas or vapor that are collected with a sorbent tube, impinger solution, filter, or other device.
2. Aqueous. Any aqueous sample excluded from the definition of drinking water matrix or saline/estuarine source. Includes surface water, groundwater, effluents, and TCLP or other extracts.
3. Biological tissue. Any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origin.
4. Chemical waste. A product or byproduct of an industrial process that results in a matrix not previously defined.
5. Drinking water. Any aqueous sample that has been designated a potable or potential potable water source.
6. Non-aqueous liquid. Any organic liquid with less than 15% settleable solids.
7. Saline/estuarine. Any aqueous sample from an ocean or estuary, or other salt

water source such as the Great Salt Lake.

8. Solids. Includes soils, sediments, sludges, and other matrices with more than 15% settleable solids.

"Responsible official" means one of the following, as appropriate:

1. If the laboratory is owned or operated by a private corporation, "responsible official" means (i) a president, secretary, treasurer, or a vice-president of the corporation in charge of a principal business function, or any other person who performs similar policy-making or decision-making functions for the corporation or (ii) the manager of one or more manufacturing, production, or operating facilities employing more than 250 persons or having gross annual sales or expenditures exceeding \$25 million (in second-quarter 1980 dollars), if authority to sign documents has been assigned or delegated in accordance with corporate procedures.

2. If the laboratory is owned or operated by a partnership, association, or a sole proprietor, "responsible official" means a general partner, officer of the association, or the proprietor, respectively.

3. If the laboratory is owned or operated by a governmental body, "responsible official" means a director or highest official appointed or designated to oversee the operation and performance of the activities of the governmental laboratory.

4. Any person designated as the responsible official by an individual described in subdivision 1, 2 or 3 of this definition provided the designation is in writing, the designation specifies an individual or position with responsibility for the overall operation of the laboratory, and the designation is submitted to DCLS.

"Sampling" means the act of collection for the purpose of analysis.

"Sanitation district" means a sanitation district created under the provisions of Chapters 3 (§ 21-141 et seq.) through 5 (§ 21-291 et seq.) of Title 21 of the Code of Virginia.

"Secondary accreditation body" or "secondary AB" means the accreditation body that grants TNI accreditation to laboratories based on their accreditation by a TNI-recognized primary accreditation body.

"Sewage" means the water-carried human wastes from residences, buildings, industrial establishments or other places together with such industrial wastes and underground, surface, storm, or other water as may be present.

"Standard operating procedure" or "SOP" means a written document that details the method for an operation, analysis, or action with thoroughly prescribed techniques and steps. An SOP is officially approved as the method for performing certain routine or repetitive tasks.

"TCLP" or "toxicity characteristic leachate procedure" means Test Method 1311 in "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods," EPA Publication SW-846, as incorporated by reference in 40 CFR 260.11. This method is used to determine whether a solid waste exhibits the characteristic of toxicity (see 40 CFR 261.24).

"Technical manager (however named)" means the person who has overall

responsibility for the technical operation of the environmental laboratory and who exercises actual day-to-day supervision of laboratory operation for the appropriate fields of testing and reporting of results. The title of this person may include but is not limited to laboratory director, technical manager, laboratory supervisor, or laboratory manager.

"Technology" means a specific arrangement of analytical instruments, detection systems, or preparation techniques, or any combination of these elements.

"Test" means a technical operation that consists of the determination of one or more characteristics or performance of a given product, material, equipment, organism, physical phenomenon, process or service according to a specified procedure.

"Test, analysis, measurement or monitoring required pursuant to the Virginia Air Pollution Control Law" means any method of analysis required by the Virginia Air Pollution Control Law (§ 10.1-1300 et seq. of the Code of Virginia); by the regulations promulgated under this law (9VAC5), including any method of analysis listed either in the definition of "reference method" in 9VAC5-10-20, or listed or adopted by reference in 9VAC5; or by any permit or order issued under and in accordance with this law and these regulations.

"Test, analysis, measurement or monitoring required pursuant to the Virginia Waste Management Act" means any method of analysis required by the Virginia Waste Management Act (§ 10.1-1400 et seq. of the Code of Virginia); by the regulations promulgated under this law (9VAC20), including any method of analysis listed or adopted by reference in 9VAC20; or by any permit or order issued under and in accordance with this law and these regulations.

"Test, analysis, measurement or monitoring required pursuant to the Virginia Water Control Law" means any method of analysis required by the Virginia Water Control Law (§ 62.1-44.2 et seq. of the Code of Virginia); by the regulations promulgated under this law (9VAC25), including any method of analysis listed or adopted by reference in 9VAC25; or by any permit or order issued under and in accordance with this law and these regulations.

"Test method" means an adoption of a scientific technique for performing a specific measurement, as documented in a laboratory standard operating procedure or as published by a recognized authority.

"The NELAC Institute (TNI)" or "TNI" means the organization whose standards environmental laboratories must meet to be accredited in Virginia.

"TNI standards" means the 2009 Standards for Environmental Laboratories and Accreditation Bodies approved by TNI.

"Virginia Air Pollution Control Law" means Chapter 13 (§ 10.1-1300 et seq.) of Title 10.1 of the Code of Virginia that is titled "Air Pollution Control Board."

"Virginia Environmental Laboratory Accreditation Program" or "VELAP" means the program DCLS operates to accredit environmental laboratories under this chapter.

"Wastewater" means liquid and water-carried industrial wastes and domestic sewage from residential dwellings, commercial buildings, industrial and manufacturing facilities, and institutions.

"Waterworks" means each system of structures and appliances used in connection with the collection, storage, purification, and treatment of water for drinking or domestic

use and the distribution thereof to the public, except distribution piping.

"Zooplankton" means microscopic animals that float freely with voluntary movement in a body of water.

Statutory Authority: § 2.2-1105 of the Code of Virginia.

Historical Notes: Derived from Virginia Register Volume 25, Issue 7, eff. January 1, 2009; amended, Virginia Register Volume 29, Issue 4, eff. November 21, 2012; Volume 32, Issue 1, eff. November 1, 2015; Errata, 32:3 VA.R. 447 October 5, 2015.

1VAC30-46-50. Scope of accreditation.

A. Commercial environmental laboratories shall be accredited based on the general laboratory standards set out in Part II (1VAC30-46-200 et seq.) of this chapter and on the specific test methods or analysis, monitoring or measurement required by Virginia Air Pollution Control Law (§ 10.1-1300 et seq. of the Code of Virginia), Virginia Waste Management Act (§ 10.1-1400 et seq. of the Code of Virginia) or Virginia Water Control Law (§ 62.1-44.2 et seq. of the Code of Virginia), the regulations promulgated under these laws, and by permits and orders issued under and in accordance with these laws and regulations.

B. DCLS shall review alternative test methods and procedures for accreditation when these are proposed by the applicant laboratory. The provisions of 1VAC30-46-70 E and 1VAC30-46-90 B govern alternative test methods and procedures.

C. Accreditation shall be granted for one or more fields of accreditation, including the matrix, the technology and methods used by the commercial environmental laboratory, and the individual analytes determined by the particular method.

Statutory Authority: § 2.2-1105 of the Code of Virginia.

Historical Notes: Derived from Virginia Register Volume 25, Issue 7, eff. January 1, 2009; amended, Virginia Register Volume 32, Issue 1, eff. November 1, 2015.

1VAC30-46-60. General: accreditation requirements.

A. Components of accreditation. The components of accreditation include review of personnel qualifications, on-site assessment, proficiency testing and quality assurance and quality control standards. The criteria for these components, specified in Part II (1VAC30-46-200 et seq.) of this chapter, shall be fulfilled for accreditation.

B. Individual laboratory sites and mobile laboratories.

1. Individual laboratory sites are subject to the same application process, assessments, and other requirements as environmental laboratories. Any remote laboratory sites are considered separate sites and subject to separate on-site assessments.

2. Laboratories located at the same physical location shall be considered an individual laboratory site if these laboratories are owned by the same person, and have the same technical manager and quality system.

3. A mobile laboratory, which is configured with equipment to perform environmental analyses, whether associated with a fixed-based laboratory or not,

is considered an environmental laboratory and shall require separate accreditation. This accreditation shall remain with the mobile laboratory and be site independent. Moving the configured mobile laboratory to a different site shall not require a new or separate accreditation. Before performing analyses at each new site, the laboratory shall ensure that instruments and equipment have been checked for performance and have been calibrated.

Statutory Authority: § 2.2-1105 of the Code of Virginia.

Historical Notes: Derived from Virginia Register Volume 25, Issue 7, eff. January 1, 2009; amended, Virginia Register Volume 32, Issue 1, eff. November 1, 2015.

1VAC30-46-70. Process to apply and obtain accreditation.

A. Duty to apply. All owners of (i) commercial environmental laboratories and (ii) TNI-accredited commercial environmental laboratories applying for secondary accreditation shall apply for accreditation as specified by the provisions of this section. Applications for accreditation must be obtained from DCLS program staff by email at Lab_Cert@dgs.virginia.gov.

B. Initial applications. Owners of commercial environmental laboratories applying for accreditation under this chapter for the first time shall submit an application to DCLS as specified under subsection F of this section.

C. Renewal and reassessment.

1. DCLS shall renew accreditation annually for the accredited laboratory provided the laboratory does the following:

- a. Maintains compliance with this chapter.
- b. Attests to this compliance by signing the certificate of compliance provided under subdivision F 3 of this section.
- c. Reports acceptable proficiency test values as required by 1VAC30-46-210 B.
- d. Pays the fee required by 1VAC30-46-150.

2. DCLS shall reassess the accredited environmental laboratory during an on-site assessment as required by 1VAC30-46-220.

D. Responsibilities of the owner and operator when the laboratory is owned by one person and operated by another person.

1. When an environmental laboratory is owned by one person but is operated by another person, the operator may submit the application for the owner.
2. If the operator fails to submit the application, the owner is not relieved of his responsibility to apply for accreditation.
3. While DCLS may notify environmental laboratories of the date their applications are due, failure of DCLS to notify does not relieve the owner of his obligation to apply under this chapter.

E. Submission of applications for modifications to accreditation. An owner of an accredited environmental laboratory shall follow the process set out in 1VAC30-46-90 B to modify the laboratory's scope of accreditation.

F. Contents of application.

1. Applications shall include but not be limited to the following information and documents:

- a. Legal name of laboratory;
- b. Name of owner of laboratory;
- c. Name of operator of laboratory, if different than owner;
- d. Street address and description of location of laboratory;
- e. Mailing address of laboratory, if different from street address;
- f. Address of owner, if different from laboratory address;
- g. Name, address, telephone number, facsimile number and email, as applicable, of responsible official;
- h. Name, address, telephone number, facsimile number and email, as applicable, of technical manager;
- i. Name, address, telephone number, facsimile number and email, as applicable, of designated quality assurance officer;
- j. Name and telephone number of laboratory contact person;
- k. Laboratory type (e.g., commercial, public wastewater system, mobile);
- l. Laboratory hours of operation;
- m. Fields of accreditation for which the laboratory is seeking accreditation;
- n. The results of two successful unique TNI-compliant PT studies for each accreditation field of proficiency testing as required by 1VAC30-46-210 B (for primary accreditation only);
- o. Quality assurance manual (for primary accreditation only);
- p. Copy of the primary certificate of accreditation for secondary accreditation applications; and
- q. For mobile laboratories, a unique vehicle identification number, such as a manufacturer's vehicle identification number (VIN #), serial number, or license number.

2. Fee. The application shall include payment of the fee as specified in 1VAC30-46-150.

3. Certification of compliance.

a. The application shall include a "Certification of Compliance" statement signed and dated by (i) the quality assurance officer, and (ii) the responsible official or the technical manager, or both.

b. The certification of compliance shall state: "The applicant understands and acknowledges that the laboratory is required to be continually in compliance with the Virginia environmental laboratory accreditation program regulation (1VAC30 Chapter 46) and is subject to the provisions of 1VAC30-46-100 in the event of noncompliance. Specifically the applicant:

(1) Shall commit to fulfill continually the requirements for accreditation set by DCLS for the areas where accreditation is sought or granted.

(2) When requested, shall afford such accommodation and cooperation as is necessary to enable DCLS to verify fulfillment of requirements for accreditation. This applies to all premises where laboratory services take place.

(3) Shall provide access to information, documents, and records as necessary for the assessment and maintenance of the accreditation.

(4) Shall provide access to those documents that provide insight into the level of independence and impartiality of the laboratory from its related bodies, where applicable.

(5) Shall arrange the witnessing of laboratory services when requested by DCLS.

(6) Shall claim accreditation only with respect to the scope for which it has been granted accreditation.

(7) Shall pay fees as shall be determined by the accreditation body.

I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the laboratory or those persons directly responsible for gathering and evaluating the information, the information submitted is, to the best of my knowledge and belief, true, accurate and complete. Submitting false information or data shall result in denial or withdrawal of accreditation. I further certify that I am authorized to sign this application."

G. Completeness determination.

1. DCLS shall determine whether an application is complete and notify the laboratory of the result of such determination. DCLS shall provide this notice within 90 calendar days of its receipt of the application.

2. An application shall be determined complete if it contains all the information required pursuant to subsection F of this section and is sufficient to evaluate the laboratory prior to the on-site assessment. Designating an application complete does not preclude DCLS from requesting or accepting additional information.

3. If DCLS determines that an application is incomplete, the DCLS notification of such determination shall explain why the application is incomplete and specify the additional information needed to make the application complete.

4. If DCLS makes no determination within 90 calendar days of its receipt of either (i) the application or (ii) additional information, in the case of an application determined to be incomplete, the application shall be determined to be complete.

5. If the laboratory has not submitted the required additional information within 90 days of receiving a notice from DCLS requesting additional information, DCLS may inform the laboratory that the application cannot be processed. The laboratory may then submit a new application.

H. Grant of interim accreditation pending final determination on application.

1. DCLS shall grant interim accreditation status to laboratories applying initially

under the following conditions:

- a. The laboratory's application is determined to be complete;
 - b. The laboratory has satisfied all the requirements for accreditation, including all requests for additional information, with the exception of on-site assessment; and
 - c. DCLS is unable to schedule the on-site assessment within 120 days of its determination that the application is complete.
2. A laboratory with interim accreditation status shall have the same rights and status as a laboratory that has been granted accreditation by DCLS.
 3. Interim accreditation status shall not exceed 12 months.

I. On-site assessment. An on-site assessment shall be performed and the follow-up and reporting procedures for such assessments shall be completed in accordance with 1VAC30-46-220 prior to issuance of a final determination on accreditation.

J. Final determination on accreditation. Upon completion of the accreditation review process and corrective action, if any, DCLS shall grant accreditation in accordance with subsection K of this section or deny accreditation in accordance with subsection L of this section.

K. Grant of accreditation.

1. When a laboratory meets the requirements specified for receiving accreditation, DCLS shall issue a certificate to the laboratory. The certificate shall be sent to the technical manager, and the responsible official shall be notified.
2. The director of DCLS or his designee shall sign the certificate.
3. The certificate shall include the following information:
 - a. Name of owner of laboratory;
 - b. Name of operator of laboratory, if different from owner;
 - c. Name of responsible official;
 - d. Address and location of laboratory;
 - e. Laboratory identification number;
 - f. Fields of accreditation (matrix, technology/method and analyte) for which accreditation is granted;
 - g. Any addenda or attachments; and
 - h. Issuance date and expiration date.
4. TNI accreditation status.
 - a. Laboratories accredited under this chapter are accredited under the standards of TNI.
 - b. The certificate of accreditation shall contain the TNI insignia.
 - c. Accredited laboratories shall comply with the provisions of 1VAC30-46-130 with regard to the use of these certificates and their status as TNI-accredited laboratories.
5. The laboratory shall post the most recent certificate of accreditation and any addenda to the certificate issued by DCLS in a prominent place in the laboratory

facility.

6. Accreditation shall expire one year after the date on which accreditation is granted.

L. Denial of accreditation.

1. DCLS shall deny accreditation to an environmental laboratory in total if the laboratory is found to be falsifying any data or providing false information to support accreditation.

2. Denial of accreditation in total or in part.

a. DCLS may deny accreditation to an environmental laboratory in total or in part if the laboratory fails to do any of the following:

(1) Pay the required fees;

(2) Employ laboratory staff to meet the personnel qualifications as required by 1VAC30-46-210 A;

(3) Successfully analyze and report proficiency testing samples as required by 1VAC30-46-210 B;

(4) Submit a corrective action plan in accordance with 1VAC30-46-220 in response to a deficiency report from the on-site assessment team within the required 30 calendar days;

(5) Implement the corrective actions detailed in the corrective action plan within the time frame specified by DCLS;

(6) Pass required on-site assessment as specified in 1VAC30-46-220; or

(7) Implement a quality system as defined in 1VAC30-46-210 C.

b. DCLS may deny accreditation to an environmental laboratory in total or in part if the laboratory's application is not determined to be complete within 90 days following notification of incompleteness because the laboratory is delinquent in submitting information required by DCLS in accordance with this chapter.

c. DCLS may deny accreditation to an environmental laboratory in total or in part if the DCLS on-site assessment team is unable to carry out the on-site assessment pursuant to 1VAC30-46-220 because a representative of the environmental laboratory denied the team entry during the laboratory's normal business hours that it specified in the laboratory application.

3. DCLS shall follow the process specified in 1VAC30-46-110 when denying accreditation to an environmental laboratory.

M. Reapplication following denial of accreditation. DCLS shall not waive application fees for a laboratory reapplying for accreditation.

Statutory Authority: § 2.2-1105 of the Code of Virginia.

Historical Notes: Derived from Virginia Register Volume 25, Issue 7, eff. January 1, 2009; amended, Virginia Register Volume 32, Issue 1, eff. November 1, 2015; Errata, 32:3 VA.R. 447 October 5, 2015.

1VAC30-46-80. Maintaining accreditation.

A. Accreditation remains in effect until withdrawn by DCLS, withdrawn voluntarily at the written request of the accredited laboratory, or expiration of the accreditation period. To maintain accreditation, the accredited laboratory shall comply with the elements listed in this section and in 1VAC30-46-90.

B. Quality systems. A laboratory seeking to maintain accreditation under this regulation shall assure consistency and promote the use of quality assurance and quality control procedures. 1VAC30-46-210 C specifies the quality assurance and quality control requirements that shall be met to maintain accreditation. The laboratory shall establish and maintain a quality system based on these required elements.

C. Proficiency tests. Laboratories seeking to maintain accreditation under this regulation shall perform proficiency tests as required under 1VAC30-46-210 B.

D. Recordkeeping and retention. All laboratory records associated with accreditation parameters shall be kept as provided by the requirements for records under Part II (1VAC30-46-200 et seq.) of this chapter. These records shall be maintained for a minimum of five years unless designated for a longer period by another regulation or authority. All such records shall be available to DCLS upon request.

Statutory Authority: § 2.2-1105 of the Code of Virginia.

Historical Notes: Derived from Virginia Register Volume 25, Issue 7, eff. January 1, 2009; amended, Virginia Register Volume 32, Issue 1, eff. November 1, 2015.

1VAC30-46-90. Notifications and changes to accreditation elements and status.

A. Changes to key accreditation criteria. The accredited laboratory shall notify DCLS in writing of any changes in key accreditation criteria within 30 calendar days of the change. Key accreditation criteria are laboratory ownership (including legal, commercial, or organizational status), location, resources and premises, key personnel (including top management), major instrumentation, and quality system policies.

B. Changes to scope of accreditation.

1. DCLS may approve a laboratory's application to add a new matrix, technology, analyte, or test method to a laboratory's scope of accreditation or otherwise modify the laboratory's scope of accreditation by performing a data review.

2. To apply, the owner of the accredited laboratory shall submit the following to DCLS:

a. A written request signed by the owner that briefly summarizes the addition to be made to the laboratory's scope of accreditation.

b. Pertinent information demonstrating the laboratory's capability to perform the additional matrix, technology/method, or analyte, such as proficiency testing performance and quality control performance.

c. A written standard operating procedure covering the new matrix, technology/method, or analyte.

3. DCLS may approve a laboratory's application for modification to its scope of accreditation by performing a review of the application materials submitted, without an on-site assessment. The addition of a new technology or test method requiring the use of specific equipment may require an on-site assessment.

Other reviews of performance and documentation may be carried out by DCLS, depending on the modification for which the laboratory applies.

4. Within 90 calendar days of the receipt of the application from the accredited environmental laboratory, DCLS shall review and determine whether the proposed modification may be approved.

5. If the proposed modification to the laboratory's scope of accreditation is approved, DCLS shall amend the laboratory's certificate of accreditation.

6. DCLS shall not send the amended certificate of accreditation to the laboratory until DCLS receives the payment of the fee required under 1VAC30-46-150 E 1.

C. Change of ownership or location of laboratory.

1. The accredited laboratory shall submit a written notification to DCLS of the change of ownership or location of the laboratory within 30 calendar days of the change. This requirement pertaining to change of location does not apply to mobile laboratories.

2. Accreditation may be transferred when the legal status or ownership of an accredited laboratory changes as long as the transfer does not affect the laboratory's personnel, equipment, or organization.

3. If the laboratory's personnel, equipment, or organization are affected by the change of legal status or ownership, DCLS may require reaccreditation or reapplication in any or all of the categories for which the laboratory is accredited.

4. DCLS may require an on-site assessment depending on the nature of the change of legal status or ownership. DCLS shall determine the elements of any on-site assessment required.

5. When there is a change in ownership, the new owner of the accredited laboratory shall keep for a minimum of five years all records and analyses performed by the previous owner pertaining to accreditation. These records and analyses are subject to inspection by DCLS during this five-year period. This provision applies regardless of change of ownership, accountability or liability.

D. Voluntary withdrawal. Any environmental laboratory owner who wishes to withdraw the laboratory from its accreditation status or from being accredited, in total or in part, shall submit written notification to DCLS. DCLS shall provide the laboratory with a written notice of withdrawal.

Statutory Authority: § 2.2-1105 of the Code of Virginia.

Historical Notes: Derived from Virginia Register Volume 25, Issue 7, eff. January 1, 2009; amended, Virginia Register Volume 32, Issue 1, eff. November 1, 2015.

1VAC30-46-95. Suspension of accreditation.

A. Before withdrawing accreditation, DCLS may suspend accreditation from an environmental laboratory in total or in part to allow the laboratory time to correct the reason for which DCLS may withdraw accreditation. Suspension is limited to the reasons listed in subsection B of this section.

B. DCLS may suspend accreditation from an environmental laboratory in part or in

total when the laboratory has failed to do any of the following:

1. Participate in the proficiency testing program as required by 1VAC30-46-210 B.
2. Complete proficiency testing studies and maintain a history of at least two successful proficiency testing studies for each accredited field of testing out of the three most recent proficiency testing studies as defined in 1VAC30-46-210 B.
3. Maintain a quality system as defined in 1VAC30-46-210 C.
4. Employ staff that meets the personnel qualifications of 1VAC30-46-210 A.
5. Notify DCLS of any changes in key accreditation criteria as set forth in 1VAC30-46-90.

C. Process to suspend accreditation.

1. When DCLS determines that cause exists to suspend a laboratory, the agency shall send notification to the responsible official and the technical manager stating the agency's determination that the laboratory has failed to meet the 1VAC30-46 standards for one or more of the reasons listed in subsection B of this section. DCLS shall send the notification by certified mail.
2. In its notice, DCLS shall request the laboratory to notify DCLS in writing if the laboratory believes the agency is incorrect in its determination.
3. The notification shall state that the laboratory is required to take corrective action whenever a failure occurs and to document the corrective action. The notification shall require the laboratory to provide DCLS with documentation of the corrective action taken with regard to its failure to meet a standard under this chapter.
4. The notification shall state what the laboratory is required to do to restore its accreditation status and the time allowed to do so.
5. The environmental laboratory may proceed to correct the deficiencies for which DCLS has suspended the laboratory's accreditation.
6. Alternatively the laboratory may state in writing that DCLS is incorrect in its determination regarding suspension, giving specific reasons why the laboratory believes DCLS should not suspend accreditation.
7. With the exception of subdivision B 4 of this section, DCLS may allow the laboratory up to 60 days to correct the problem for which it may have its accreditation suspended.
8. DCLS shall set a date for suspension that follows the period provided under subdivision 7 of this subsection to restore accreditation.
9. If the laboratory does not correct its deficiencies within the time period allowed, DCLS shall suspend a laboratory in part or in total.
10. DCLS shall notify the laboratory by letter of its suspension status. DCLS shall send the notification by certified mail. DCLS shall also notify the pertinent Virginia state agency of the laboratory's suspension status.
11. The laboratory may provide information demonstrating why suspension is not warranted in accordance with the standard referenced in the initial DCLS

notification. If such information is not provided prior to the suspension date, the laboratory accepts the DCLS decision to suspend.

12. The laboratory has the right to due process as set forth in 1VAC30-46-110.

D. Responsibilities of the environmental laboratory and DCLS when accreditation has been suspended.

1. The term of suspension shall be limited to six months or the period of accreditation whichever is longer.

2. The environmental laboratory shall not continue to analyze samples or report analysis for the fields of accreditation for which DCLS has suspended accreditation.

3. The environmental laboratory shall retain accreditation for the fields of accreditation, methods, and analytes where it continues to meet the requirements of this chapter.

4. The laboratory's suspended accreditation status shall change to accredited when the laboratory demonstrates to DCLS that the laboratory has corrected the deficiency or deficiencies for which its accreditation was suspended.

5. An environmental laboratory with suspended accreditation shall not have to reapply for accreditation if the cause or causes for suspension are corrected within the term of suspension.

6. If the laboratory fails to correct the causes of suspension within the term of suspension, DCLS shall withdraw the laboratory's accreditation in total or in part.

Statutory Authority: § 2.2-1105 of the Code of Virginia.

Historical Notes: Derived from Virginia Register Volume 32, Issue 1, eff. November 1, 2015.

1VAC30-46-100. Withdrawal of accreditation.

A. DCLS shall withdraw accreditation from an environmental laboratory in total if the laboratory is found to be falsifying any data or providing false information to support accreditation.

B. DCLS may withdraw accreditation from an environmental laboratory in part or in total when the laboratory has failed to do any of the following:

1. Participate in the proficiency testing program as required by 1VAC30-46-210 B.

2. Complete proficiency testing studies and maintain a history of at least two successful proficiency testing studies for each affected accredited field of testing out of the three most recent proficiency testing studies as defined in 1VAC30-46-210 B.

3. Maintain a quality system as defined in 1VAC30-46-210 C.

4. Employ staff that meets the personnel qualifications of 1VAC30-46-210 A.

5. Submit an acceptable corrective action plan after two opportunities as specified in 1VAC30-46-220.

6. Implement corrective action specified in the laboratory's corrective action plan as set out under 1VAC30-46-220.

7. Notify DCLS of any changes in key accreditation criteria as set forth in 1VAC30-46-90.
8. Use correct and authorized references to the laboratory's accreditation status or that of DCLS in the laboratory's documentation and advertising as set forth in 1VAC30-46-130.
9. Allow a DCLS assessment team entry during normal business hours to conduct an on-site assessment required by 1VAC30-46-220.
10. Pay required fees specified in 1VAC30-46-150.

C. DCLS shall follow the process specified in 1VAC30-46-110 when withdrawing accreditation from an environmental laboratory.

D. Responsibilities of the environmental laboratory and DCLS when accreditation has been withdrawn.

1. Laboratories that lose their accreditation in full shall return their certificate to DCLS.
2. If a laboratory loses accreditation in part, DCLS shall issue a revised certificate to the laboratory.
3. The laboratory shall discontinue the use of all materials that contain either a reference to the environmental laboratory's past accreditation status or that display the TNI logo. These materials may include catalogs, advertising, business solicitations, proposals, quotations, laboratory analytical reports, or other materials.
4. The environmental laboratory shall not continue to analyze samples or report analyses for the fields of accreditation for which DCLS has withdrawn accreditation.

E. After correcting the reason or cause for the withdrawal of accreditation under 1VAC30-46-100 A or B, the laboratory owner may reapply for accreditation under 1VAC30-46-70 B and E.

Statutory Authority: § 2.2-1105 of the Code of Virginia.

Historical Notes: Derived from Virginia Register Volume 25, Issue 7, eff. January 1, 2009; amended, Virginia Register Volume 32, Issue 1, eff. November 1, 2015.

1VAC30-46-110. Procedures to deny or withdraw accreditation, and appeal procedures.

A. Notification.

1. If DCLS determines that cause exists to deny accreditation to or withdraw accreditation from an environmental laboratory, DCLS shall notify the environmental laboratory in writing of its determination. DCLS shall send this notification by certified mail to the responsible official and provide a copy to the technical manager of the environmental laboratory.
2. For denial of accreditation, the notice shall state that the laboratory has failed to meet the standards in 1VAC30-46 and shall specify one or more of the reasons for denial of accreditation under 1VAC30-46-70 L, providing a detailed

explanation of the basis for the denial of accreditation.

3. For withdrawal of accreditation, the notice shall state that the laboratory has failed to meet the standards in 1VAC30-46 and shall specify one or more of the reasons for withdrawal of accreditation under 1VAC30-46-100 A or B, providing a detailed explanation of the basis for the withdrawal of accreditation.

4. In its notice, DCLS shall request the laboratory to notify DCLS in writing if the laboratory believes the agency is incorrect in its determination.

5. If the laboratory believes DCLS to be incorrect in its determination, the laboratory shall provide DCLS with a detailed written demonstration of why DCLS should not deny or withdraw accreditation.

B. An environmental laboratory may appeal a final decision by DCLS to deny or withdraw accreditation pursuant to the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia).

C. The accreditation status of an environmental laboratory appealing withdrawal of accreditation shall not change pending the final decision of the appeals filed under the Virginia Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia) and Part 2A of the Rules of the Supreme Court of Virginia.

Statutory Authority: § 2.2-1105 of the Code of Virginia.

Historical Notes: Derived from Virginia Register Volume 25, Issue 7, eff. January 1, 2009; amended, Virginia Register Volume 32, Issue 1, eff. November 1, 2015.

1VAC30-46-120. Information about accredited environmental laboratories.

DCLS shall make available to the public information identifying the environmental laboratories that it has accredited under this chapter.

Statutory Authority: § 2.2-1105 of the Code of Virginia.

Historical Notes: Derived from Virginia Register Volume 25, Issue 7, eff. January 1, 2009; amended, Virginia Register Volume 32, Issue 1, eff. November 1, 2015.

1VAC30-46-130. Use of accreditation status by environmental laboratories accredited under this chapter.

A. The owner of an environmental laboratory accredited under this chapter shall not misrepresent the laboratory's fields of accreditation or its accreditation status on any document. This includes laboratory reports, catalogs, advertising, business solicitations, proposals, quotations or other materials.

B. Environmental laboratories accredited under this chapter shall comply with all of the following:

1. Post or display their most recent accreditation certificate or their fields of accreditation in a prominent place in the laboratory facility.
2. Make accurate statements concerning their fields of accreditation and accreditation status.
3. Accompany DCLS's name or the TNI logo or both with at least the phrase

"TNI-accredited" and the laboratory's identification number or other identifier when DCLS's name is used on general literature such as catalogs, advertising, business solicitations, proposals, quotations, laboratory analytical reports or other materials.

4. Not use their accreditation certificate, their accreditation status or the TNI logo to imply endorsement by DCLS.

C. The owners of laboratories accredited under this chapter who choose to (i) use DCLS's name; (ii) make reference to its TNI accreditation status; or (iii) use the TNI logo in any catalogs, advertising, business solicitations, proposals, quotations, laboratory analytical reports or other materials, shall comply with both of the following:

1. Distinguish between proposed testing for which the laboratory is accredited and the proposed testing for which the laboratory is not accredited.
2. Include the laboratory's identification number or other identifier.

Statutory Authority: § 2.2-1105 of the Code of Virginia.

Historical Notes: Derived from Virginia Register Volume 25, Issue 7, eff. January 1, 2009; amended, Virginia Register Volume 32, Issue 1, eff. November 1, 2015.

1VAC30-46-140. Secondary accreditation.

A. DCLS may grant secondary accreditation to an environmental laboratory that holds a current accreditation from another TNI-recognized primary accreditation body.

B. The owner of a TNI-accredited environmental laboratory that seeks accreditation under this chapter shall apply as specified in 1VAC30-46-70 with the exception of 1VAC30-46-70 F 1 n and o.

C. The owner of the applicant laboratory shall pay the fee required by 1VAC30-46-150.

D. DCLS shall not require a TNI-accredited environmental laboratory that seeks accreditation under this section to meet any additional proficiency testing, quality assurance, or on-site assessment requirements for the fields of accreditation for which the laboratory holds primary TNI accreditation.

E. DCLS shall consider only the current certificate of accreditation issued by the TNI-recognized primary accreditation body.

F. DCLS shall grant secondary accreditation for only the fields of accreditation offered under this chapter for which the laboratory holds current primary TNI accreditation.

Statutory Authority: § 2.2-1105 of the Code of Virginia.

Historical Notes: Derived from Virginia Register Volume 25, Issue 7, eff. January 1, 2009; amended, Virginia Register Volume 32, Issue 1, eff. November 1, 2015.

1VAC30-46-150. Fees.

A. General.

1. Environmental laboratories shall pay a fee with all applications, including

reapplications, for accreditation. DCLS shall not designate an application as complete until it receives payment of the fee.

2. Each accredited environmental laboratory shall pay an annual fee to maintain its accreditation. DCLS shall send an invoice to the accredited environmental laboratory.

3. An environmental laboratory applying for secondary accreditation under 1VAC30-46-140 shall pay the same fee as other laboratories subject to this chapter.

4. Fees shall be nonrefundable.

B. Fee computation.

1. Fees shall be applied on an annual basis.

2. Environmental laboratories shall pay the total of the base fee and the test category fees set out in subsections C and D of this section.

C. Base fee.

1. DCLS determines the base fee for a laboratory by taking into account both the total number of methods and the total number of field of accreditation matrices for which the laboratory would be accredited.

2. DCLS shall charge the base fees set out in Table 1. The base fee for a laboratory is located by first finding the row for the total number of methods to be accredited and then finding the box on that row located in the column headed by the total number of matrices to be accredited. For example, DCLS charges a base fee of \$1300 to a laboratory performing a total of eight methods for one matrix.

Number of Methods	One Matrix	Two Matrices	Three Matrices	Four or more Matrices
1 - 9	\$1300	\$1430	\$1575	\$1730
10 - 29	\$1400	\$1575	\$1750	\$1950
30 - 99	\$1550	\$1825	\$2150	\$2550
100 - 149	\$1650	\$1980	\$2375	\$2850
150+	\$1800	\$2250	\$2825	\$3525

D. Test category fees.

1. The test category fees cover the types of testing for which a laboratory may be accredited as specified in the laboratory's application or as accredited at the time of annual billing.

2. Fees shall be charged for each category of tests to be accredited.

3. Fees shall be charged for the total number of field of accreditation matrices to be accredited under the specific test category. For example, if a laboratory is performing inorganic chemistry for both nonpotable water and solid and chemical

matrices, the fee for this test category would be found in the column for two matrices.

4. The fee for each category includes one or more analytical methods unless otherwise specified.

5. Test category fees. DCLS shall charge the test category fees set out in Table 2. The test category fees for a laboratory are located by first finding the row with the total number of test methods for the test category to be accredited. The fee to be charged for the test category will be found on that row in the column headed by the total number of matrices to be accredited. A laboratory performing four test methods for bacteriology in both nonpotable and drinking water (two matrices) would be charged a test category fee of \$330.

TABLE 2: TEST CATEGORY FEES			
Test Category	Fees by Number of Matrices		
	One	Two	Three or More
Aquatic toxicity, acute methods only	\$400	N/A	N/A
Aquatic toxicity, acute and chronic methods	\$600	N/A	N/A
Oxygen demand	\$225	\$335	\$435
Bacteriology, 1 - 3 total methods	\$175	\$265	\$345
Bacteriology, 4 or more total methods	\$220	\$330	\$430
Physical, 1 - 5 total methods	\$175	\$265	\$345
Physical, 6 - 10 total methods	\$220	\$330	\$430
Physical, 11 or more total methods	\$275	\$415	\$540
Inorganic chemistry, 1 - 10 total methods	\$250	\$375	\$490
Inorganic chemistry, 11 - 20 total methods	\$315	\$475	\$620
Inorganic chemistry, 21 - 49 total methods	\$394	\$590	\$767
Inorganic chemistry, 50 or more total methods	\$492	\$740	\$962
Chemistry metals, 1 - 5 total methods	\$325	\$490	\$637
Chemistry metals, 6 - 20 total methods	\$410	\$615	\$800
Chemistry metals, 21 or more total methods	\$512	\$770	\$1000
Organic chemistry, 1 - 5 total methods	\$400	\$600	\$780
Organic chemistry, 6 - 20 total methods	\$500	\$750	\$975
Organic chemistry, 21 - 40 total methods	\$625	\$940	\$1222

Organic chemistry, 41 or more total methods	\$780	\$1170	\$1520
Radiochemical, 1 - 10 total methods	\$600	\$900	\$1170
Radiochemical, 11 or more total methods	\$725	\$1090	\$1420
Asbestos	\$725	\$1090	\$1420

6. Fee examples. Three examples are provided.

a. Example 1:

Base Fee	One matrix and four test methods	\$1300
Test Category Fees		
One Matrix		
Nonpotable Water	Bacteriology (2 methods)	\$175
Nonpotable Water	Oxygen demand (1 method)	\$225
Nonpotable Water	Physical (1 method)	\$175
TOTAL		\$1875

b. Example 2:

Base Fee	One matrix and 15 test methods	\$1400
Test Category Fees		
One Matrix		
Nonpotable Water	Bacteriology (2 methods)	\$175
Nonpotable Water	Inorganic chemistry (9 methods)	\$250
Nonpotable Water	Metals (2 methods)	\$325
Nonpotable Water	Oxygen demand (1 method)	\$225
Nonpotable Water	Physical (1 method)	\$175
TOTAL		\$2550

c. Example 3:

Base Fee	Two matrices and 27 test methods	\$1575
Test Category Fees		
One Matrix		
Nonpotable Water	Bacteriology (4 methods)	\$220
Nonpotable Water	Oxygen demand (1 method)	\$225
Solid and Chemical Materials	Metals (1 method)	\$325

Two Matrices		
Nonpotable Water and Solid and Chemical Materials	Inorganic chemistry (13 methods)	\$475
Nonpotable Water and Solid and Chemical Materials	Physical (7 methods)	\$330
TOTAL		\$3150

E. Additional fees. Additional fees shall be charged to laboratories applying for the following: (i) modification to scope of accreditation under 1VAC30-46-90 B, (ii) transfer of ownership under 1VAC30-46-90 C, or (iii) petition for a variance under 1VAC30-46-160.

1. For any accredited environmental laboratory that applies to modify its scope of accreditation as specified under 1VAC30-46-90 B, DCLS shall assess a fee determined by the method in subsection F of this section.

2. Under 1VAC30-46-90 C, DCLS may charge a transfer fee to a certified laboratory that transfers ownership. A fee shall be charged if DCLS (i) needs to review documentation sent by the laboratory about the transfer of ownership or (ii) determines that an on-site assessment is necessary to evaluate the effect of the transfer of ownership. DCLS shall assess a fee determined by the method in subsection F of this section. If, under 1VAC30-46-90 C, DCLS determines that the change of ownership or location of laboratory requires reaccreditation of or reapplication by the laboratory, the laboratory shall pay the application fee required under this section.

3. Under 1VAC30-46-160, any person regulated by this chapter may petition the director to grant a variance from any requirement of this chapter. DCLS shall charge a fee for the time needed to review the petition, including any on-site assessment required. The fee shall be determined by the method specified in subsection F of this section.

F. Additional fees determination.

1. The fee shall be the sum of the total hourly charges for all reviewers plus any on-site review costs incurred.

2. An hourly charge per reviewer shall be determined by (i) obtaining a yearly cost by multiplying the reviewer's annual salary by 1.35 (accounts for overhead such as taxes and insurance) and then (ii) dividing the yearly cost by 1,642 (number of annual hours established by Fiscal Services, DGS, for billing purposes).

3. The charge per reviewer shall be determined by multiplying the number of hours expended in the review by the reviewer's hourly charge.

4. If an on-site review is required, travel time and on-site review time shall be charged at the same hourly charge per reviewer, and any travel expenses shall be added.

G. Out-of-state laboratories applying for primary accreditation.

1. The owner of an environmental laboratory located in another state who applies for primary accreditation under this chapter shall pay a surcharge of \$5000 plus the labor costs of the on-site assessment and reasonable travel costs associated with conducting an on-site assessment at the laboratory. Reasonable travel costs include transportation, lodging, per diem, and telephone and duplication charges. These charges shall be in addition to the fees charged under subdivision A 1 and subsections B through D of this section.

2. Once the laboratory is accredited, DCLS shall charge the annual fee specified in subdivision A 2 and subsections B through D of this section, the labor costs for the on-site assessment, and reasonable travel costs associated with conducting the on-site assessment.

H. DCLS shall derive the travel costs charged under subsections F and G of this section from the Commonwealth of Virginia reimbursement allowances and rates for lodging, per diem, and mileage.

Statutory Authority: § 2.2-1105 of the Code of Virginia.

Historical Notes: Derived from Virginia Register Volume 25, Issue 7, eff. January 1, 2009; amended, Virginia Register Volume 32, Issue 1, eff. November 1, 2015.

1VAC30-46-160. Petitioning for a variance.

A. Any person regulated by this chapter may petition the director to grant a variance from any requirement of this chapter. Any person submitting a petition to the director shall meet the provisions of this section. Any petition submitted to the director is subject to the Virginia Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia).

B. The petition shall be submitted to the director by certified mail and shall include:

1. The petitioner's name and address;
2. A statement of the petitioner's interest in the proposed action;
3. A description of desired action and a citation of the regulation from which a variance is requested;
4. A description of need and justification for the proposed action, including impact of the proposed action on the laboratory's operation;
5. Information demonstrating that the requested variance will meet the purposes and objectives of the relevant regulatory provision and of § 2.2-1105 of the Code of Virginia (Environmental Laboratory Certification Program);
6. The duration of the variance, if applicable;
7. The potential impact of the variance on public health or the environment;
8. Other information believed by the applicant to be pertinent; and
9. The following statement signed by the petitioner or authorized representative: "I certify that I have personally examined and am familiar with the information submitted in this petition and all attached documents, and that, based on my inquiry of those individuals immediately responsible for obtaining the information, I believe that the submitted information is true, accurate, and complete. I am

aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment."

C. Petition processing.

1. After receiving a petition that includes the information required in subsection B of this section, the director will determine whether the information received is sufficient to render the decision. If the information is deemed insufficient, the director will specify additional information needed and request that it be furnished.

2. The petitioner may submit the additional information requested, or may attempt to show that no reasonable basis exists for additional information. If the director agrees that no reasonable basis exists for the request for additional information, he will act in accordance with subsection D of this section. If the director finds that a reasonable basis exists to require the submission of such information, he will proceed with the denial action in accordance with the Administrative Process Act.

D. Public review of tentative decision. The director will evaluate the application and issue a draft notice tentatively denying the petition, granting the variance as requested, or granting a modified or partial variance. Notification of this tentative decision will be published in the Virginia Register of Regulations. The director will accept comment on the tentative decision for 30 days, and shall hold a public hearing if a request is received or at his discretion if there is no request. The director will issue a final decision after receipt of comments and after the hearing (if any).

E. Conditions for granting variance request or a modified variance.

1. The director may grant the variance if the applicant demonstrates to the satisfaction of the director that:

a. The proposed variance will meet the goals and purposes of the provisions from which a variance is sought; and

b. The variance does not conflict with federal or state law or regulations.

2. If the director grants a variance request, the notice to the petitioner shall provide that the variance may be terminated upon a finding by the director that the petitioner has failed to comply with any requirements of the variance.

3. When a modified variance is granted, the director may:

a. Specify the termination date of the variance;

b. Include a schedule for:

(1) Compliance, including increments of progress, by the laboratory with each requirement of the variance; and

(2) Implementation by the laboratory of such measures as the director finds necessary in order that the variance may be granted.

F. Decisions to grant or deny a petition in whole or in part, or to modify or terminate a variance are subject to the provisions of Article 3 (§ 2.2-4018 et seq.) of the Virginia Administrative Process Act.

Statutory Authority: § 2.2-1105 of the Code of Virginia.

Historical Notes: Derived from Virginia Register Volume 25, Issue 7, eff. January 1, 2009; Errata, 25:1 VA.R. 96 September 15, 2008.

1VAC30-46-170. (Reserved.)

Historical Notes: Derived from Virginia Register Volume 25, Issue 7, eff. January 1, 2009.

1VAC30-46-180. (Reserved.)

Historical Notes: Derived from Virginia Register Volume 25, Issue 7, eff. January 1, 2009.

1VAC30-46-190. (Reserved.)

Historical Notes: Derived from Virginia Register Volume 25, Issue 7, eff. January 1, 2009.

Part II
Standards

1VAC30-46-200. Incorporation by reference of TNI standards.

A. The following TNI standards are incorporated by reference into this chapter: The Standards for Environmental Laboratories and Accreditation Bodies, 2009 (The NELAC Institute (TNI)), Volume 1: Management and Technical Requirements for Laboratories Performing Environmental Analysis, and Volume 2: General Requirements for Accreditation Bodies Accrediting Environmental Laboratories, except for section 6.6 of Module 3 concerning confidential business information.

B. Environmental laboratories applying for accreditation and accredited under this chapter shall comply with the TNI standards incorporated by reference into subsection A of this section. For convenience these standards are specified by accreditation component in 1VAC30-46-210 and 1VAC30-46-220.

C. The TNI standards are organized by volume and module.

1. Volume 1 - Management and Technical Requirements for Laboratories Performing Environmental Analysis includes the following modules:

- a. Proficiency Testing.
- b. Quality Systems General Requirements.
- c. Quality Systems for Asbestos Testing.
- d. Quality Systems for Chemical Testing.
- e. Quality Systems for Microbiological Testing.
- f. Quality Systems for Radiochemical Testing.
- g. Quality Systems for Toxicity Testing.

2. Volume 2 - General Requirements for Accreditation Bodies Accrediting Environmental Laboratories includes the following modules:

- a. General Requirements.
- b. Proficiency Testing.
- c. On-Site Assessment.

Statutory Authority: § 2.2-1105 of the Code of Virginia.

Historical Notes: Derived from Virginia Register Volume 25, Issue 7, eff. January 1, 2009; amended, Virginia Register Volume 32, Issue 1, eff. November 1, 2015.

1VAC30-46-210. Standards for accreditation.

A. Standards for personnel. The standards for personnel are found in Section 5.2 of Volume 1, Module 2 of the TNI standards.

B. Standards for proficiency testing.

1. The standards for proficiency testing are found in (i) Module 1 and (ii) section 4.11 of Module 2 of Volume 1 of the TNI standards.

2. Additional requirements from Volume 2, Module 2 of the TNI standards.

a. A laboratory shall perform two proficiency test studies each calendar year for each FoPT. These proficiency testing studies shall be performed at least five months apart and no longer than seven months apart within the calendar year.

b. The following proficiency testing studies shall not apply when meeting the requirements of subdivision 2 a of this subsection:

(1) Studies used for corrective action to reestablish successful history in order to maintain accreditation; and

(2) Studies used to reinstate accreditation after DCLS suspends accreditation.

c. DCLS shall consider a laboratory's analytical result for a FoPT not acceptable for the following reasons:

(1) When the laboratory does not report the results within the time frames specified in Volume 1, Module 1 of the TNI standards.

(2) When the laboratory makes any reporting error or omission that results in a nonspecific match between the analytical result for the FoPT and any criterion that identifies the laboratory or the field of accreditation for which the PT sample was analyzed for the purpose of initial or continued accreditation.

d. If DCLS requests a corrective action plan from a laboratory, the laboratory shall provide the plan within 30 calendar days of the request.

e. A laboratory may withdraw from a study for any FoPT on or before the close date of the study. Withdrawing from a study shall not exempt the laboratory from meeting the semiannual analysis requirements necessary for continued accreditation.

C. Standards for quality systems.

1. General requirements for all environmental laboratories are found in Volume 1, Module 2 of the TNI standards.

2. Requirements for the specific types of testing that may be performed by an individual environmental laboratory are found in Volume 1, Modules 3 through 7 of the TNI standards.

3. Drinking water laboratories obtaining certification under this chapter shall meet

the reporting requirements set out in 1VAC30-41 for compliance with 12VAC5-590-530 and 12VAC5-590-540.

Statutory Authority: § 2.2-1105 of the Code of Virginia.

Historical Notes: Derived from Virginia Register Volume 25, Issue 7, eff. January 1, 2009; amended, Virginia Register Volume 32, Issue 1, eff. November 1, 2015.

1VAC30-46-220. On-site assessment.

A. The standards for on-site assessment are found in Volume 2, Module 3 of the TNI standards. The requirements specific to environmental laboratories are set out in this section.

B. DCLS shall conduct a comprehensive on-site assessment of an environmental laboratory prior to granting final primary accreditation to the laboratory.

C. Frequency of on-site assessment.

1. DCLS shall reassess each accredited laboratory every two years starting from the date of the previous assessment plus or minus six months.

2. Other on-site assessments.

a. If DCLS identified a deficiency on a previous on-site assessment, the agency may conduct a follow-up on-site assessment.

b. DCLS may conduct an on-site assessment under the following circumstances:

(1) A laboratory applies to modify its scope of accreditation;

(2) A transfer of ownership occurs that affects personnel, equipment, or the laboratory facilities; or

(3) A laboratory applies for an exemption or a variance.

c. 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.

D. Announced and unannounced on-site assessments. DCLS, at its discretion, may conduct either announced or unannounced on-site assessments. Advance notice of an assessment shall not be necessary.

E. Preparation for the on-site assessment.

1. Prior to the actual site visit, DCLS may request in writing from a laboratory those records required to be maintained by this chapter.

2. DCLS may opt not to proceed with an on-site assessment based on nonconformities found during document and record review.

F. Areas to be assessed.

1. DCLS shall assess the laboratory against the standards incorporated by reference and specified in 1VAC30-46-200 and 1VAC30-46-210.

2. The laboratory shall ensure that its quality manual, analytical methods, quality control data, proficiency test data, laboratory SOPs, and all records needed to verify compliance with the standards specified in 1VAC30-46-200 and 1VAC30-

46-210 are available for review during the on-site assessment.

G. National security considerations.

1. Assessments at facilities owned or operated by federal agencies or contractors may require security clearances, appropriate badging, or a security briefing before the assessment begins.

2. The laboratory shall notify DCLS in writing of any information that is controlled for national security reasons and cannot be released to the public.

H. Arrival, admittance, and opening conference.

1. Arrival. DCLS and the laboratory shall agree to the date and schedule for announced on-site assessments.

2. Admittance of assessment personnel. A laboratory's refusal to admit the assessment personnel for an on-site assessment shall result in an automatic failure of the laboratory to receive accreditation or loss of an existing accreditation by the laboratory, unless there are extenuating circumstances that are accepted and documented by DCLS.

3. Health and safety. Under no circumstance, and especially as a precondition to gain access to a laboratory, shall assessment personnel be required or even allowed to sign any waiver of responsibility on the part of the laboratory for injuries incurred during an assessment.

4. Opening conference. An opening conference shall be conducted and shall address the following topics:

a. The purpose of the assessment;

b. The identification of assessment personnel;

c. The test methods that will be examined;

d. Any pertinent records and procedures to be examined during the assessment and the names of the individuals in the laboratory responsible for providing assessment personnel with such records;

e. The roles and responsibilities of laboratory staff and managers;

f. Any special safety procedures that the laboratory may think necessary for the protection of assessment personnel;

g. The standards and criteria that will be used in judging the adequacy of the laboratory operation;

h. Confirmation of the tentative time for the exit conference; and

i. Discussion of any questions the laboratory may have about the assessment process.

I. On-site laboratory records review and collection.

1. Records shall be reviewed by assessment personnel for accuracy, completeness, and the use of proper methodology for each analyte and test method to be evaluated.

2. Records required to be maintained pursuant to this chapter shall be examined as part of an assessment for accreditation.

J. Observations of and interviews with laboratory personnel.

1. As an element of the assessment process, the assessment team shall evaluate an analysis regimen by requesting that the analyst normally conducting the procedure give a step-by-step description of exactly what is done and what equipment and supplies are needed to complete the regimen. Any deficiencies shall be noted and discussed with the analyst. In addition, the deficiencies shall be discussed in the closing conference.
2. Assessment personnel may conduct interviews with appropriate laboratory personnel.
3. Calculations, data transfers, calibration procedures, quality control and quality assurance practices, adherence to test methods, and report preparation shall be assessed for the complete scope of accreditation with appropriate laboratory analysts.

K. Closing conference.

1. Assessment personnel shall meet with representatives of the laboratory following the assessment for a closing conference.
2. During the closing conference, assessment personnel shall inform the laboratory of the preliminary findings and the basis for such findings. The laboratory shall have an opportunity to provide further explanation or clarification relevant to the preliminary findings. If the laboratory objects to the preliminary findings during the closing conference, all objections shall be documented by the assessment personnel and included in the final report to DCLS.
3. Additional problem areas may be identified in the final report.

L. Follow-up and reporting procedures.

1. DCLS shall provide an on-site assessment report to the laboratory documenting any deficiencies found by DCLS within 30 calendar days of the last day of the on-site assessment.
2. When deficiencies are identified in the assessment report, the laboratory shall have 30 calendar days from the date of its receipt of the on-site assessment report to provide a corrective action plan to DCLS.
3. The laboratory's corrective action plan shall include the following:
 - a. Any objections that the laboratory has with regard to the on-site assessment report;
 - b. The action that the laboratory proposes to correct each deficiency identified in the assessment report;
 - c. The time period required to accomplish the corrective action; and
 - d. Documentation of corrective action that the laboratory has already completed at the time the corrective action plan is submitted.
4. If the corrective action plan, or a portion of the plan, is determined to be unacceptable to remedy the deficiency, DCLS shall provide written notification to the responsible official and technical manager of the laboratory, including a detailed explanation of the basis for such determination. Following receipt of such notification, the laboratory shall have an additional 30 calendar days to submit a revised corrective action plan acceptable to DCLS.

5. DCLS may withdraw accreditation from a laboratory under 1VAC30-46-100 B 5 if DCLS finds the second revised corrective action plan to be unacceptable.
6. The laboratory shall submit documentation to DCLS that the corrective action set out in its plan has been completed within the time period specified in the plan.
7. DCLS, under 1VAC30-46-100 B 6, may withdraw accreditation from a laboratory if the laboratory fails to implement the corrective actions set out in its corrective action plan.
8. DCLS shall grant final accreditation as specified in 1VAC30-46-70 K upon successful completion of any required corrective action following the on-site assessment.

Statutory Authority: § 2.2-1105 of the Code of Virginia.

Historical Notes: Derived from Virginia Register Volume 32, Issue 1, eff. November 1, 2015.

FORMS (1VAC30-46)

Application for Accreditation under 1VAC30-46 - must be obtained from DCLS program staff at Lab_Cert@dgs.virginia.gov

DOCUMENTS INCORPORATED BY REFERENCE (1VAC30-46)

The Standards for Environmental Laboratories and Accreditation Bodies, 2009, The NELAC Institute (TNI), P.O. Box 2439, Weatherford, TX 76086; www.nelac-institute.org:
[Volume 1: Management and Technical Requirements for Laboratories Performing Environmental Analysis \(EL-V1-2009\)](#)
[Volume 2: General Requirements for Accreditation Bodies Accrediting Environmental Laboratories \(EL-V2-2009\)](#)
