

Virginia Administrative Code

Database updated through September 5, 2016

CHAPTER 45

CERTIFICATION FOR NONCOMMERCIAL ENVIRONMENTAL LABORATORIES

Part I General Provisions

1VAC30-45-10. 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 noncommercial environmental laboratories may obtain certification for their laboratories.

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 22, eff. September 1, 2016.

1VAC30-45-20. Establishment of certification program.

A. Once the certification program has been established, laboratory certification shall be required before any environmental analyses performed by a noncommercial 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 certification 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.

1VAC30-45-30. Applicability.

A. This chapter applies to any owner of a noncommercial environmental laboratory.

B. Any environmental laboratory owned by an agency of the federal government may be certified as follows:

1. By DCLS to the standards set out in this chapter; or
2. By a federal primary accreditation body to the standards established by TNI.

C. Citizen monitoring groups. Section 62.1-44.19:11 of the Code of Virginia both establishes a citizen water quality monitoring program for Virginia and encourages the growth of the program. The Department of Environmental Quality (DEQ) has a separate program of quality assurance and quality control (QA/QC) standards for citizen

monitoring groups and their laboratories to follow. The following laboratories shall meet the DEQ QA/QC requirements developed for the purposes of citizen monitoring of water quality in lieu of the requirements of 1VAC30-45 or 1VAC30-46:

1. Laboratories owned by citizen monitoring groups.
2. Laboratories at institutions of higher education affiliated with citizen monitoring groups for the purposes of analyzing samples for the groups.

D. Institutions of higher education. Environmental laboratories owned by institutions of higher education located in Virginia that perform analyses for the purpose of providing environmental research data to DEQ at DEQ's request shall meet the QA/QC requirements specified by DEQ. An environmental laboratory owned by an institution of higher education located in Virginia that performs environmental research for DEQ shall not be subject to the requirements of either 1VAC30-45 or 1VAC30-46 unless DEQ requires the laboratory to do so.

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 22, eff. September 1, 2016.

1VAC30-45-40. Definitions.

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.

"Accuracy" means the degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components that are due to sampling and analytical operations. Accuracy is an indicator of data quality.

"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).

"Aliquot" means a portion of a sample taken for analysis.

"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.

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

"Audit" means a systematic evaluation to determine the conformance to quantitative and qualitative specifications of some operational function or activity.

"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.

"Batch" means environmental samples that are prepared together or analyzed together or both with the same process and personnel, using the same lot or lots of reagents. "Analytical batch" means a batch composed of prepared environmental samples (extracts, digestates or concentrates) that are analyzed together as a group. An analytical batch can include prepared samples originating from various environmental matrices and can exceed 20 samples. "Preparation batch" means a batch composed of one to 20 environmental samples of the same matrix that meets the criteria in this definition for "batch" and with a maximum time between the start of processing of the first and last sample in the batch to be 24 hours.

"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.

"Blank" means a sample that has not been exposed to the analyzed sample stream in order to monitor contamination during sampling, transport, storage or analysis. The blank is subjected to the usual analytical and measurement process to establish a zero baseline or background value and is sometimes used to adjust or correct routine analytical results. Blanks include the following types:

1. Field blank. A blank prepared in the field by filling a clean container with pure deionized water and appropriate preservative, if any, for the specific sampling activity being undertaken.
2. Method blank. A sample of a matrix similar to the batch of associated samples (when available) that is free from the analytes of interest and is processed simultaneously with and under the same conditions as samples through all steps of the analytical procedures, and in which no target analytes or interferences are present at concentrations that impact the analytical results for sample analyses.

"Calibration" means to determine, by measurement or comparison with a standard, the correct value of each scale reading on a meter, instrument or other device. The levels of the applied calibration standard should bracket the range of planned or expected sample measurements.

"Calibration curve" means the graphical relationship between the known values, such as concentrations, of a series of calibration standards and their instrument response.

"Calibration standard" means a substance or reference material used to calibrate an instrument.

"Certified reference material" means a reference material one or more of whose property values are certified by a technically valid procedure, accompanied by or traceable to a certificate or other documentation that is issued by a certifying body.

"Client" or "customer" means the Department of Environmental Quality (DEQ) when used in the context of quality assurance and specific quality control provisions.

"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.

"Demonstration of capability" means the procedure to establish the ability of the analyst to generate data of acceptable accuracy and precision.

"Detection limit" means the lowest concentration or amount of the target analyte that can be determined to be different from zero by a single measurement at a stated degree of confidence.

"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 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 1VAC30-46 and the certification program to be established under this chapter.

"Establishment of certification program" or "established program" means that DCLS has completed the initial accreditation of environmental laboratories covered by 1VAC30-46 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 certification" or "FoC" means those matrix, technology/method, and analyte combinations for which DCLS offers certification.

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

"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 certification standard and supported by objective evidence that identifies a deviation from a laboratory certification 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.

"International System of Units (SI)" means the coherent system of units adopted and recommended by the General Conference on Weights and Measures.

"Laboratory control sample" or "LCS" means 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. It is generally used to establish intra-laboratory or analyst specific precision and bias or to assess the performance of all or a portion of the measurement system. "Laboratory control sample" or "LCS" may also be named laboratory fortified blank, spiked blank, or QC check sample.

"Laboratory manager" 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 director, laboratory supervisor or laboratory manager.

"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.

"Limit of detection" or "LOD" means 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.

"Limit of quantitation" or "LOQ" means the minimum levels, concentrations, or quantities of a target variable (e.g., target analyte) that can be reported with a specified degree of confidence.

"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 component or substrate that may contain the analyte of interest. A matrix can be a field of certification matrix or a quality system matrix.

1. Field of certification matrix. These matrix definitions shall be used when certifying a laboratory.

a. Nonpotable water. Any aqueous sample that has not been designated a potable or potential potable water source. Includes surface water, groundwater, effluents, water treatment chemicals, and TCLP or other extracts.

b. Solid and chemical materials. Includes soils, sediments, sludges, products and byproducts of an industrial process that results in a matrix not previously defined.

c. Biological tissue. Any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origin.

d. 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. Quality system matrix. For purposes of batch and quality control requirement determinations, the following matrix types shall be used:

a. Drinking water. Any aqueous sample that has been designated a potable or potential potable water source.

b. 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.

c. Saline/estuarine. Any aqueous sample from an ocean or estuary, or other salt water source.

d. Nonaqueous liquid. Any organic liquid with less than 15% settleable solids.

e. Biological tissue. Any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origin.

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

g. Chemical waste. A product or byproduct of an industrial process that results in a matrix not previously defined.

h. 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.

"Matrix spike (spiked sample or fortified sample)" means a sample prepared by adding a known mass of target analyte to a specified amount of matrix sample for which an independent estimate of target analyte concentration is available. Matrix spikes are used, for example, to determine the effect of the matrix on a method's recovery efficiency.

"Matrix spike duplicate (spiked sample or fortified sample duplicate)" means a second replicate matrix spike prepared in the laboratory and analyzed to obtain a measure of the precision of the recovery for each analyte.

"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.

"National Institute of Standards and Technology" or "NIST" means an agency of the U.S. Department of Commerce's Technology Administration that is working with EPA, states, NELAC, and other public and commercial entities to establish a system under which private sector companies and interested states can be certified by NIST to provide NIST-traceable proficiency testing (PT) samples.

"Negative control" means measures taken to ensure that a test, its components, or the environment do not cause undesired effects, or produce incorrect test results.

"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.

"Positive control" means measures taken to ensure that a test or its components are working properly and producing correct or expected results from positive test subjects.

"Precision" means the degree to which a set of observations or measurements of the same property, obtained under similar conditions, conform to themselves. Precision is an indicator of data quality. Precision is expressed usually as standard deviation, variance or range, in either absolute or relative terms.

"Primary accreditation body" 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 or testing (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 (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 (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.

"Program," in the context of a regulatory program, means the relevant U.S. Environmental Protection Agency program such as the water program under the Clean Water Act (CWA), the air program under the Clean Air Act (CAA), the waste program under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA or Superfund) or the waste program under the Resource Conservation and Recovery Act (RCRA).

"Publicly Owned Treatment Works (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 laboratory manager.

"Quality control" or "QC" means the 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; operational techniques and activities that are used to fulfill requirements for quality; and also the 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.

"Range" means the difference between the minimum and maximum of a set of values.

"Reference material" means a material or substance one or more properties of which are sufficiently well established to be used for the calibration of an apparatus, the assessment of a measurement test method, or for assigning values to materials.

"Reference standard" means a standard, generally of the highest metrological quality available at a given location, from which measurements made at that location are derived.

"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 environmental 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 environmental 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.

"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.

"Simple test procedures" or "STP" means any of the following:

1. Field testing and measurement performed in an environmental laboratory.
2. The test procedures to determine:
 - a. Biochemical oxygen demand (BOD) or carbonaceous BOD (CBOD);
 - b. Fecal coliform;
 - c. Total coliform;
 - d. Fecal streptococci;
 - e. E. coli;
 - f. Enterococci;
 - g. Settleable solids (SS);
 - h. Total dissolved solids (TDS);
 - i. Total solids (TS);
 - j. Total suspended solids (TSS);
 - k. Total volatile solids (TVS); and
 - l. Total volatile suspended solids (TVSS).

"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.

"Standardized reference material" or "SRM" means a certified reference material produced by the U.S. National Institute of Standards and Technology or other

equivalent organization and characterized for absolute content, independent of analytical method.

"System laboratory" means a noncommercial laboratory that analyzes samples from multiple facilities having the same owner.

"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.); 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.); 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.); 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" or "TNI" means the organization whose standards environmental laboratories must meet to become accredited under 1VAC30-46, the regulation governing commercial environmental laboratories in Virginia.

"Toxicity characteristic leachate procedure" or "TCLP" 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).

"Traceability" means the property of a result of a measurement whereby it can be related to appropriate standards, generally international or national standards, through an unbroken chain of comparisons.

"U.S. Environmental Protection Agency" or "EPA" means the federal government agency with responsibility for protecting, safeguarding and improving the natural environment (i.e., air, water and land) upon which human life depends.

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

"Virginia Environmental Laboratory Accreditation Program" or "VELAP" means the program DCLS operates to certify 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 22, eff. September 1, 2016.

1VAC30-45-50. Scope of certification.

A. Noncommercial environmental laboratories shall be certified based on the general laboratory standards set out in Part II (1VAC30-45-200 et seq.) of this chapter and on the specific test methods or analysis, monitoring or measurement required by regulatory permit or other requirement under the Virginia Air Pollution Control Law, Virginia Waste Management Act, or Virginia Water Control Law, the regulations promulgated under these laws, and by permits and orders issued under and in accordance with these laws or regulations.

B. DCLS shall review alternative test methods and procedures for certification when these are proposed by the applicant laboratory. The provisions of 1VAC30-45-70 E and 1VAC30-45-90 B govern alternative test methods and procedures.

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

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 22, eff. September 1, 2016.

1VAC30-45-60. General: certification requirements.

A. Components of certification. The components of certification include review of personnel qualifications, on-site assessment, proficiency testing, and quality systems. The criteria for these components, set out in Part II (1VAC30-45-200 et seq.) of this chapter, shall be fulfilled for certification.

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 laboratory manager and quality system.

3. A mobile laboratory, which is configured with equipment to perform analyses, whether associated with a fixed-based laboratory or not, is considered an environmental laboratory and shall require separate certification. This certification shall remain with the mobile laboratory and be site independent. Moving the configured mobile laboratory to a different site will not require a new or separate certification. 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 22, eff. September 1, 2016.

1VAC30-45-70. Process to apply and obtain certification.

A. Duty to apply. All owners of noncommercial environmental laboratories shall apply for certification as specified by the provisions of this section. Applications for certification must be obtained from DCLS program staff by email at Lab_Cert@dgs.virginia.gov.

B. Owners of noncommercial environmental laboratories applying for certification 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 certification annually for the certified 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 Article 3 (1VAC30-45-500 et seq.) of Part II of this chapter.

d. Pays the fee required by 1VAC30-45-130.

2. DCLS shall reassess the certified environmental laboratory during an on-site assessment as required by Article 2 (1VAC30-45-300 et seq.) of Part II of this chapter.

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 certification.

3. While DCLS may notify noncommercial 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 certification. An owner of a certified noncommercial environmental laboratory shall follow the process set out in 1VAC30-45-90 B to modify the laboratory's scope of certification.

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 laboratory 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., public water system, public wastewater system or combination of the two, or industrial (with type of industry indicated));
 - l. Laboratory hours of operation;
 - m. Fields of certification (matrix, technology/method, and analyte) for which certification is sought;
 - n. The results of one successful unique PT study for each field of proficiency testing as required by Article 3 (1VAC30-45-500 et seq.) of Part II of this chapter;
 - o. Quality assurance manual; and
 - p. 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 1VAC30-45-130.
3. Certification of compliance.
- a. The application shall include a "Certification of Compliance" statement signed and dated by the responsible official, by the quality control officer and by the laboratory manager.
 - 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 certification program regulation (1VAC30, Chapter 45) and is subject to the provisions of 1VAC30-45-100 in the event of noncompliance. 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 of certification or decertification. I hereby 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 a laboratory's initial 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 certification pending final determination on application.

1. DCLS shall grant a laboratory interim certification status under the following conditions:
 - a. The laboratory's application is determined to be complete;
 - b. The laboratory has satisfied all the requirements for certification, 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 certification status shall have the same rights and status as a laboratory that has been granted certification by DCLS.
3. Interim certification expires when DCLS issues a final determination on certification.

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

Article 2 (1VAC30-45-300 et seq.) of Part II of this chapter prior to issuance of a final determination on certification.

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

K. Grant of certification.

1. When a laboratory meets the requirements specified for receiving certification, DCLS shall issue a certificate to the laboratory. DCLS shall send the certificate to the laboratory manager and shall notify the responsible official.

2. The director of DCLS or his designee shall sign the certificate. 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 certification (matrix, technology/method, and analyte) for which certification is granted;
- g. Any addenda or attachments; and
- h. Issuance date and expiration date.

3. The laboratory shall post the most recent certificate of certification and any addenda to the certificate issued by DCLS in a prominent place in the laboratory facility.

4. Certification shall expire one year after the date on which certification is granted.

L. Denial of certification.

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

2. Denial of certification in total or in part.

a. DCLS may deny certification 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 Part II (1VAC30-45-200 et seq.) of this chapter.
- (3) Successfully analyze and report proficiency testing samples as required by Part II of this chapter.
- (4) Submit a corrective action plan in accordance with Part II of this chapter 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 timeframe specified by DCLS.

(6) Pass required on-site assessment as specified in Part II of this chapter.

(7) Implement a quality system as defined in Part II of this chapter.

b. DCLS may deny certification to an environmental laboratory in total or in part if the laboratory's application is not determined to be complete within 90 calendar 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 certification 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 Article 2 (1VAC30-45-300 et seq.) of Part II of this chapter because a representative of the environmental laboratory denied the team entry during the laboratory's normal business hours that it specified in its application.

3. DCLS shall follow the process specified in 1VAC30-45-110 when denying certification to an environmental laboratory.

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

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 22, eff. September 1, 2016.

1VAC30-45-80. Maintaining certification.

A. Certification remains in effect until withdrawn by DCLS, withdrawn voluntarily at the written request of the certified laboratory, or until expiration of the certification period. To maintain certification, the certified laboratory shall comply with the elements listed in this section and in 1VAC30-45-90.

B. Quality systems. Laboratories seeking to maintain certification under this chapter shall assure consistency and promote the use of quality assurance and quality control procedures. Article 4 (1VAC30-45-600 et seq.) of Part II of this chapter specifies the quality assurance and quality control requirements that shall be met to maintain certification.

C. Proficiency tests. Laboratories seeking to maintain certification under this chapter shall perform proficiency tests as required under Article 3 (1VAC30-45-500 et seq.) of Part II of this chapter.

D. Recordkeeping and retention. All laboratory records associated with certification parameters shall be kept as provided by the requirements for records under Part II (1VAC30-45-200 et seq.) of this chapter. These records shall be maintained for a minimum of three years unless the records are required to be maintained for a longer period by another section of this regulation or another regulation. 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 22, eff. September 1, 2016.

1VAC30-45-90. Notifications and changes to certification elements and status.

A. Changes to key certification criteria. The certified laboratory shall notify DCLS in writing of any changes in key certification criteria within 30 calendar days of the change. Key certification criteria are laboratory ownership, location, key personnel, and major instrumentation.

B. Changes to scope of certification.

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

2. To apply, the owner of the certified 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 certification.

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 certification by performing a review of the application materials submitted, without an on-site assessment. The addition of a 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 certified 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 certification is approved, DCLS shall amend the laboratory's certificate of certification.

6. DCLS shall not send the amended certificate of certification to the laboratory until DCLS receives the payment of the fee required under 1VAC30-45-130 F 1.

C. Change of ownership or location of laboratory.

1. The certified 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. Certification may be transferred when the legal status or ownership of a certified 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 recertification or reapplication in any or all of the categories for which the laboratory is certified.

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 certified laboratory shall keep all records and analyses performed by the previous owner pertaining to certification for a period of three years, or longer if required by other regulations. These records and analyses are subject to inspection by DCLS during this three-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 certification status or from being certified, 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 22, eff. September 1, 2016.

1VAC30-45-95. Suspension of certification.

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

B. DCLS may suspend certification 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 Article 3 (1VAC30-45-500 et seq.) of Part II of this chapter.

2. Satisfactorily complete proficiency testing studies as required by Article 3 (1VAC30-45-500 et seq.) of Part II of this chapter.

3. Maintain a quality system as defined in Article 4 (1VAC30-45-600 et seq.) of Part II of this chapter.

4. Employ staff that meets the personnel qualifications of Article 1 (1VAC30-45-200 et seq.) of Part II of this chapter.

5. Notify DCLS of any changes in key certification criteria as set forth in 1VAC30-45-90.

C. Process to suspend certification.

1. When DCLS becomes aware of a cause to suspend a laboratory, the agency shall send notification to the responsible official and the laboratory manager stating it appears to DCLS that the laboratory has failed to meet the 1VAC30-45 standards for one or more of the reasons listed in subsection B of this section. DCLS shall send the notification by certified mail.

2. The DCLS notification shall do the following:

- a. Require the laboratory to provide DCLS with documentation of the corrective action already taken with regard to its failure to meet a standard under subsection B of this section.
 - b. State the corrective action the laboratory must take and the time allowed for this corrective action to be completed in order to retain certification.
3. The environmental laboratory may proceed to correct the deficiencies for which DCLS may suspend the laboratory's certification.
 4. Alternatively the laboratory may state in writing that DCLS is incorrect in its observations regarding potential suspension and give specific reasons why the laboratory believes DCLS should not suspend certification. The laboratory has the right to due process as set forth in 1VAC30-45-110, the 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.
 5. 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 certification suspended.
 6. DCLS shall set a date for suspension that follows the period provided under subdivision 5 of this subsection to restore certification.
 7. If the laboratory does not correct its deficiencies within the time period allowed or pursue options under subdivision 4 of this subsection, DCLS may suspend a laboratory in part or in total.
 8. DCLS shall notify the laboratory by letter if the laboratory's certification is suspended in part or in total. DCLS shall send the notification by certified mail. DCLS shall also notify the pertinent Virginia state agency of the laboratory's suspension status.
 9. The laboratory may provide information demonstrating why suspension is not warranted in accordance with subdivision 4 of this subsection.
- D. Responsibilities of the environmental laboratory and DCLS when certification has been suspended.
1. The term of suspension shall be limited to six months or the period of certification whichever is longer.
 2. The environmental laboratory shall not continue to analyze samples or report analysis for the fields of certification for which DCLS has suspended certification.
 3. The environmental laboratory shall retain certification for the fields of certification, methods, and analytes where it continues to meet the requirements of this chapter.
 4. The laboratory's suspended certification status shall change to certified when the laboratory demonstrates to DCLS that the laboratory has corrected the deficiency or deficiencies for which its certification was suspended.
 5. An environmental laboratory with suspended certification shall not have to reapply for certification 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 decertify the laboratory in total or in part.

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

Historical Notes: Derived from Virginia Register Volume 32, Issue 22, eff. September 1, 2016.

1VAC30-45-100. Decertification.

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

B. DCLS may decertify 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 Article 3 (1VAC30-45-500 et seq.) of Part II of this chapter.
2. Satisfactorily complete proficiency testing studies as required by Article 3 (1VAC30-45-500 et seq.) of Part II of this chapter.
3. Maintain a quality system as defined in Article 4 (1VAC30-45-600 et seq.) of Part II of this chapter.
4. Employ staff that meets the personnel qualifications in Article 1 (1VAC30-45-200 et seq.) of Part II of this chapter.
5. Submit an acceptable corrective action plan after two opportunities as specified in 1VAC30-45-390.
6. Implement corrective action specified in the laboratory's corrective action plan as set out under 1VAC30-45-390.
7. Notify DCLS of any changes in key certification criteria as set forth in 1VAC30-45-90.
8. Use accurate references to the laboratory's certification status in the laboratory's documentation.
9. Allow a DCLS assessment team entry during normal business hours to conduct an on-site assessment required by Article 2 (1VAC30-45-300 et seq.) of Part II of this chapter.
10. Pay the required fees specified in 1VAC30-45-130.

C. DCLS shall follow the process specified in 1VAC30-45-110 when decertifying an environmental laboratory.

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

1. Laboratories that lose their certification in full shall return their certificate to DCLS.
2. If a laboratory loses certification in part, DCLS shall issue a revised certificate to the laboratory.
3. When the environmental laboratory has lost certification in full or in part, the laboratory shall not continue to analyze samples or report analyses for the fields of certification that DCLS has decertified.

E. After correcting the reason or cause for decertification under subsection A or B of this section, the laboratory owner may reapply for certification under 1VAC30-45-70.

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 22, eff. September 1, 2016.

1VAC30-45-110. Procedures to deny certification or decertify a laboratory; appeal procedures.

A. Notification.

1. If DCLS becomes aware of a cause to deny certification or to decertify an environmental laboratory, DCLS shall notify the environmental laboratory in writing of this information and require a response from the responsible official. DCLS shall send this notification by certified mail to the responsible official and provide a copy to the manager of the environmental laboratory.

2. For a potential denial of certification, the notice shall state that the laboratory has failed to meet the 1VAC30-45 standards and shall specify one or more of the reasons for denial of certification under 1VAC30-45-70 L, providing a detailed explanation of the basis for the denial of certification.

3. For a potential decertification, the notice shall state that the laboratory has failed to meet the 1VAC30-45 standards and shall specify one or more of the reasons for decertification under 1VAC30-45-100 A or B, providing a detailed explanation of the basis for decertification.

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. Before rendering a decision on decertification or denial of certification, DCLS shall provide the opportunity for the laboratory to meet with DCLS in an informal fact-finding proceeding pursuant to § 2.2-4019 of the Code of Virginia.

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 certification to or decertify the laboratory. The laboratory shall include this demonstration in the response required under subdivision 6 of this subsection.

6. The laboratory shall provide DCLS with a written response within 30 calendar days of the date of notification from DCLS. The laboratory shall indicate whether it disputes the DCLS determination provided in the agency notice and whether the laboratory requests an informal fact-finding proceeding. If the laboratory does not respond, DCLS shall render its case decision.

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

C. The certification status of an environmental laboratory appealing decertification 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 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 22, eff. September 1, 2016.

1VAC30-45-120. Exemptions.

A. DCLS may grant a partial or full exemption from the requirements of this chapter based on compliance and performance.

B. DCLS may consider granting an exemption if a laboratory applies for an exemption and has met all certification requirements for a period of four consecutive years.

C. An environmental laboratory may apply for an exemption by submitting a request. The request shall include the following information:

1. The scope of the requested exemption;
2. Whether the exemption should be partial or total;
3. If partial, what form the exemption will take; and
4. Why the exemption is appropriate.

D. Upon receiving an application for an exemption, DCLS shall provide notice of the request for an exemption in the Virginia Register of Regulations.

E. The notice shall provide a 30-day comment period on the request and shall specify the nature of the request.

F. DCLS shall grant or deny the exemption request and provide a written response to the requesting laboratory within 90 calendar days of receipt of the request.

G. Exemptions granted by DCLS shall be for a period of no more than 24 months.

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 22, eff. September 1, 2016.

1VAC30-45-130. Fees.

A. General.

1. Environmental laboratories shall pay a fee with all applications, including reapplications, for certification. DCLS shall not designate an application as complete until it receives payment of the fee.
2. Each certified environmental laboratory shall pay an annual fee to maintain its certification. DCLS shall send an invoice to the certified environmental laboratory.
3. Fees shall be nonrefundable.

B. Environmental laboratories performing only simple test procedures shall pay an annual fee of \$600.

C. Fee computation for general environmental laboratories.

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 D and E of this section.

D. Base fees for general environmental laboratories.

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 certification matrices for which the laboratory would be certified.

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 certified and then finding the box on that row located in the column headed by the total number of matrices to be certified. For example, DCLS charges a base fee of \$1300 to a laboratory performing a total of eight methods for one matrix.

Number of Methods	1 Matrix	2 Matrices
1 - 9	\$1300	\$1430
10 - 29	\$1400	\$1575
30 - 99	\$1550	\$1825

E. Test category fees for general environmental laboratories.

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

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

3. Fees shall be charged for the total number of field of certification matrices to be certified under the specific test category. For example, if a laboratory is performing inorganic chemistry for both nonpotable water and solid and chemical materials 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. 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 certified. 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 certified. A laboratory performing four test methods for inorganic chemistry in nonpotable water and solid and chemical materials (two matrices) would be charged a test category fee of \$375.

6. Noncommercial environmental laboratories that perform toxicity, radiochemical, or asbestos testing shall pay the test category fees established for these types of testing in 1VAC30-46-150.

TABLE 2: TEST CATEGORY FEES		
Test Category	Fees by Number of Matrices	
	One	Two
Oxygen demand	\$225	\$335
Bacteriology, 1 - 3 total methods	\$175	\$265
Bacteriology, 4 or more total methods	\$220	\$330
Physical, 1 - 5 total methods	\$175	\$265
Physical, 6 - 10 total methods	\$220	\$330
Inorganic chemistry, 1 - 10 total methods	\$250	\$375
Inorganic chemistry, 11 - 20 total methods	\$315	\$475
Inorganic chemistry, 21 - 49 total methods	\$394	\$590
Chemistry metals, 1 - 5 total methods	\$325	\$490
Chemistry metals, 6 - 20 total methods	\$410	\$615
Organic chemistry, 1 - 5 total methods	\$400	\$600
Organic chemistry, 6 - 20 total methods	\$500	\$750

7. 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)	\$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	Chemistry metals (2 methods)	\$325
Nonpotable Water	Oxygen demand (1 method)	\$225
Nonpotable Water	Physical (1)	\$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	Chemistry 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

F. Additional fees. Additional fees shall be charged to laboratories applying for the following: (i) modification to scope of certification under 1VAC30-45-90 B, (ii) transfer of ownership under 1VAC30-45-90 C, (iii) exemption under 1VAC30-45-120, or (iv) petition for a variance under 1VAC30-45-140.

1. For any certified environmental laboratory that applies to modify its scope of certification as specified under 1VAC30-45-90 B, DCLS shall assess a fee determined by the method in subsection G of this section.

2. Under 1VAC30-45-90 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 G of this section. If, under 1VAC30-45-90 C, DCLS determines that the change of ownership or location of laboratory requires recertification of or reapplication by the laboratory, the laboratory shall pay the application fees required under this section.

3. General environmental laboratories applying for an exemption under 1VAC30-45-120 shall pay an initial application fee of \$700 plus an additional fee based on the actual time needed for DCLS to assess the exemption request. The total fee shall not exceed the actual time DCLS takes to assess the exemption request. Laboratories performing only simple test procedures applying for an exemption under 1VAC30-45-120 shall pay an initial application fee of \$300 plus an additional fee based on the actual time needed for DCLS to assess the exemption request. The total fee shall not exceed the actual time DCLS takes to assess the exemption request. The fee assessed shall be calculated using the method in subsection G of this section.

4. Under 1VAC30-45-140, any person regulated by this chapter may petition the director to grant a variance from any requirement of this chapter. DCLS shall charge an initial fee of \$700 plus an additional fee based on the actual time needed for DCLS to review the petition, including any on-site assessment required. The total fee shall not exceed the actual time DCLS takes to review and make a determination on the request for a variance. The fee shall be determined by the method specified in subsection G of this section.

G. Fee 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.

H. Out-of-state laboratories - travel costs. The owner of an environmental laboratory located in another state who applies for certification under this chapter shall also pay a fee equal to the 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.

I. DCLS shall derive the travel costs charged under subsections G and H 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 22, eff. September 1, 2016.

1VAC30-45-140. 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.

1VAC30-45-150. (Reserved.) through 1VAC30-45-190. (Reserved.)

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

Part II
Standards

Article 1: Personnel

1VAC30-45-200. Laboratory manager.

A. Laboratory manager - general.

1. Each environmental laboratory shall designate a person to be responsible for the general oversight of the operation of the laboratory in accordance with this chapter, including the day-to-day functioning and administration of the laboratory, the technical operations, supervision of laboratory procedures, reporting of laboratory results, and implementation of any corrective actions.
2. The title of this person may include but is not limited to laboratory director, technical director, laboratory supervisor or laboratory manager.
3. A laboratory may appoint one or more technical directors for the appropriate fields of certification for which the laboratory seeks certification.

B. Laboratory manager - qualifications.

1. For an environmental laboratory that performs procedures beyond simple test procedures, a laboratory manager shall have two years of experience managing an environmental laboratory or performing the analyses for which the environmental laboratory seeks certification or both.
2. For an environmental laboratory that performs only simple test procedures, there are no qualification requirements for a laboratory manager except that the responsible official shall designate the laboratory manager.
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.

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

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

1VAC30-45-210. Quality assurance officer.

A. The laboratory shall have a quality assurance officer who shall be responsible for the quality system and its implementation. Where staffing is limited, the quality assurance officer may also be the laboratory manager. The quality assurance officer may be employed on a part-time basis or be a consultant.

B. The quality assurance officer shall have documented training or experience in quality assurance and quality control procedures and be knowledgeable in the quality system as defined in Article 4 (1VAC30-45-600 et seq.) of Part II of this chapter. The quality assurance officer shall have a general knowledge of the analytical test methods for which data review is performed.

C. The responsibilities of the quality assurance officer shall include, but not be limited to, the implementation and oversight of the quality system, the implementation of new quality assurance and control practices, periodic audits of the quality system in place, periodic review of final data reports, and documentation of laboratory quality system deficiencies.

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

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

1VAC30-45-220. Laboratory personnel requirements and management responsibilities.

A. The laboratory shall have sufficient personnel, having the necessary education, training, technical knowledge and experience for their assigned functions.

B. The laboratory manager shall ensure that the training of the laboratory personnel is kept up to date.

C. Laboratory personnel shall be responsible for complying with all quality systems requirements set out in Article 4 (1VAC30-45-600 et seq.) of Part II of this chapter that are pertinent to their assigned functions.

D. The laboratory manager shall ensure that laboratory personnel have demonstrated initial and ongoing capability to perform their assigned functions. See 1VAC30-45-730 E and F.

E. Records on the relevant qualifications, training skills and experience of the laboratory personnel, including records on demonstrated proficiency for each test method, shall be maintained by the laboratory manager.

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

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

1VAC30-45-230. Absence of laboratory manager.

When a laboratory manager will be absent for a period exceeding 15 consecutive calendar days, the laboratory shall designate a qualified replacement to perform the manager's function.

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

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

1VAC30-45-240. (Reserved.) through 1VAC30-45-290. (Reserved.)

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

Article 2: On-Site Assessment

1VAC30-45-300. Frequency of on-site assessment.

A. Frequency.

1. A comprehensive on-site assessment shall be conducted of each laboratory as a condition for granting certification initially.
2. DCLS shall reassess each certified laboratory at least once every three years starting from the date of the previous assessment plus or minus six months.
3. DCLS may conduct an on-site assessment of a laboratory every two years plus or minus six months under any of the following circumstances:
 - a. When a laboratory has received "not acceptable" PT results.
 - b. When a laboratory's corrective action presented to VELAP for "not acceptable" PT studies does not identify and correct the root cause of the PT study failure.
 - c. When DCLS has suspended certification for a laboratory in full or in part.
 - d. When on-site observations include nonconformances previously identified at an on-site assessment, indicating the corrective action was not implemented or not maintained.
 - e. When on-site observations include failure to qualify nonconforming data to the data user.
 - f. When on-site observations indicate the laboratory's failure to monitor and maintain regulatory conformance in documentation, traceability, or quality control requirements such that data generated by the laboratory are of questionable quality or defensibility.

B. Other on-site assessments.

1. If DCLS identified a deficiency on a previous on-site assessment, the agency may conduct a follow-up on-site assessment.
2. DCLS may conduct an on-site assessment when a laboratory applies to modify its scope of certification; when a transfer of owner occurs that affects personnel, equipment, or the laboratory facilities; or when a laboratory applies for an exemption or a variance. 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.

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 22, eff. September 1, 2016.

1VAC30-45-310. Announced and unannounced on-site assessments.

A. DCLS may conduct, at its discretion, either announced or unannounced on-site assessments.

B. Advance notice of an assessment shall not be necessary.

C. To the maximum extent practical, DCLS, when necessary, shall work with the owner of an environmental laboratory to obtain government security clearances for

assessment personnel as far in advance as possible. The owner of the environmental laboratory shall facilitate expeditious attainment of the necessary clearances.

D. To the maximum extent practical, assessment personnel shall minimize disruption of a laboratory's operations and take into account competing demands on the time of laboratory personnel.

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 22, eff. September 1, 2016.

1VAC30-45-320. Request for records.

Prior to the actual site visit, DCLS may request in writing from a laboratory those records required to be maintained by 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 22, eff. September 1, 2016.

1VAC30-45-330. Areas to be assessed.

DCLS shall assess the laboratory against the personnel and quality control standards in Article 1 (1VAC30-45-200 et seq.) and Article 4 (1VAC30-45-600 et seq.) of this part. The specific areas evaluated in an on-site assessment shall include but not be limited to:

1. Adequacy of the laboratory facility.
2. Organization and management of the laboratory.
3. Qualifications and experience of laboratory personnel.
4. Receipt, tracking and handling of samples.
5. Quantity, condition, and performance of laboratory instrumentation and equipment.
6. Preparation and traceability of calibration standards.
7. Test methods (including the adequacy of the laboratory's standard operating procedures as well as confirmation of the analyst's adherence to SOPs, and the analyst's proficiency with the described task).
8. Data reduction procedures, including an examination of raw data and confirmation that final reported results can be traced to the raw data/original observations.
9. Quality assurance and quality control procedures, including adherence to the laboratory's quality assurance plan and adequacy of the plan.
10. Recordkeeping.

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 22, eff. September 1, 2016.

1VAC30-45-340. National security considerations.

A. 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.

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

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 22, eff. September 1, 2016.

1VAC30-45-350. Arrival, admittance, and opening conference.

A. Arrival. Assessment personnel shall arrive at the laboratory during established working hours. The laboratory manager (or, if unavailable, the laboratory manager's designee) shall be located as soon as possible after the assessment personnel arrive on the premises.

B. Admittance of assessment personnel.

1. 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 certification or loss of an existing certification by the laboratory, unless there are extenuating circumstances that are accepted and documented by DCLS. The team leader for the assessment personnel shall notify DCLS as soon as possible after refusal of entry.

2. DCLS shall consider any verbal or physical threat to the health and safety of its assessors or any overt antagonism towards its assessors as a refusal to admit the assessors for the purpose of on-site assessment. The assessors shall vacate the laboratory and shall notify DCLS as soon as possible of the circumstances of this refusal to admit. This refusal to admit shall result in an automatic failure of the laboratory to receive certification or the automatic loss of an existing certification by the laboratory.

C. Health and safety.

1. 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.

2. Assessment personnel shall comply with all facility and laboratory safety procedures.

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

1. The purpose of the assessment;
2. The identification of assessment personnel;
3. The test methods that will be examined;

4. 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;
5. The roles and responsibilities of laboratory staff and managers;
6. Any special safety procedures that the laboratory may think necessary for the protection of assessment personnel;
7. The standards and criteria that will be used in judging the adequacy of the laboratory operation;
8. Confirmation of the tentative time for the exit conference; and
9. Discussion of any questions the laboratory may have about the assessment process.

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 22, eff. September 1, 2016.

1VAC30-45-360. On-site laboratory records review and collection.

A. 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.

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

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

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

1VAC30-45-370. Observations of and interviews with laboratory personnel.

A. 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.

B. Assessment personnel may conduct interviews with appropriate laboratory personnel.

C. 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 certification with appropriate laboratory analysts.

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

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

1VAC30-45-380. Closing conference.

A. Assessment personnel shall meet with representatives of the laboratory following the assessment for a closing conference.

B. 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.

C. Additional problem areas may be identified in the final report.

D. Any potentially illegal activity that may be the subject of further action shall not be discussed in the closing conference.

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 22, eff. September 1, 2016.

1VAC30-45-390. Follow-up and reporting procedures.

A. DCLS shall present an assessment report to the laboratory within 30 calendar days of the assessment.

B. If there are deficiencies identified in the assessment report, the laboratory shall have 30 calendar days from the date of its receipt of the assessment report to provide a response to DCLS. This response shall be called a corrective action plan.

C. An exception to the deadlines specified in subsections A and B of this section may occur in appropriate circumstances. Two circumstances that may be considered appropriate by DCLS are where a possible enforcement investigation or other action has been initiated or where the laboratory shows good cause for an extension.

D. The corrective action plan shall include the following:

1. Any objections that the laboratory has with regard to the assessment report;
2. The action that the laboratory proposes to implement to correct each deficiency identified in the assessment report; and
3. The time period required to accomplish the corrective action.

E. DCLS shall determine and shall notify the laboratory within 30 calendar days of receipt whether the corrective action plan is an acceptable response to the deficiencies identified in the assessment report.

F. 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 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.

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 22, eff. September 1, 2016.

1VAC30-45-400. Documentation of on-site assessment.

A. Checklists. The checklists used by assessment personnel during the assessment shall become a part of DCLS's file for the laboratory.

B. Assessment report format.

1. The final assessment report shall contain a narrative description of the adequacy of the laboratory as it relates to the assessment standards specified in this chapter and in 1VAC30-45-330.

2. Assessment reports shall contain:

- a. Name of owner of the laboratory (or operator of the laboratory, if different from the owner);
- b. Identification of the laboratory assessed;
- c. Date of the assessment;
- d. Identification and affiliation of all assessment personnel;
- e. Identification of participants in the assessment process;
- f. Identification of analytes and test methods assessed;
- g. Statement of the objective of the assessment;
- h. Summary;
- i. Assessment observations, findings (including any deficiencies), objections noted by the laboratory, and requirements; and
- j. Comments and recommendations.

3. The assessment findings and requirements shall be referenced to the standards in Part II (1VAC30-45-200 et seq.) of this chapter so that both the finding is understood and the specific requirement is outlined. The assessor shall specify the laboratory records, documents, equipment, procedures, or staff evaluated and the observations that contributed to each identified deficiency. The assessment report shall support with sufficient data all assessment findings and the overall evaluation of the laboratory.

4. The comments and recommendations section may be used to convey recommendations aimed at helping the laboratory improve.

C. Release of report.

1. The assessment report shall be released initially by DCLS to the responsible official and the laboratory manager. The assessment report shall not be released to the public until findings of the assessment and the corrective actions have been finalized, all information relating to national security has been stricken from the report in accordance with prescribed procedures, and the report has been provided to the laboratory.

2. Once the assessment report has been released to the laboratory, any member of the public may request a copy of the report under the requirements of the Virginia Freedom of Information Act (§ 2.2-3700 et seq. of the Code of Virginia).

3. Checklists used by assessment personnel during the on-site assessment shall be provided to the laboratory with the final on-site assessment report upon request.

D. The laboratory shall have access to documentation pertaining to any on-site assessment of its facilities. Any laboratory wishing to review its files shall request such assistance of DCLS five days prior to visiting DCLS. A laboratory may request copies of its documents without visiting DCLS. A reasonable fee may be charged for copying, mailing, and staff time.

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 22, eff. September 1, 2016.

1VAC30-45-410. (Reserved.) through 1VAC30-45-490. (Reserved.)

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

Article 3: Proficiency Testing

1VAC30-45-500. Laboratory enrollment in proficiency testing program.

A. Required level of participation.

1. To be certified initially and to maintain certification, a laboratory shall participate in PT studies as specified in 1VAC30-45-520 B for the fields of certification (FoC) for which the laboratory seeks or wants to maintain certification.

2. The applicant laboratory shall obtain PT samples from a PT provider approved by TNI. If a PT sample is not available from a TNI-approved provider, the laboratory shall consult DCLS for an approved provider.

B. Requesting certification.

1. When applying for certification, the laboratory owner shall notify DCLS of the fields of certification for which the laboratory chooses to become certified and shall participate in the appropriate PT studies.

2. For all fields of certification 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 of Article 4 (1VAC30-45-600 et seq.) of Part II of this chapter.

C. Reporting results. Each laboratory shall authorize the PT study provider to release the results of the final evaluation report of the laboratory's PT study directly to DCLS, in addition to the laboratory.

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 22, eff. September 1, 2016.

1VAC30-45-510. Requirements for laboratory testing of PT study samples.

A. The laboratory shall report the analytical results from its analysis of the PT study to the PT provider on or before the closing date of the study using the reporting format specified by the PT provider.

B. The laboratory's management and all analysts shall ensure that 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, and facilities. When analyzing a PT sample, the laboratory shall employ the same calibration, laboratory quality control and acceptance criteria, sequence of analytical steps, number of replicates and other procedures as used when analyzing routine samples.

C. Restrictions on exchanging information. Laboratories shall comply with all of the following restrictions on the transfer of PT samples and communication of PT sample results prior to the time the results of the study are released. Laboratory management or staff shall not:

1. Send any PT sample, or a portion of a PT sample, to another laboratory for any analysis for which it seeks certification or is certified.
2. Knowingly receive any PT sample or portion of a PT sample from another laboratory for any analysis for which the sending laboratory seeks certification or is certified.
3. Communicate with any individual at another laboratory (including intra-company communication) concerning the PT sample.
4. Attempt to obtain the assigned value of any PT sample from their PT provider.

D. Maintenance of records. The laboratory shall maintain copies of all written, printed, and electronic records, including but not limited to bench sheets, instrument strip charts or printouts, data calculations, and data reports, resulting from the analysis of any PT sample for three years or for as long as is required by the applicable regulatory program. These records shall include a copy of the PT study report forms used by the laboratory to record PT results. All of these laboratory records shall be made available to the DCLS assessors during on-site assessments of the laboratory.

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 22, eff. September 1, 2016.

1VAC30-45-520. PT criteria for laboratory certification.

A. Result categories.

1. The criteria described in this section apply individually to each FoPT, as defined by the laboratory seeking to obtain or maintain certification in its certification request. These criteria apply only to the PT portion of the overall certification standard.

2. There are two PT result categories: "acceptable" and "not acceptable."

B. Initial and continuing certification.

1. A laboratory seeking to obtain or maintain certification shall successfully complete one PT study for each requested FoC.
2. Once a laboratory has been granted certification status, it shall continue to complete PT studies for each FoPT and maintain a history of at least one acceptable PT study each calendar year. The laboratory shall complete its PT studies by September 30 of each calendar year.
3. When the PT sample used for initial certification was analyzed by the laboratory prior to the date of application, the analysis date of the PT sample shall be no more than 12 months prior to the application date of certification.
4. For a laboratory performing supplemental testing, the PT studies shall be at least 15 calendar days apart from the closing date of one study to the shipment date of another study for the same FoPT.
5. When the PT study result is reported by the PT provider as "acceptable" the environmental laboratory has satisfied the PT requirement.
6. When the PT study result is "not acceptable," the environmental laboratory shall follow the procedure in subsection C of this section.
7. DCLS shall consider a laboratory's analytical result for a FoPT not acceptable 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 certification for which the PT sample was analyzed for the purpose of initial or continued certification.

C. Procedure and requirements for "not acceptable" PT study results.

1. When a laboratory receives a PT study result of "not acceptable," the laboratory shall determine the cause for the failure and perform and document corrective action. The corrective action documentation shall be completed within 30 days of receiving the "not acceptable" PT study result and be submitted to DCLS upon request. DCLS may extend the time for corrective action and documentation.
2. Upon completion of the corrective action the laboratory shall perform another PT study for each FoPT that had a "not acceptable" result.
3. If the laboratory successfully completes the makeup PT study by receiving an "acceptable" result before December 31, DCLS shall not suspend the laboratory's certification for the pertinent FoC.
4. If the laboratory receives a "not acceptable" result on the makeup PT study, DCLS shall notify the laboratory that there is cause to suspend the laboratory's certification for the FoC for which the PT study was "not acceptable."
5. DCLS shall not extend the period for annual PT study completion beyond December 31 each year. Failure to satisfactorily complete a PT study, including any corrective action and makeup PT study, by December 31 shall result in suspension of certification in total or in part.
6. If the laboratory receives a "not acceptable" result on three successive PT studies, DCLS shall decertify the laboratory for the pertinent FoC until such time that the laboratory:

- a. Completes corrective action for all failed studies and submits its corrective action report to DCLS;
 - b. Obtains an "acceptable" result for the PT studies; and
 - c. Applies for a change to its scope of certification and pays applicable fees required by 1VAC30-45-90 B and 1VAC30-45-130 F.
7. DCLS shall follow the provisions of 1VAC30-45-110 in decertifying the laboratory.

D. **Withdrawal from PT studies.** A laboratory may withdraw from a PT 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 annual analysis requirements necessary for continued certification.

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 22, eff. September 1, 2016.

1VAC30-45-530. (Repealed.) through 1VAC30-45-590. (Reserved.)

Historical Notes: Derived from Virginia Register Volume 25, Issue 7, eff. January 1, 2009; repealed, Virginia Register Volume 32, Issue 22, eff. September 1, 2016.

Article 4: Quality System

1VAC30-45-600. Quality system.

A. This article sets out the general requirements that an environmental laboratory has to successfully demonstrate to be recognized as competent to carry out specific environmental tests. The environmental laboratory shall establish, implement and maintain a quality system based on the required elements contained in this article.

B. The quality system shall be appropriate to the type, range and volume of testing, analysis, measurement or monitoring performed by the laboratory.

C. The quality system's documentation shall be communicated to, understood by, available to, and implemented by the appropriate personnel. All personnel concerned with testing and calibration activities within the laboratory shall familiarize themselves with the quality documentation and implement the policies and procedures in their work.

D. If more stringent standards or requirements are included in a mandated test method or by regulation, the laboratory shall demonstrate that such requirements are met. If it is not clear which standard or requirement is more stringent, the standard or requirement from the method or regulation is to be followed.

E. Provisions pertaining to the management of the quality system appear in 1VAC30-45-610 through 1VAC30-45-700. Provisions pertaining to the technical requirements for the quality system appear in 1VAC30-45-710 through 1VAC30-45-770.

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 22, eff. September 1, 2016.

1VAC30-45-610. Quality manual.

A. General.

1. The laboratory shall document its quality system in a quality manual. The quality manual shall reflect all quality assurance and quality control practices and programs used by the laboratory. The required elements of the quality system may be described in more than one document.
2. The quality manual shall be maintained current under the responsibility of the quality assurance officer.
3. The quality manual and any related documents shall be communicated to, understood by, available to, and implemented by all laboratory personnel.
4. The quality manual shall include but not be limited to the elements listed in subsections B and C of this section.

B. The elements of a quality manual shall include but not be limited to:

1. A document title;
2. The laboratory's full name and address;
3. The name, address (if different from above), and telephone number of the responsible official, laboratory manager, and quality assurance officer;
4. The laboratory facility or facilities covered by the quality manual;
5. Signed and dated concurrence, with appropriate titles, of the responsible official, laboratory manager, and quality assurance officer;
6. The effective date of the quality manual;
7. Table of contents and applicable lists of references, glossaries, and appendices; and
8. A quality policy statement, including objectives of the quality system and commitment to ethical laboratory practices and to upholding the requirements of this chapter's standards.

C. The quality manual shall include or reference but not be limited to:

1. The organization and management structure of the laboratory, its place in any parent organization and relevant organizational charts.
2. Job descriptions of key staff and reference to the job descriptions of other staff.
3. Processes or procedures for establishing that personnel have adequate training and experience in the duties they are expected to carry out and are receiving any needed training.
4. Mechanisms for ensuring that the laboratory reviews all new work to ensure that it has the appropriate facilities and resources before commencing such work.
5. Procedures to ensure that all records required by this chapter are retained, as well as procedures for control and maintenance of documentation through a document control system that ensures that all standard operating procedures, manuals, or documents clearly indicate the time period during which the procedure or document was in force.

6. Procedures for dealing with complaints.
 7. Procedures for audits and data review.
 8. Verification practices that may include inter-laboratory comparisons, proficiency testing programs, use of reference materials and internal quality control schemes.
 9. Procedures to be followed for feedback and corrective action whenever testing discrepancies are detected, or departures from documented policies and procedures occur.
 10. The laboratory management arrangements for permitting departures from documented policies and procedures or from standard specifications when the departures are planned and controlled.
 11. The major equipment and reference measurement standards used as well as the physical facility and environment used by the laboratory in conducting tests.
 12. Procedures for calibration, verification and maintenance of equipment.
 13. A list of all technology/methods under which the laboratory performs its certified testing.
 14. Procedures for achieving traceability of measurements, including standards.
 15. Procedures for receiving, handling, storing, and disposing of submitted samples.
 16. Procedures for reporting analytical results.
 17. Policy addressing the use of unique electronic signatures, where applicable.
- D. Review and approval of quality manual.
1. The quality assurance officer shall review the laboratory's quality assurance program, manual and any related documentation whenever there is any change in test methods employed by the laboratory, change in equipment, or any other change in the laboratory that affects the quality assurance program.
 2. The quality assurance manual shall be reviewed and approved by the quality assurance officer, the laboratory manager, and the responsible official at least annually.

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 22, eff. September 1, 2016.

1VAC30-45-620. Organization.

The laboratory shall specify and document the functional responsibility, level of authority, and interrelationship or lines of communication of all personnel who manage, perform or verify work affecting the quality of tests, analyses, measurements and monitoring. One person may cover more than one organizational function. Each manager and employee of the laboratory shall have a clear understanding of his or her duties and responsibilities and the relationship of those responsibilities to the overall work of the laboratory.

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

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

1VAC30-45-630. Records.

The laboratory shall maintain a record system to suit its particular circumstances and comply with any applicable regulations. This system shall produce unequivocal, accurate records that document all laboratory activities.

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

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

1VAC30-45-640. Recordkeeping system and design.

A. The laboratory shall have a recordkeeping system that allows historical reconstruction of all laboratory activities that produced the analytical data. The history of the sample shall be readily understood through the documentation. This shall include inter-laboratory transfers of samples or extracts or both.

B. The records shall include the identity of personnel involved in sampling, sample preservation, sample receipt, preparation, calibration or testing, all documentation sent by the person transmitting the sample, including a chain of custody record form, if utilized.

C. The laboratory shall document all information relating to the laboratory facility's equipment, analytical test methods, and related laboratory activities, such as sample receipt, sample preparation, or data verification.

D. The laboratory shall have a recordkeeping system that facilitates the retrieval of all working files and archived records for inspection and verification purposes, e.g., set format for naming electronic files.

E. Responsible staff shall sign or initial all changes to records. The reason for the signature or initials shall be clearly indicated in the records such as "sampled by," "prepared by," or "reviewed by."

F. All generated data except those that are generated by automated data collection systems, shall be recorded directly, promptly and legibly in permanent ink.

G. Entries in records shall not be obliterated by methods such as erasures, overwritten files or markings. All corrections to recordkeeping errors shall be made by one line marked through the error. The individual making the correction shall sign or initial and date the correction. These criteria also shall apply to electronically maintained records.

H. The laboratory shall keep computer and electronic data records in accordance with the pertinent provisions of this section, 1VAC30-45-650 C and E and 1VAC30-45-730 K.

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

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

1VAC30-45-650. Records management and storage.

A. The laboratory shall keep all records, certificates and reports as required by applicable state and federal recordkeeping laws and regulations. The laboratory shall safely store these records and hold them secure.

B. The laboratory shall retain all records for a minimum of three years from generation of the last entry in the records, or longer, if required by an applicable regulatory program, whichever is greater. The laboratory shall maintain all information necessary for the historical reconstruction of data, including all original observations, calculations and derived data, calibration records and a copy of the test report.

C. Records that are stored only on electronic media shall be supported by the hardware and software necessary for their retrieval. Records that are stored or generated by computers or personal computers shall have hard copy or write-protected backup copies.

D. The laboratory shall establish a record management system for control of laboratory notebooks, instrument logbooks, standards logbooks, and records for data reduction, validation storage and reporting.

E. Access to archived information shall be documented with an access log. The laboratory shall protect these records against fire, theft, loss, environmental deterioration, vermin and, in the case of electronic records, electronic or magnetic sources.

F. The laboratory shall have a plan to ensure that the records are maintained or transferred in the event that a laboratory transfers ownership or goes out of business. In addition, in cases of bankruptcy, the laboratory shall follow appropriate regulatory and state legal requirements concerning laboratory records.

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

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

1VAC30-45-660. Required records.

A. Sample handling.

1. The laboratory shall maintain a record of all procedures to which a sample is subjected while in the possession of the laboratory. These shall include but are not limited to all records pertaining to sample preservation, identification, receipt, acceptance or rejection, log-in, storage and tracking. The laboratory shall also maintain sampling information on each sample. This includes time and date of collection, type of sample (grab or composite), type of container, sampling point and preservation.

2. The laboratory shall have documented procedures for the receipt and retention of samples, including provisions necessary to protect the integrity of the samples.

B. Laboratory support activities. The laboratory shall retain the following documents and data:

1. All original raw data, whether hard copy or electronic, for calibrations, samples and quality control measures, including analysts' work sheets and data output

records (chromatograms, strip charts, and other instrument response readout records).

2. A written description or reference to the specific test method used that includes a description of the specific computational steps used to translate parametric observations into a reportable analytical value.
3. Copies of final reports.
4. Archived standard operating procedures.
5. Correspondence relating to laboratory activities.
6. All corrective action plans, audits, and audit responses.
7. Proficiency test results and raw data.
8. Results of data review, verification, and cross-checking procedures.

C. Analytical records. The laboratory shall retain essential information associated with analytical documents, such as strip charts, tabular printouts, computer data files, analytical notebooks, and run logs. This information includes, but is not limited to, all manual calculations (e.g., manual integrations); sample preparation; standard and reagent origin, receipt, preparation, and use; quality control protocols and assessment; and method performance criteria.

D. Administrative records. The laboratory shall maintain the following administrative records:

1. Personnel qualifications, experience and training records.
2. Records of demonstration of capability for each analyst or work cell.
3. A log of names, initials and signatures for all individuals who are responsible for signing or initialing any laboratory record.

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 22, eff. September 1, 2016.

1VAC30-45-670. Audits.

A. Internal audits.

1. The laboratory shall arrange for annual internal audits to verify that its operations continue to comply with the requirements of the laboratory's quality system. It is the responsibility of the quality assurance officer to plan and organize audits as required by a predetermined schedule and requested by management.
2. Trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited shall carry out these audits. Personnel shall not audit their own activities except when it can be demonstrated that an effective audit will be carried out.
3. Where the audit findings cast doubt on the correctness or validity of the laboratory's calibrations or test results, the laboratory shall take immediate corrective action.

4. A laboratory may have an audit performed under contract by an outside source competent to audit the laboratory's operations.

B. Managerial review.

1. The laboratory management shall conduct a review, at least annually, of its quality system and its testing and calibration activities to ensure its continuing suitability and effectiveness and to introduce any necessary changes or improvements in the quality system and laboratory operations.

2. The review shall take account of reports from managerial and supervisory personnel, the outcome of recent internal audits, assessments by external bodies, the results of inter-laboratory comparisons or proficiency tests, corrective actions and other relevant factors.

3. The laboratory shall have a procedure for review by management and maintain records of review findings and actions.

4. Where the staff of a laboratory is limited to a single analyst, a supervisor may perform a managerial review.

C. Audit review. All audit and review findings and any corrective actions that arise from them shall be documented. The laboratory management shall ensure that these actions are discharged within the agreed timeframe as indicated in the quality manual or standard operating procedures or both. For clarification, documentation of audit and review findings should be a simple procedure, essentially a memorandum setting out the findings of the audit and managerial review and any action to follow.

D. Corrective actions.

1. In addition to providing acceptance criteria and specific protocols for corrective actions in the method standard operating procedures, the laboratory shall implement general procedures to be followed to determine consistently when departures from documented policies, procedures and quality control have occurred. These procedures may include but are not limited to the following:

- a. Identify the individual or individuals responsible for assessing each quality control data type;
- b. Identify the individual or individuals responsible for initiating or recommending corrective actions or both;
- c. Define how the analyst shall treat a data set if the associated quality control measurements are unacceptable;
- d. Specify how out-of-control situations and subsequent corrective actions are to be documented; and
- e. Specify procedures for management (including the quality assurance officer) to review corrective action plans.

2. To the extent possible, samples shall be reported only if all quality control measures are acceptable. If a quality control measure is found to be out of control, and the data are to be reported, all samples associated with the failed quality control measure shall be reported with the appropriate data qualifiers.

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 22, eff. September 1, 2016.

1VAC30-45-680. Subcontracting analytical samples.

A. Where a laboratory subcontracts any part of the testing covered under this chapter, the testing shall only be subcontracted to a laboratory certified under 1VAC30-46.

B. The report from the subcontractor shall be a separate part of the laboratory report and identified as laboratory testing done by a subcontractor.

C. The laboratory shall retain records demonstrating that the requirements of this section have been met.

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

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

1VAC30-45-690. Outside support services and supplies.

A. The laboratory shall have a policy and procedures for the selection and purchasing of services and supplies it uses that affect the quality of environmental tests. Procedures shall exist for the purchase, reception and storage of reagents and laboratory consumable materials relevant for the environmental tests.

B. The laboratory shall ensure that purchased equipment and consumable materials are not used until they have been inspected, calibrated or otherwise verified as complying with standard specifications or requirements defined in the methods for the tests concerned. These services and supplies used shall comply with specified requirements. Records of actions taken to check compliance shall be maintained.

C. The laboratory shall maintain records of all suppliers from whom it obtains support services or supplies required for tests.

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

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

1VAC30-45-700. Complaints.

The laboratory shall have documented policy and procedures for the resolution of complaints about the laboratory's activities. Where a complaint or any other circumstance raises doubt concerning the laboratory's compliance with the laboratory's policies or procedures, or with the requirements of this chapter or otherwise concerning the quality of the laboratory's calibrations or tests, the laboratory shall ensure that those areas of activity and responsibility involved are promptly audited in accordance with 1VAC30-45-670 A. Records of the complaint and subsequent actions shall be maintained.

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

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

1VAC30-45-710. Environment and work areas.

Laboratory accommodations, test areas, energy sources, lighting, heating and ventilation shall be such as to facilitate proper performance of tests. Laboratories shall

meet the requirements of subdivisions 1 through 8 of this section as appropriate to provide compliance with this requirement.

1. The environment in which these activities are undertaken shall not invalidate the results or adversely affect the required accuracy of measurement. Particular care shall be taken when such activities are undertaken at sites other than the permanent laboratory premises.
2. The laboratory shall provide for the effective monitoring, control and recording of environmental conditions as appropriate. Such environmental conditions may include biological sterility, dust, electromagnetic interference, humidity, mains voltage, temperature, and sound and vibration levels.
3. In instances where monitoring or control of any of the above-mentioned items are specified in a test method or by regulation, the laboratory shall meet and document adherence to the laboratory facility requirements.
4. There shall be effective separation between neighboring areas in which there are incompatible activities including culture handling or incubation areas and volatile organic chemical handling areas. The laboratory shall take measures to prevent cross-contamination.
5. Access to and use of all areas affecting the quality of these activities shall be defined and controlled.
6. Adequate measures shall be taken to ensure good housekeeping in the laboratory and to ensure that any contamination does not adversely affect data quality.
7. Work spaces shall be available to ensure an unencumbered work area.
8. Work areas include:
 - a. Access and entryways to the laboratory;
 - b. Sample receipt areas;
 - c. Sample storage areas;
 - d. Chemical and waste storage areas; and
 - e. Data handling and storage areas.

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

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

1VAC30-45-720. Equipment and reference materials.

A. The laboratory shall be furnished with all items of equipment, including reference materials, required for the correct performance of tests for which certification is sought. The laboratory shall maintain records of reference materials sufficient to provide proper performance of tests. In those cases where the laboratory needs to use equipment outside its permanent control it shall ensure that the relevant requirements of this article are met.

B. All equipment shall be properly maintained, inspected and cleaned. Maintenance procedures shall be documented.

C. Any item of the equipment that has been subjected to overloading or mishandling, or that gives suspect results, or has been shown by verification or otherwise to be

defective shall be taken out of service immediately, clearly identified as being out of service and, wherever possible, stored at a specified place until it has been repaired and shown by calibration, verification or test to perform satisfactorily. The laboratory shall examine the effect of this defect on previous calibrations or tests.

D. Each item of equipment including reference materials shall be labeled, marked or otherwise identified to indicate its calibration status.

E. Records of each major item of equipment significant to the tests performed shall be maintained. These records shall include documentation on all routine and nonroutine maintenance activities. The laboratory shall maintain records of reference materials sufficient to provide proper performance of tests. The records shall include:

1. The name of the item of equipment;
2. The manufacturer's name, type identification, and serial number or other unique identification;
3. Current location, where appropriate;
4. Copy of the manufacturer's instructions, where available;
5. Dates and results of calibrations or verifications or both and date of the next calibration or verification;
6. Details of maintenance carried out to date and planned for the future; and
7. History of any damage, malfunction, modification or repair.

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 22, eff. September 1, 2016.

1VAC30-45-730. Test methods and standard operating procedures.

A. Methods documentation.

1. The laboratory shall have documented instructions on the use and operation of all relevant equipment, on the handling and preparation of samples, and for calibration or testing, where the absence of such instructions could jeopardize the calibrations or tests.
2. All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be maintained up to date and be readily available to the staff.

B. Standard operating procedures (SOPs).

1. Laboratories shall maintain SOPs that accurately reflect all phases of current laboratory activities such as assessing data integrity, corrective actions, handling customer complaints, and all test methods. These documents, for example, may be equipment manuals provided by the manufacturer or internally written documents. The test methods may be copies of published methods as long as any changes or selected options in the methods are documented and included in the laboratory methods manual.
2. The SOPs shall be organized. Each SOP shall clearly indicate the effective date of the document, the revision number, and the signature or signatures of the responsible laboratory manager or managers.
3. Copies of all SOPs shall be accessible to all personnel.

C. SOPs for laboratory methods.

1. The laboratory shall have and maintain an SOP for each certified analyte or test method.
2. This SOP may be a copy of a published or referenced method or may be written by the laboratory. In cases where modifications to the published method have been made by the laboratory or where the referenced test method is ambiguous or provides insufficient detail, these changes or clarifications shall be clearly described. Each test method shall include or reference where applicable:
 - a. Identification of the test method;
 - b. Applicable matrix or matrices;
 - c. Limits of detection or quantitation;
 - d. Scope and application, including parameters to be analyzed;
 - e. Summary of the test method;
 - f. Definitions;
 - g. Interferences;
 - h. Safety;
 - i. Equipment and supplies;
 - j. Reagents and standards;
 - k. Sample collection, preservation, shipment and storage;
 - l. Quality control;
 - m. Calibration and standardization;
 - n. Procedure;
 - o. Data analysis and calculations;
 - p. Method performance;
 - q. Pollution prevention;
 - r. Data assessment and acceptance criteria for quality control measures;
 - s. Corrective actions for out-of-control data;
 - t. Contingencies for handling out-of-control or unacceptable data;
 - u. Waste management;
 - v. References; and
 - w. Any tables, diagrams, flowcharts and validation data.

D. Test methods.

1. Laboratories shall use (i) promulgated test methods in accordance with the Code of Federal Regulations; (ii) test methods stated in any current permit issued by the State Air Pollution Control Board, the Virginia Waste Management Board, or the State Water Control Board; or (iii) alternate test procedures approved by the board issuing the permit or the Department of Environmental Quality, including applicable quality assurance requirements, and sample preservation, container, storage, and holding time requirements.

2. The laboratory shall use appropriate test methods and procedures for all tests and related activities within its responsibility (including sample handling, transport and storage, preparation and analysis). The method and procedures shall be consistent with the accuracy required and with any standard specifications relevant to the calibrations or tests concerned.
3. When the use of reference test methods for a sample analysis is mandated, only those methods shall be used.
4. Where test methods are employed that are not required, as in the Performance Based Measurement System approach, the methods shall be fully documented and validated (see subsection E of this section).

E. Demonstration of capability.

1. Prior to acceptance and institution of any test method, satisfactory initial demonstration of method capability is required. In general, this demonstration does not test the performance of the method in real world samples, but in the applicable and available clean quality system matrix sample (a quality system matrix in which no target analytes or interferences are present at concentrations that impact the results of a specific test method), for example, drinking water, solids, biological tissue and air. Laboratories shall follow the procedure in subsection F of this section to demonstrate capability.
2. Thereafter, ongoing demonstration of method performance, such as laboratory control samples, is required.
3. In cases where a laboratory analyzes samples using a test method that has been in use by the laboratory for at least one year prior to applying for certification, and there have been no significant changes in instrument type, personnel or test method, the continuing demonstration of method performance and the analyst's documentation of continued proficiency shall be acceptable. The laboratory shall have records on file to demonstrate that an initial demonstration of capability is not required.
4. In all cases, the laboratory shall document each demonstration of capability as required by subsection G of this section.
5. The laboratory shall complete a demonstration of capability each time there is a change in instrument type, personnel or test method, including the addition of an analyte to a certified test method.

F. Procedure for demonstration of capability. The following steps shall be performed for mandated test methods. However, before any results are reported using this method, actual sample spike results may be used to meet this standard (i.e., at least four consecutive matrix spikes within the last 12 months). For analytes that do not lend themselves to spiking (e.g., TSS) the demonstration of capability may be performed using quality control samples. The laboratory may document that other approaches to demonstration of capability are adequate. This documentation shall be included in the laboratory's quality manual:

1. A quality control (QC) 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.

2. The analyte or analytes shall be diluted in a volume of clean quality system matrix sufficient to prepare four aliquots at the concentration specified, or if unspecified, to a concentration of 1-4 times the limit of quantitation.

3. At least four aliquots shall be prepared and analyzed according to the test method either concurrently or over a period of days.

4. Using all of the results, calculate the mean recovery in the appropriate reporting units (such as g/L) and the standard deviations of the population sample (n-1) (in the same units) for each parameter of interest. When it is not possible to determine mean and standard deviations, such as for presence or absence of the analyte and logarithmic values, the laboratory shall assess performance against established and documented criteria.

5. Compare the information from subdivision 4 of this subsection to the corresponding acceptance criteria for precision and accuracy in the test method (if applicable) or in laboratory-generated acceptance criteria (if there are not established mandatory criteria). If all parameters meet the acceptance criteria, the analysis of actual samples may begin. If any one of the parameters do not meet the acceptance criteria, the performance is unacceptable for that parameter.

6. When one or more of the tested parameters fail at least one of the acceptance criteria, the analyst shall proceed according to either subdivision 6 a or 6 b of this subsection.

a. Locate and correct the source of the problem and repeat the test for all parameters of interest beginning with subdivision 3 of this subsection.

b. Beginning with subdivision 3 of this subsection, repeat the test for all parameters that failed to meet criteria. Repeated failure, however, confirms a general problem with the measurement system. If this occurs, locate and correct the source of the problem and repeat the test for all compounds of interest beginning with subdivision 3 of this subsection.

G. Documentation of demonstration of capability. The laboratory shall document each demonstration of capability so that the following information shall be readily available for each employee:

1. Analyst or analysts involved in preparation and analysis.

2. Matrix.

3. Analytes, class of analytes, measured parameters, or organisms.

4. Identification of methods performed.

5. Identification of laboratory-specific SOP used for analysis, including revision number.

6. Date or dates of analysis.

7. All raw data necessary to reconstruct and validate the analyses.

8. Data evaluation required by subsection F of this section.

H. Sample aliquots. Where sampling (as in obtaining sample aliquots from a submitted sample) is carried out as part of the test method, the laboratory shall use

documented procedures and appropriate techniques to obtain representative subsamples.

I. Data verification. Calculations and data transfers shall be subject to appropriate checks. The laboratory shall establish standard operating procedures to ensure that (i) the reported data are free from transcription and calculation errors and (ii) all quality control measures are reviewed and evaluated before data are reported. The laboratory also shall establish standard operating procedures addressing manual calculations including manual integrations.

J. Documentation and labeling of standards and reagents. Documented procedures shall exist for the reception and storage of consumable materials used for the technical operations of the laboratory.

1. 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 available), the date of receipt, recommended storage conditions, and an expiration date after which the material shall not be used unless its reliability is verified by the laboratory.

2. Original containers (such as provided by the manufacturer or vendor) shall be labeled with an expiration date if this date is provided by the manufacturer or vendor.

3. Records shall be maintained on standard and reference material preparation. These records shall indicate traceability to purchased stocks or neat compounds, reference to the method of preparation, date of preparation, expiration date and preparer's initials.

4. Sufficient identification of containers of prepared reagents and standards shall be provided to ensure proper performance of tests.

K. Computers and electronic data related requirements. Where computers, automated equipment or microprocessors are used for the capture, processing, manipulation, recording, reporting, storage or retrieval of test data, the laboratory shall ensure the following:

1. Computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use.

2. Procedures are established and implemented for protecting the integrity of data, such as integrity of data entry or capture, data storage, data transmission and data processing.

3. Computer and automated equipment are maintained to ensure proper functioning and provided with the environmental and operating conditions necessary to maintain the integrity of calibration and test data.

4. Appropriate procedures are established and implemented for the maintenance of security of data including the prevention of unauthorized access to, and the unauthorized amendment of, computer records.

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 22, eff. September 1, 2016.

1VAC30-45-740. Measurement traceability and calibration.

A. General requirements. All equipment used for environmental tests, including equipment for subsidiary measurements (e.g., for environmental conditions) having a significant effect on the accuracy or validity of the result of the environmental test or sampling shall be calibrated before being put into service and on a continuing basis. The laboratory shall have an established program and procedure for the calibration of its equipment. This includes balances, thermistors, thermometers and control standards. Such a program shall include a system for selecting, using, calibrating, checking, controlling and maintaining measurement standards, reference materials used as measurement standards, and measuring and test equipment used to perform environmental tests.

B. Traceability of calibration.

1. The laboratory shall ensure that the equipment used can provide the uncertainty of measurement needed.
2. The overall program of calibration or verification or both and validation of equipment shall be designed and operated so as to ensure that measurements made by the laboratory are traceable to national standards of measurement.
3. Where traceability of measurements to the International System of Units (SI) is not possible or not relevant, the same requirements for traceability to, for example, certified reference materials, agreed methods or consensus standards, are required. The laboratory shall provide satisfactory evidence of correlation of results, for example by participation in a suitable program of inter-laboratory comparisons, proficiency testing, or independent analysis.

C. Reference standards and reference materials.

1. Reference standards. The laboratory shall have a program and procedure for the calibration of its reference standards. Reference standards of measurement shall be calibrated by a body that can provide traceability as described in subsection B of this section. Such reference standards of measurement held by the laboratory (such as Class S or equivalent weights or traceable thermometers) shall be used for calibration only and for no other purpose, unless it can be demonstrated that their performance as reference standards would not be invalidated. Where commercially available, this traceability shall be to a national standard of measurement.
2. Reference materials. Reference materials shall, where commercially available, be traceable to SI units of measurement, or to certified reference materials. Where possible, traceability shall be to national or international standards of measurement, or to national or international standard reference materials. Internal reference materials shall be checked as far as is technically and economically practicable.

D. Calibration. Calibration requirements are divided into two parts: (i) requirements for analytical support equipment and (ii) requirements for instrument calibration. In addition, the requirements for instrument calibration are divided into initial instrument calibration and continuing instrument calibration verification.

1. Support equipment. These standards apply to all devices that may not be the actual test instrument, but are necessary to support laboratory operations. These include but are not limited to balances, ovens, refrigerators, freezers, incubators, water baths, temperature measuring devices (including thermometers and thermistors), thermal/pressure sample preparation devices and volumetric dispensing devices (such as Eppendorf®, or automatic dilutor or dispensing devices) if quantitative results are dependent on their accuracy, as in standard preparation and dispensing or dilution into a specified volume.

a. All support equipment shall be maintained in proper working order. The records of all repair and maintenance activities, including service calls, shall be kept.

b. All support equipment shall be calibrated or verified at least annually, using NIST traceable references when available, over the entire range of use. The results of such calibration shall be within the specifications required of the application for which this equipment is used. If not, the laboratory shall either (i) remove the equipment from service until repaired or (ii) maintain records of established correction factors to correct all measurements.

c. Raw data records shall be retained to document equipment performance.

d. On each day the equipment is used, balances, ovens, refrigerators, freezers, and water baths shall be checked in the expected use range, with NIST traceable references where available. The acceptability for use or continued use shall be according to the needs of the analysis or application for which the equipment is being used.

e. Mechanical volumetric dispensing devices including burettes (except Class A glassware) shall be checked for accuracy on at least a quarterly use basis. Glass microliter syringes are to be considered in the same manner as Class A glassware, but shall come with a certificate attesting to established accuracy or the accuracy shall be initially demonstrated and documented by the laboratory.

f. For chemical tests, the temperature, cycle time and pressure of each run of autoclaves shall be documented by the use of appropriate chemical indicators or temperature recorders and pressure gauges.

g. For biological tests that employ autoclave sterilization, the following requirements apply:

(1) The performance of each autoclave shall be initially evaluated by establishing its functional properties and performance, for example heat distribution characteristics with respect to typical uses. Autoclaves shall meet specified temperature tolerances. Pressure cookers fitted only with a pressure gauge are not recommended for sterilization of media or decontamination of wastes.

(2) Records of autoclave operations including temperature and time shall be maintained. This shall be done for every cycle. Acceptance and rejection criteria shall be established and used to evaluate the autoclave efficiency and effectiveness.

2. Instrument calibration.

a. This standard specifies the essential elements that define the procedures and documentation for initial instrument calibration and continuing instrument calibration verification to ensure that the data shall be of known quality and be appropriate for a given regulation or decision. This standard does not specify detailed procedural steps for calibration, but establishes the essential elements for selection of the appropriate technique or techniques. If more stringent standards or requirements are included in a mandated test method or by regulation, the laboratory shall demonstrate that such requirements are met. If it is not apparent which standard is more stringent, then the requirements of the regulation or mandated test method are to be followed.

b. Initial instrument calibrations. The following items are essential elements of initial instrument calibration:

(1) The laboratory shall include or reference the details of the initial instrument calibration procedures, including calculations, integrations, acceptance criteria and associated statistics in the standard operating procedure for the test method. When initial instrument calibration procedures are referenced in the test method, then the laboratory shall retain the referenced material and make it available for review.

(2) The laboratory shall retain sufficient raw data records to permit reconstruction of the initial instrument calibration (e.g., calibration date, test method, instrument, analysis date, each analyte name, analyst's initials or signature, concentration and response, calibration curve or response factor, or unique equation or coefficient used to reduce instrument responses to concentration).

(3) Sample results shall be quantitated from the initial instrument calibration and may not be quantitated from any continuing instrument calibration verification unless otherwise required by regulation, method, or program.

(4) All initial instrument calibrations shall be verified with a standard obtained from a second manufacturer or lot. Traceability shall be to a national standard, when available. This element does not apply to laboratories performing only simple test procedures.

(5) Criteria for the acceptance of an initial instrument calibration shall be established (e.g., correlation coefficient and relative percent difference). The criteria used shall be 0.995 or greater for the calibration coefficient unless a different criterion is included in the method being used.

(6) Results of samples not bracketed by initial calibration standards (within calibration range) shall be reported as having less certainty (e.g., defined qualifiers or flags or explained in the case narrative). The lowest calibration standard shall be above the detection limit.

(7) If the initial instrument calibration results are outside established acceptance criteria, corrective actions shall be performed. Data associated with an unacceptable initial instrument calibration shall not be reported.

(8) Calibration standards shall include concentrations at or below the regulatory limit or decision level, if these limits or levels are known by the laboratory, unless these concentrations are below the laboratory's demonstrated detection limits.

(9) If a reference or mandated method does not specify the number of calibration standards, the minimum number is two, not including blanks or a zero standard. The laboratory shall have a standard operating procedure for determining the number of points for establishing the initial instrument calibration.

c. Continuing instrument calibration verification.

(1) When an initial instrument calibration is not performed on the day of analysis, the validity of the initial calibration shall be verified prior to sample analyses by a continuing instrument calibration check with each analytical batch. This provision does not apply to laboratories performing only simple test procedures.

(2) The following items are essential elements of continuing instrument calibration verification:

(a) The laboratory shall include or reference the details of the continuing instrument calibration procedure, calculations and associated statistics in the standard operating procedure for the test method.

(b) The laboratory shall verify calibration for each compound, element, or other discrete chemical species, except for multicomponent analytes such as aroclors, total petroleum hydrocarbons, or toxaphene where a representative chemical related substance or mixture can be used.

(c) The laboratory shall perform a continuing instrument calibration verification as follows:

(i) At the beginning and end of each analytical batch. If an internal standard is used, only one verification needs to be performed at the beginning of the analytical batch;

(ii) Whenever it is expected that the analytical system may be out of calibration or might not meet the verification acceptance criteria;

(iii) If the time period for calibration or the most previous calibration verification has expired; or

(iv) For analytical systems that contain a calibration verification requirement.

(d) Sufficient raw data records shall be retained to permit reconstruction of the continuing instrument calibration verification (e.g., or test method, instrument, analysis date, each analyte name, concentration and response, calibration curve or response factor, or unique equations or coefficients used to convert instrument responses into concentrations). Continuing calibration verification records shall explicitly connect the continuing verification data to the initial instrument calibration.

(e) Criteria for the acceptance of a continuing instrument calibration verification shall be established (e.g., percent recovery or relative percent difference).

(f) If the continuing instrument calibration verification results obtained are outside established acceptance criteria, corrective actions shall be performed. If routine corrective action procedures fail to produce a second consecutive (immediate) calibration verification within acceptance criteria, then either the laboratory has to demonstrate acceptable performance after corrective action with two consecutive successful calibration verifications, or a new initial instrument calibration shall be performed. If the laboratory has not verified calibration, sample analyses shall not occur until the analytical system is calibrated or calibration verified. If samples are analyzed using a system on which the calibration has not yet been verified, the results shall be flagged. Data associated with an unacceptable calibration verification may be fully useable under the following special conditions:

(i) When the acceptance criteria for the continuing calibration verification are exceeded high (i.e., high bias) and there are associated samples that are nondetects, then those nondetects may be reported. Otherwise the samples affected by the unacceptable calibration verification shall be reanalyzed after a new calibration curve has been established, evaluated and accepted.

(ii) When the acceptance criteria for the continuing calibration verification are exceeded low (i.e., low bias) those sample results may be reported if they exceed a maximum regulatory limit or decision level. Otherwise the samples affected by the unacceptable verification shall be reanalyzed after a new calibration curve has been established, evaluated and accepted.

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 22, eff. September 1, 2016.

1VAC30-45-750. Quality assurance.

A. General. The laboratory shall have quality control procedures for monitoring the validity of environmental tests undertaken. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results. This monitoring shall be planned and reviewed and may include, but not be limited to, the following:

1. Regular use of certified reference materials or internal quality control using secondary reference materials or both.
2. Participation in interlaboratory comparison or proficiency testing program.
3. Replicate tests using the same or different methods.
4. Retesting of retained samples.
5. Correlation of results for different characteristics of a sample (e.g., total phosphate should be greater than or equal to orthophosphate).

B. Essential quality control procedures. The general quality control principles in subsection C of this section shall apply, where applicable, to all environmental laboratories. The manner in which they are implemented is dependent on the types of tests performed by the laboratory. 1VAC30-45-770 through 1VAC30-45-775, 1VAC30-45-790 through 1VAC30-45-798, and 1VAC30-45-810 through 1VAC30-45-818 specify

quality control requirements for chemical testing, microbiological testing, and air testing, respectively. Noncommercial environmental laboratories that analyze environmental samples using other types of testing such as toxicity, radiochemical, or asbestos testing shall meet the quality control standards for the specific method and the specific type of testing in the 2009 TNI Standards for Environmental Laboratories. The standards for any given test type shall assure that the applicable principles are addressed.

C. All laboratories shall have detailed written protocols in place to monitor the following quality controls:

1. Positive and negative controls to monitor tests such as blanks, spikes, reference toxicants.
2. Tests to define the variability or repeatability of the laboratory results or both such as replicates.
3. Measures to assure the accuracy of the test method including calibration or continuing calibrations or both, use of certified reference materials, proficiency test samples, or other measures.
4. Measures to evaluate test method capability, such as method detection limits and quantitation limits or range of applicability such as linearity.
5. Selection of appropriate formulae to reduce raw data to final results such as regression analysis, comparison to internal and external standard calculations, and statistical analyses.
6. Selection and use of reagents and standards of appropriate quality.
7. Measures to assure the selectivity of the test for its intended purpose.
8. Measures to assure constant and consistent test conditions (both instrumental and environmental) where required by the test method such as temperature, humidity, light, or specific instrument conditions.

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 22, eff. September 1, 2016.

1VAC30-45-760. Quality control requirements.

A. General.

1. The quality control protocols specified by the laboratory's SOPs shall be followed (1VAC30-45-730 C). The laboratory shall ensure that either the (i) applicable essential standards outlined in this section through 1VAC30-45-775, 1VAC30-45-790 through 1VAC30-45-798, and 1VAC30-45-810 through 1VAC30-45-818 or (ii) mandated methods or regulations, whichever are more stringent, are incorporated into their method SOPs. When it is not apparent which is more stringent, the quality controls in the mandated method or regulations are to be followed.
2. All quality control measures shall be assessed and evaluated on an ongoing basis and quality control acceptance criteria shall be used to determine the validity of the data. The laboratory shall have procedures for the development of acceptance/rejection criteria where no method or regulatory criteria exists.

B. Initial test method evaluation. For all test methods other than microbiology, the requirements of subdivisions 1 and 2 of this subsection apply. For microbiology testing, the initial test method evaluation requirements are contained in 1VAC30-45-790 through 1VAC30-45-798. For the evaluation of precision and bias (subdivision 3 of this subsection), the requirements of subdivision 3 a of this subsection apply to standard methods. The requirements of subdivision 3 b of this subsection apply to the methods referenced in that subdivision.

1. Limit of detection (LOD).

a. The laboratory shall determine the LOD for the method for each target analyte of concern in the quality system matrices. All sample processing steps of the analytical method shall be included in the determination of the LOD.

b. The validity of the LOD shall be confirmed by qualitative identification of the analyte or analytes in a quality control sample in each quality system matrix containing the analyte at no more than two to three times the LOD for single analyte tests and one to four times the LOD for multiple analyte tests. This verification shall be performed on every instrument that is to be used for analysis of samples and reporting of data.

c. An LOD study is not required for any component for which spiking solutions or quality control samples are not available such as temperature, or, when test results are not to be reported to the LOD (versus the limit of quantitation or working range of instrument calibration), according to 1VAC30-45-771 and 1VAC30-45-814. Where an LOD study is not performed, the laboratory may not report a value below the limit of quantitation.

2. Limit of quantitation (LOQ).

a. The laboratory shall determine the LOQ for each analyte of concern according to a defined, documented procedure.

b. The LOQ study is not required for any component or property for which spiking solutions or quality control samples are not commercially available or otherwise inappropriate (e.g., pH).

c. The validity of the LOQ shall be confirmed by successful analysis of a QC sample containing the analytes of concern in each quality system matrix one to two times the claimed LOQ. A successful analysis is one where the recovery of each analyte is within the established test method acceptance criteria or client data quality objectives for accuracy. This single analysis is not required if the bias and precision of the measurement system is evaluated at the LOQ.

3. Evaluation of precision and bias.

a. Standard methods. The laboratory shall evaluate the precision and bias of a standard method for each analyte of concern for each quality system matrix according to either of the following:

(1) The single-concentration four-replicate recovery study procedures in 1VAC30-45-730 F; or

(2) An alternate procedure documented in the quality manual when the analyte cannot be spiked into the sample matrix and quality control samples are not commercially available.

b. Nonstandard methods.

(1) For laboratory-developed test methods or nonstandard test methods that were not in use by the laboratory before July 2003, the laboratory shall have a documented procedure to evaluate precision and bias. The laboratory shall also compare results of the precision and bias measurements with criteria given in the reference method or criteria established by the laboratory.

(2) Precision and bias measurements shall evaluate the method across the analytical calibration range of the method. The laboratory shall also evaluate precision and bias in the relevant quality system matrices and shall process the samples through the entire measurement system for each analyte of interest.

(3) The following are examples of a systematic approach to evaluate precision and bias:

(a) Example 1. Analyze QC samples in triplicate containing the analytes of concern at or near the limit of quantitation, at the upper-range of the calibration (upper 20%) and at a mid-range concentration. Process these samples on different days as three sets of samples through the entire measurement system for each analyte of interest. Each day one QC sample at each concentration is analyzed. A separate method blank shall be subjected to the analytical method along with the QC samples on each of the three days. (Note that the three samples at the LOQ concentration can demonstrate sensitivity as well.) For each analyte, calculate the mean recovery for each day, for each level over days, and for all nine samples. Calculate the relative standard deviation for each of the separate means obtained. Compare the standard deviations for the different days and the standard deviations for the different concentrations. If the different standard deviations are all statistically insignificant (e.g., F-test), then compare the overall mean and standard deviation with the established criteria from above.

(b) Example 2. A validation protocol such as the Tier I, Tier II, and Tier III requirements in U.S. EPA Office of Water's Alternate Test Procedure (ATP) approval process.

4. Evaluation of selectivity. The laboratory shall evaluate selectivity by following the checks established within the method. These checks may include mass spectral tuning, second column confirmation, ICP inter-element interference checks, chromatography retention time windows, sample blanks, spectrochemical absorption or fluorescence profiles, co-precipitation evaluations, and electrode response factors.

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 22, eff. September 1, 2016; Errata, 32:24 VA.R. XXX July 25, 2016.

1VAC30-45-770. Chemical testing: positive and negative controls.

A. Negative control – method performance.

1. Purpose. The method blank is used to assess the preparation batch for possible contamination during the preparation and processing steps. The method blank shall be processed along with and under the same conditions as the associated samples to include all steps of the analytical procedure. Procedures shall be in place to determine if a method blank is contaminated. Any affected samples associated with a contaminated method blank shall be reprocessed for analysis or the results reported with appropriate data qualifying codes.

2. Frequency. The method blank shall be analyzed at a minimum of one per preparation batch. In those instances for which no separate preparation method is used (e.g., volatiles in water) the batch shall be defined as environmental samples that are analyzed together with the same method and personnel, using the same lots of reagents, not to exceed the analysis of 20 environmental samples.

3. Composition. The method blank shall consist of a quality system matrix that is similar to the associated samples and is known to be free of the analytes of interest.

4. Evaluation criteria and corrective action. While the goal is to have no detectable contaminants, each method blank shall be critically evaluated as to the nature of the interference and the effect on the analysis of each sample within the batch. The source of contamination shall be investigated and measures taken to minimize or eliminate the problem and affected samples reprocessed or data shall be appropriately qualified if:

a. The concentration of a targeted analyte in the blank is at or above the reporting limit as established by the test method or by regulation, and is greater than 1/10 of the amount measured in any sample.

b. The blank contamination otherwise affects the sample results as per the test method requirements or the individual project data quality objectives.

c. When a blank is determined to be contaminated, the cause shall be investigated and measures taken to minimize or eliminate the problem. Samples associated with a contaminated blank shall be evaluated as to the best corrective action for the samples (e.g., reprocessing or data qualifying codes). In all cases the corrective action shall be documented.

B. Positive control – method performance. Laboratory control sample (LCS).

1. Purpose. The LCS is used to evaluate the performance of the total analytical system, including all preparation and analysis steps. Results of the LCS are compared to established criteria and, if found to be outside of these criteria, indicates that the analytical system is "out of control." Any affected samples associated with an out of control LCS shall be reprocessed for re-analysis or the results reported with appropriate data qualifying codes.

2. Frequency. The LCS shall be analyzed at a minimum of one per preparation batch. Exceptions would be for those analytes for which no spiking solutions are

available such as total suspended solids, total dissolved solids, total volatile solids, total solids, pH, color, odor, temperature, dissolved oxygen or turbidity. In those instances for which no separate preparation method is used (example: volatiles in water) the batch shall be defined as environmental samples that are analyzed together with the same method and personnel, using the same lots of reagents, not to exceed the analysis of 20 environmental samples.

3. Composition. The LCS is a quality system matrix, known to be free of analytes of interest, spiked with known and verified concentrations of analytes. NOTE: the matrix spike may be used in place of this control as long as the acceptance criteria are as stringent as for the LCS. Alternatively the LCS may consist of a media containing known and verified concentrations of analytes or as Certified Reference Material (CRM). All analyte concentrations shall be within the calibration range of the methods. The following shall be used in choosing components for the spike mixtures:

The components to be spiked shall be as specified by the mandated test method or other regulatory requirement or as requested by the client. In the absence of specified spiking components the laboratory shall spike per the following:

a. For those components that interfere with an accurate assessment such as spiking simultaneously with technical chlordane, toxaphene and PCBs, the spike should be chosen that represents the chemistries and elution patterns of the components to be reported.

b. For those test methods that have extremely long lists of analytes, a representative number may be chosen. The analytes selected should be representative of all analytes reported. The following criteria shall be used for determining the minimum number of analytes to be spiked. However, the laboratory shall insure that all targeted components are included in the spike mixture over a two-year period. For methods that include 1-10 targets, spike all components; for methods that include 11-20 targets, spike at least 10 components or 80%, whichever is greater; and for methods with more than 20 targets, spike at least 16 components.

4. Evaluation criteria and corrective action.

a. The results of the individual batch LCS are calculated in percent recovery or other appropriate statistical technique that allows comparison to established acceptance criteria. The laboratory shall document the calculation.

b. The individual LCS is compared to the acceptance criteria as published in the mandated test method. Where there are no established criteria, the laboratory shall determine internal criteria and document the method used to establish the limits or utilize client specified assessment criteria.

c. A LCS that is determined to be within the criteria effectively establishes that the analytical system is in control and validates system performance for the samples in the associated batch. Samples analyzed along with a LCS determined to be "out of control" shall be considered suspect and the samples reprocessed and re-analyzed or the data reported with appropriate data qualifying codes.

5. If a large number of analytes are in the LCS, it becomes statistically likely that a few will be outside control limits. This may not indicate that the system is out of control, therefore corrective action may not be necessary. Upper and lower marginal exceedance (ME) limits can be established to determine when corrective action is necessary. A ME is defined as being beyond the LCS control limit (3 standard deviations), but within the ME limits. ME limits are between 3 and 4 standard deviations around the mean.

a. The number of allowable marginal exceedances is based on the number of analytes in the LCS. If more analytes exceed the LCS control limits than is allowed, or if any one analyte exceeds the ME limits, the LCS fails and corrective action is necessary. This marginal exceedance approach is relevant for methods with long lists of analytes. It will not apply to target analyte lists with fewer than 11 analytes.

b. The number of allowable marginal exceedances is as follows:

Number of analytes in LCS	Number of analytes allowed in ME of the LCS control limit
Greater than 90	Five
71-90	Four
51-70	Three
31-50	Two
11-30	One
Fewer than 11	None

c. Marginal exceedances shall be random. If the same analyte exceeds the LCS control limit repeatedly, it is an indication of a systemic problem. The source of the error shall be located and corrective action taken. Laboratories shall have a written procedure to monitor the application of marginal exceedance allowance to the LCS to ensure random behavior.

C. Sample specific controls - general.

1. The laboratory shall document procedures for determining the effect of the sample matrix on method performance. These procedures relate to the analyses of quality system matrix specific Quality Control (QC) samples and are designed as data quality indicators for a specific sample using the designated test method. These controls alone are not used to judge laboratory performance.

2. Examples of matrix specific QC include: Matrix Spike (MS); Matrix Spike Duplicate (MSD); sample duplicates; and surrogate spikes. The laboratory shall have procedures in place for tracking, managing, and handling matrix specific QC criteria including spiking appropriate components at appropriate

concentrations, calculating recoveries and relative percent difference, evaluating and reporting results based on performance of the QC samples.

D. Sample specific controls - matrix spike and matrix spike duplicates.

1. Purpose. Matrix specific QC samples indicate the effect of the sample matrix on the precision and accuracy of the results generated using the selected method. The information from these controls is sample/matrix specific and would not normally be used to determine the validity of the entire batch.

2. Frequency. The frequency of the analysis of matrix specific samples shall be determined as part of a systematic planning process (e.g., Data Quality Objectives) or as specified by the test method.

3. Composition. The components to be spiked shall be as specified by the mandated test method. Any permit specified analytes, as specified by regulation or client requested analytes shall also be included. If there are no specified components, the laboratory shall spike per the following:

a. For those components that interfere with an accurate assessment such as spiking simultaneously with technical chlordane, toxaphene and PCBs, the spike should be chosen that represents the chemistries and elution patterns of the components to be reported.

b. For those test methods that have extremely long lists of analytes, a representative number may be chosen using the following criteria for choosing the number of analytes to be spiked. However, the laboratory shall insure that all targeted components are included in the spike mixture over a two-year period.

(1) For methods that include 1-10 targets, spike all components;

(2) For methods that include 11-20 targets, spike at least 10 components or 80%, whichever is greater;

(3) For methods with more than 20 targets, spike at least 16 components.

4. Evaluation criteria and corrective action.

a. The results from matrix spike/matrix spike duplicate are primarily designed to assess the precision and accuracy of analytical results in a given matrix and are expressed as percent recovery (%R), relative percent difference (RPD), or other appropriate statistical technique that allows comparison to established acceptance criteria. The laboratory shall document the calculation for %R, RPD or other statistical treatment used.

b. The results are compared to the acceptance criteria as published in the mandated test method. Where there are no established criteria, the laboratory shall determine internal criteria and document the method used to establish the limits. For matrix spike results outside established criteria corrective action shall be documented or the data reported with appropriate data qualifying codes.

E. Sample specific controls - matrix duplicates.

1. Purpose. Matrix duplicates are defined as replicate aliquots of the same sample taken through the entire analytical procedure. The results from this

analysis indicate the precision of the results for the specific sample using the selected method. The matrix duplicate provides a usable measure of precision only when target analytes are found in the sample chosen for duplication.

2. Frequency. The frequency of the analysis of matrix duplicates may be determined as part of a systematic planning process (e.g., Data Quality Objectives) or as specified by the mandated test method.

3. Composition. Matrix duplicates are performed on replicate aliquots of actual samples. The composition is usually not known.

4. Evaluation criteria and corrective action.

a. The results from matrix duplicates are primarily designed to assess the precision of analytical results in a given matrix and are expressed as relative percent difference (RPD) or another statistical treatment (e.g., absolute differences). The laboratory shall document the calculation for relative percent difference or other statistical treatments.

b. Results are compared to the acceptance criteria as published in the mandated test method. Where there are no established criteria, the laboratory shall determine internal criteria and document the method used to establish the limits. For matrix duplicates results outside established criteria corrective action shall be documented or the data reported with appropriate data qualifying codes.

F. Sample specific controls - surrogate spikes.

1. Purpose. Surrogates are used most often in organic chromatography test methods and are chosen to reflect the chemistries of the targeted components of the method. Added prior to sample preparation/extraction, they provide a measure of recovery for every sample matrix.

2. Frequency. Except where the matrix precludes its use or when not commercially available, surrogate compounds shall be added to all samples, standards, and blanks for all appropriate test methods.

3. Composition. Surrogate compounds are chosen to represent the various chemistries of the target analytes in the method or measurement quality objectives. They are often specified by the mandated method and are deliberately chosen for their being unlikely to occur as an environmental contaminant. Often this is accomplished by using deuterated analogs of select compounds.

4. Evaluation criteria and corrective action. The results are compared to the acceptance criteria as published in the mandated test method. Where there are no established criteria, the laboratory should determine internal criteria and document the method used to establish the limits. Surrogates outside the acceptance criteria shall be evaluated for the effect indicated for the individual sample results. Data quality objectives or other site-specific requirements may guide the appropriate corrective action. Results reported from analyses with surrogate recoveries outside the acceptance criteria should include appropriate data qualifiers.

Historical Notes: Derived from Virginia Register Volume 25, Issue 7, eff. January 1, 2009; amended, Virginia Register Volume 32, Issue 22, eff. September 1, 2016.

1VAC30-45-771. Chemical testing: limit of detection and limit of quantitation.

A. General. All procedures used shall be documented. Documentation shall include the quality system matrix type. All supporting data shall be retained.

B. Limit of detection (LOD). The laboratory shall utilize a test method that provides an LOD that is appropriate and relevant for the intended use of the data. An LOD is not required for a test method when test results are not reported outside of the calibration range. LODs shall be determined by the protocol in the mandated test method or applicable regulation. If the protocol for determining LODs is not specified, the selection of the procedure shall reflect instrument limitations and the intended application of the test method.

1. The LOD shall be initially determined for the compounds of interest in each test method in a quality system matrix in which there are no target analytes or interferences at a concentration that would impact the results. Alternatively the LOD shall be determined in the quality system matrix of interest (see definition of matrix).

2. LODs shall be determined each time there is a change in the test method that affects how the test is performed, or when a change in instrumentation occurs that affects the sensitivity of the analysis.

3. The LOD shall be verified annually for each quality system matrix, method and analyte according to the procedure specified in 1VAC30-45-760 B 1.

C. Limit of quantitation (LOQ).

1. Any established LOQ shall be above the LOD.

2. The LOQ shall be verified annually for each quality system matrix, method and analyte according to the procedure specified in 1VAC30-45-760 B 2. Alternatively, the annual LOQ verification is not required if the LOD is reevaluated or verified according to subdivision B 3 of this section.

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 22, eff. September 1, 2016.

1VAC30-45-772. Chemical testing: data reduction.

The procedures for data reduction, such as use of linear regression, shall be documented.

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

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

1VAC30-45-773. Chemical testing: quality of standards and reagents.

A. The source of standards shall comply with 1VAC30-45-740 C.

B. Reagent quality, water quality and checks.

1. Reagents. In methods where the purity of reagents is not specified, analytical reagent grade shall be used. Reagents of lesser purity than those specified by the test method shall not be used. The labels on the container should be checked to verify that the purity of the reagents meets the requirements of the particular test method. Such information shall be documented.
2. Water. The quality of water sources shall be monitored and documented and shall meet method specified requirements.
3. The laboratory will verify the concentration of titrants in accordance with written laboratory procedures.

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

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

1VAC30-45-774. Chemical testing: selectivity.

A. The laboratory shall evaluate selectivity by following the checks established within the method, which may include mass spectral tuning, second column confirmation, ICP inter-element interference checks, chromatography retention time windows, sample blanks, spectrochemical absorption or fluorescence profiles, co-precipitation evaluations, and electrode response factors.

B. A confirmation shall be performed to verify the compound identification when positive results are detected on a sample from a location that has not been previously tested by the laboratory. Such confirmations shall be performed on organic tests such as pesticides, herbicides, or acid extractable or when recommended by the analytical test method except when the analysis involves the use of a mass spectrometer. Confirmation is required unless stipulated in writing by the client. All confirmation shall be documented.

C. The laboratory shall document acceptance criteria for mass spectral tuning.

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

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

1VAC30-45-775. Chemical testing: constant and consistent test conditions.

A. The laboratory shall assure that the test instruments consistently operate within the specifications required of the application for which the equipment is used.

B. Any cleaning and storage procedures that are not specified by the test method shall be documented in laboratory records and SOPs.

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 22, eff. September 1, 2016.

1VAC30-45-780. (Repealed.) through 1VAC30-45-789. (Reserved.)

Historical Notes: Derived from Virginia Register Volume 25, Issue 7, eff. January 1, 2009; repealed, Virginia Register Volume 32, Issue 22, eff. September 1, 2016.

1VAC30-45-790. Microbiology testing: general.

These standards apply to laboratories undertaking microbiological analysis of environmental samples. Microbiological testing refers to and includes the detection, isolation, enumeration, or identification of microorganisms and/or their metabolites, or determination of the presence or absence of growth in materials and media.

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

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

1VAC30-45-791. Microbiology testing: sterility checks and blanks, positive and negative controls.

A. Sterility checks and blanks. The laboratory shall demonstrate that the filtration equipment and filters, sample containers, media and reagents have not been contaminated through improper handling or preparation, inadequate sterilization, or environmental exposure.

1. A sterility blank shall be analyzed for each lot of pre-prepared, ready-to-use medium (including chromofluorogenic reagent) and for each batch of medium prepared in the laboratory. This shall be done prior to first use of the medium.
2. For filtration technique, the laboratory shall conduct one beginning and one ending sterility check for each filtration series. The filtration series may include single or multiple filtration units, which have been sterilized prior to beginning the series. For presterilized single use funnels a sterility check shall be performed on one funnel per lot. The filtration series is considered ended when more than 30 minutes elapses between successive filtrations. During a filtration series, filter funnels shall be rinsed with three 20-30 ml portions of sterile rinse water after each sample filtration. In addition, laboratories shall insert a sterility blank after every 10 samples or sanitize filtration units by UV light after each sample filtration.
3. For pour plate technique, sterility blanks of the medium shall be made by pouring, at a minimum, one uninoculated plate for each lot of pre-prepared, ready-to-use media and for each batch of medium prepared in the laboratory.
4. Sterility checks on sample containers shall be performed on at least one container for each lot of purchased, presterilized containers with nonselective growth media. For containers prepared and sterilized in the laboratory, a sterility check shall be performed on one container per sterilized batch with nonselective growth media.
5. A sterility blank shall be performed on each batch of dilution water prepared in the laboratory and on each batch of pre-prepared, ready-to-use dilution water with nonselective growth media.
6. At least one filter from each new lot of membrane filters shall be checked for sterility with nonselective growth media.

B. Positive controls.

1. Positive culture controls demonstrate that the medium can support the growth of the target organism or organism, and that the medium produces the specified or expected reaction to the target organism or organism.
2. Each preprepared, ready-to-use lot of medium (including chromofluorogenic reagent) and each batch of medium prepared in the laboratory shall be tested and demonstrate a known positive response. This shall be done prior to first use of the medium.

C. Negative controls. The provisions of this subsection shall not apply to wastewater treatment plants.

1. Negative culture controls demonstrate that the medium does not support the growth of nontarget organisms or does not demonstrate the typical positive reaction of the target organism or organisms.
2. Each pre-prepared, ready-to-use lot of selective medium (including chromofluorogenic reagent) and each batch of selective medium prepared in the laboratory shall be analyzed with one or more known negative culture controls (i.e., nontarget organisms) as appropriate to the method. This shall be done prior to first use of the medium.

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 22, eff. September 1, 2016; Errata, 32:24 VA.R. XXX July 25, 2016.

1VAC30-45-792. Microbiology testing: test variability and reproducibility.

For test methods that specify colony counts such as membrane filter or plated media, duplicate counts shall be performed monthly on one positive sample, for each month that the test is performed. If the lab has two or more analysts, each analyst shall count typical colonies on the same plate. Counts shall be within 10% difference to be acceptable. In a laboratory with only one microbiology analyst, the analyst shall count the same plate twice, with no more than 5.0% difference between the counts.

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

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

1VAC30-45-793. Microbiology testing: method evaluation.

A. Laboratories are required to demonstrate proficiency with the test method prior to first use. This shall be achieved by comparison to a method already approved for use in the laboratory, or by analyzing a minimum of 10 spiked samples whose quality system matrix is representative of those normally submitted to the laboratory, or by analyzing and passing one proficiency test series provided by an approved proficiency sample provider. The laboratory shall maintain this documentation as long as the method is in use and for at least five years past the date of last use.

B. Laboratories shall participate in the proficiency test programs required by Article 3 (1VAC30-45-500 et seq.). The results of these analyses shall be used to evaluate the ability of the laboratory to produce acceptable data.

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

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

1VAC30-45-794. Microbiology testing: test performance.

A. All growth and recovery media shall be checked to assure that the target organism(s) respond in an acceptable and predictable manner (see 1VAC30-45-791 B).

B. To ensure that analysis results are accurate, target organism identity shall be verified as specified in the method, e.g., by use of the completed test, or by use of secondary verification tests such as a catalase test.

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

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

1VAC30-45-795. Microbiology testing: data reduction.

The calculations, data reduction and statistical interpretations specified by each test method shall be followed.

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

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

1VAC30-45-796. Microbiology testing: quality of standards, reagents, and media.

A. The laboratory shall ensure that the quality of the reagents and media used is appropriate for the test concerned.

B. Culture media may be prepared from commercial dehydrated powders or may be purchased ready to use. The laboratory may prepare media from basic ingredients when commercial media are not available or when it can be demonstrated that commercial media do not provide adequate results. Media prepared by the laboratory from basic ingredients shall be tested for performance (e.g., for selectivity, sensitivity, sterility, growth promotion, growth inhibition) prior to first use. Detailed testing criteria information shall be defined in either the laboratory's test methods, SOPs, quality manual, or similar documentation.

C. Reagents, commercial dehydrated powders and media shall be used within the shelf-life of the product and shall be documented according to 1VAC30-45-730 J.

D. Distilled water, deionized water or reverse osmosis produced water free from bactericidal and inhibitory substances shall be used in the preparation of media, solutions and buffers. The quality of the water shall be monitored for chlorine residual, specific conductance, and heterotrophic bacteria plate count monthly (when in use), when maintenance is performed on the water treatment system, or at startup after a period of disuse longer than one month.

E. Analysis for metals and the Bacteriological Water Quality Test (to determine presence of toxic agents or growth promoting substances) shall be performed annually. Results of these analyses shall meet the specifications of the required method and records of analyses shall be maintained for three years. (An exception to performing the Bacteriological Water Quality Test shall be given to laboratories that can supply documentation to show that their water source meets the criteria, as specified by the method, for Type I or Type II reagent water.)

F. Media, solutions and reagents shall be prepared, used and stored according to a documented procedure following the manufacturer's instructions or the test method.

Documentation for media prepared in the laboratory shall include date of preparation, preparer's initials, type and amount of media prepared, manufacturer and lot number, final pH of the media, and expiration date. Documentation for media purchased pre-prepared, ready to use shall include manufacturer, lot number, type of media received, date of receipt, expiration date of the media, and pH of the media.

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 22, eff. September 1, 2016.

1VAC30-45-797. Microbiology testing: selectivity.

In order to ensure identity and traceability, reference cultures used for positive and negative controls shall be obtained from a recognized national collection, organization, or manufacturer. Microorganisms may be single use preparations or cultures maintained by documented procedures that demonstrate the continued purity and viability of the organism.

1. Reference cultures may be revived (if freeze-dried) or transferred from slants and subcultured once to provide reference stocks. The reference stocks shall be preserved by a technique that maintains the characteristics of the strains. Reference stocks shall be used to prepare working stocks for routine work. If reference stocks have been thawed, they shall not be refrozen and reused.
2. Working stocks shall not be sequentially cultured more than five times and shall not be subcultured to replace reference stocks.

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

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

1VAC30-45-798. Microbiology testing: constant and consistent test conditions.

A. Laboratory facilities. Floors and work surfaces shall be nonabsorbent and easy to clean and disinfect. Work surfaces shall be adequately sealed. Laboratories shall provide sufficient storage space, and shall be clean and free from dust accumulation. Plants, food, and drink shall be prohibited from the laboratory work area.

B. Laboratory equipment.

1. Temperature measuring devices. Temperature measuring devices such as liquid-in-glass thermometers, thermocouples, and platinum resistance thermometers used in incubators, autoclaves and other equipment shall be the appropriate quality to meet specifications in the test method. The graduation of the temperature measuring devices shall be appropriate for the required accuracy of measurement and they shall be calibrated to national or international standards for temperature (see 1VAC30-45-740 C). Calibration shall be done at least annually.
2. Autoclaves.
 - a. The performance of each autoclave shall be initially evaluated by establishing its functional properties and performance, for example, heat distribution characteristics with respect to typical uses. Autoclaves shall meet

- specified temperature tolerances. Pressure cookers shall not be used for sterilization of growth media.
- b. Demonstration of sterilization temperature shall be provided by use of continuous temperature recording device or by use of a maximum registering thermometer with every cycle. Appropriate biological indicators shall be used once per month to determine effective sterilization. Temperature sensitive tape shall be used with the contents of each autoclave run to indicate that the autoclave contents have been processed.
 - c. Records of autoclave operations shall be maintained for every cycle. Records shall include date, contents, maximum temperature reached, pressure, time in sterilization mode, total run time (may be recorded as time in and time out) and analyst's initials.
 - d. Autoclave maintenance shall be performed annually, either internally or by service contract, and shall include a pressure check and calibration of temperature device. Records of the maintenance shall be maintained in equipment logs. If the laboratory demonstrates regular monitoring of pressure (e.g., for each autoclaved batch) and annual calibration of the maximum registering thermometer, the annual autoclave pressure and temperature device checks shall not be required.
 - e. The autoclave mechanical timing device shall be checked quarterly against a stopwatch and the actual time elapsed documented.
3. Volumetric equipment. Volumetric equipment shall be calibrated as follows:
- a. Equipment with movable parts such as automatic dispensers, dispensers/diluters, and mechanical hand pipettes shall be verified for accuracy quarterly.
 - b. Equipment such as filter funnels, bottles, nonclass A glassware, and other marked containers shall be calibrated once per lot prior to first use.
 - c. The volume of the disposable volumetric equipment such as sample bottles and disposable pipettes shall be checked once per lot.
4. UV instruments. UV instruments used for sanitization shall be tested quarterly for effectiveness with an appropriate UV light meter or by plate count agar spread plates. Replace bulbs if output is less than 70% of original for light tests or if count reduction is less than 99% for a plate containing 200 to 300 organisms.
5. Conductivity meters, oxygen meters, pH meters, hygrometers, and other similar measurement instruments shall be calibrated according to the method specified requirements (see 1VAC30-45-740 D 1 d).
6. Incubators, water baths, and ovens.
- a. The uniformity of temperature distribution in incubators and water baths shall be established. Temperature of incubators and water baths shall be documented twice daily, at least four hours apart, on each day of use.
 - b. Ovens used for sterilization shall be checked for sterilization effectiveness monthly with appropriate biological indicators. Records shall be maintained for each cycle that include date, cycle time, temperature, contents and analyst's initials.

7. Labware (glassware and plasticware).

- a. The laboratory shall have a documented procedure for washing labware, if applicable. Detergents designed for laboratory use shall be used.
- b. Glassware shall be made of borosilicate or other noncorrosive material, free of chips and cracks, and shall have readable measurement marks.
- c. Labware that is washed and reused shall be tested for possible presence of residues that 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.
- d. Washed labware shall be tested at least once daily, each day of washing, for possible acid or alkaline residue by testing at least one piece of labware with a suitable pH indicator such as bromothymol blue. Records of tests shall be maintained.

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 22, eff. September 1, 2016.

1VAC30-45-800. (Repealed.) through 1VAC30-45-809. (Reserved.)

Historical Notes: Derived from Virginia Register Volume 25, Issue 7, eff. January 1, 2009; repealed, Virginia Register Volume 32, Issue 22, eff. September 1, 2016.

1VAC30-45-810. Air testing: general.

These standards shall apply to samples that are submitted to a laboratory for the purpose of analysis. They do not apply to field activities such as source air emission measurements or the use of continuous analysis devices.

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

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

1VAC30-45-811. Air testing: negative and positive controls.

A. Negative controls.

1. Method blanks shall be performed at a frequency of at least one per batch of 20 environmental samples or less per sample preparation method. The results of the method blank analysis shall be used to evaluate the contribution of the laboratory provided sampling media and analytical sample preparation procedures to the amount of analyte found in each sample. If the method blank result is greater than the limit of quantitation and contributes greater than 10% of the total amount of analyte found in the sample, the source of the contamination shall be investigated and measures taken to eliminate the source of contamination. If contamination is found, the data shall be qualified in the report.
2. Collection efficiency. Sampling trains consisting of multiple sections (e.g., filters, sorbent tubes, impingers) that are received intact by the laboratory shall be separated into "front" and "back" sections if required by the client. Each section shall be processed and analyzed separately and the analytical results reported separately.

B. Positive controls. Laboratory control sample (LCS) shall be analyzed at a rate of at least one per batch of 20 or fewer samples per sample preparation method for each analyte. If a spiking solution is not available, a calibration solution whose concentration approximates that of the samples shall be included in each batch and with each lot of media. The concentration of the LCS shall be relevant to the intended use of the data and either at a regulatory limit or below it.

C. Surrogates shall be used as required by the test method.

D. Matrix spike shall be used as required by the test 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 22, eff. September 1, 2016.

1VAC30-45-812. Air testing: analytical variability/reproducibility.

Matrix spike duplicates (MSDs) or laboratory duplicates shall be analyzed at a minimum of one in 20 samples per sample batch. The laboratory shall document their procedure to select the use of appropriate types of spikes and duplicates. The selected samples(s) shall be rotated among sampling points or sampling locations so that various sample matrix problems may be noted and/or addressed. Poor performance in the spikes and duplicates may indicate a problem with the sample composition and shall be reported to the client.

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

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

1VAC30-45-813. Air testing: method evaluation.

In order to ensure the accuracy of the reported result, the following procedures shall be in place:

1. Demonstration of capability shall be performed prior to the analysis of any samples and with a significant change in instrument type, personnel, quality system matrix, or test method.
2. Calibration. Calibration protocols specified in 1VAC30-45-740 shall be followed.
3. Proficiency test samples. The results of such analyses shall be used by the laboratory to evaluate the ability of the laboratory to produce accurate data.

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

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

1VAC30-45-814. Air testing: limit of detection.

The requirements of 1VAC30-45-771 shall apply.

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

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

1VAC30-45-815. Air testing: data reduction.

The procedures for data reduction, such as use of linear regression, shall be documented.

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

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

1VAC30-45-816. Air testing: quality of standards and reagents.

A. The source of standards shall comply with 1VAC30-45-740 C.

B. The purity of each analyte standard and each reagent shall be documented by the laboratory through certificates of analyses from the manufacturer/vendor, manufacturer/vendor specifications, and/or independent analysis.

C. In methods where the purity of reagents is not specified, analytical reagent grade or higher quality, if available, shall be used.

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

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

1VAC30-45-817. Air testing: selectivity.

The laboratory shall develop and document acceptance criteria for test method selectivity such as absolute and relative retention times, wavelength assignments, mass spectral library quality of match, and mass spectral tuning.

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

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

1VAC30-45-818. Air testing: constant and consistent test conditions.

A. The laboratory shall assure that the test instruments consistently operate within the specifications required of the application for which the equipment is used.

B. The laboratory shall document that all sampling equipment, containers and media used or supplied by the laboratory meet required test method criteria.

C. If supplied or used by the laboratory, procedures for field equipment decontamination shall be developed and their use documented.

D. The laboratory shall have a documented program for the calibration and verification of sampling equipment such as pumps, meter boxes, critical orifices, flow measurement devices and continuous analyzers, if these equipment are used or supplied by the laboratory.

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

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

1VAC30-45-819. (Reserved.)

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

1VAC30-45-820. (Repealed.) through 1VAC30-45-829. (Repealed.)

Historical Notes: Derived from Virginia Register Volume 25, Issue 7, eff. January 1, 2009; repealed, Virginia Register Volume 32, Issue 22, eff. September 1, 2016.

1VAC30-45-830. (Reserved.)

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

1VAC30-45-840. (Reserved.)

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

1VAC30-45-850. Sample handling, sample acceptance policy, and sample receipt.

While the laboratory may not have control of field sampling activities, the following are essential to ensure the validity of the laboratory's data.

1. Sample tracking. The laboratory shall have a documented system for uniquely identifying the items to be tested to ensure that there can be no confusion regarding the identity of such items at any time. This system shall include identification for all samples, subsamples and subsequent extracts or digestates or both. The use of container shape, size or other physical characteristic, such as amber glass or purple top, is not an acceptable means of identifying the sample. System laboratories shall use a permanent chronological record such as a logbook or electronic database to document receipt of all containers. This sample receipt log shall record the following at a minimum: name of facility where sample was taken, date and time of laboratory receipt, unique laboratory ID code, and signature or initials of the person making the entries.
2. Sample acceptance policy. The laboratory shall have a written sample acceptance policy that clearly outlines the circumstances under which samples shall be accepted or rejected. The policy shall ensure that only properly obtained samples with appropriate sampling records (see 1VAC30-45-640 B) are analyzed and that the samples are handled properly. This sample acceptance policy shall be made available to sample collection personnel. The policy shall include elements such as appropriate documentation of the sample's identification, use of appropriate sample containers, adherence to specified holding times, adequate sample volume to perform necessary tests, and procedures to be used when samples show signs of damage, contamination or inadequate preservation.
3. Sample receipt protocols.
 - a. Upon receipt, the condition of the sample, including any abnormalities or departures from standard condition as prescribed in the relevant test method, shall be recorded. All items specified by the sample acceptance policy shall be checked.
 - b. All samples that require thermal preservation shall be considered acceptable if the arrival temperature is either within 2°C of the required temperature or the method specified range. For samples with a specified temperature of 4°C, samples with a temperature of ranging from just above freezing temperature of water to 6°C shall be acceptable. Samples that are hand delivered to the laboratory immediately after collection or on the same

day that are collected may not meet these criteria. In these cases, the samples shall be considered acceptable if there is evidence that the chilling process has begun such as arrival on ice. Thermal preservation is not required in the field if the laboratory receives the sample and either begins the analysis or refrigerates the sample within 15 minutes of collection.

c. The laboratory shall implement procedures for checking chemical preservation using readily available techniques, such as pH or free chlorine prior to or during sample preparation or analysis.

d. The results of all checks required by the sample acceptance policy and relevant test method shall be recorded.

4. Storage conditions.

a. The laboratory shall have documented procedures and appropriate facilities to avoid deterioration, contamination or damage to the sample during storage, handling, preparation, and testing. Any relevant instructions provided with the item shall be followed. Where items have to be stored or conditioned under specific environmental conditions, these conditions shall be maintained, monitored and recorded.

b. Samples shall be stored according to the conditions specified by preservation protocols:

(1) Samples that require thermal preservation shall be stored under refrigeration that is within 2°C of the specified preservation temperature unless method specific criteria exist. For samples with a specified storage temperature of 4°C, storage at a temperature above the freezing point of water to 6°C shall be acceptable.

(2) Samples shall be stored away from all standards, reagents, food and other potentially contaminating sources. Samples shall be stored in such a manner to prevent cross contamination.

c. Sample fractions, extracts, leachates and other sample preparation products shall be stored according to subdivision 4 a of this section or according to specifications in the test method.

d. Where a sample or portion of the sample is to be held secure (e.g., for reasons of record, safety or value, or to enable check calibrations or tests to be performed later), the laboratory shall have storage and security arrangements that protect the condition and integrity of the secured items or portions concerned.

5. Sample disposal. The laboratory shall have standard operating procedures for the disposal of samples, digestates, leachates and extracts or other sample preparation products.

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 22, eff. September 1, 2016.

1VAC30-45-860. Laboratory report format and contents.

A. The results of each test or series of tests carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively. The results shall normally be reported in a test report required by regulation and shall include all the information necessary for the interpretation of the test results and all information required by the method used.

B. Where the certificate or report contains results of tests performed by subcontractors, these results shall be clearly identified by subcontractor name or applicable certification number.

C. After issuance of the report, the laboratory report shall remain unchanged. Material amendments to a calibration certificate, test report or test certificate after issue shall be made only in the form of a further document, or data transfer including the statement "Supplement to Test Report or Test Certificate, serial number... (or as otherwise identified)," or equivalent form of wording. Such amendments shall meet all the relevant requirements of this article.

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

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

FORMS (1VAC30-45)

Application for Certification of Environmental Laboratories DGS-21-156 (eff. 1/2009)
(Application for Certification under 1VAC30-45 must be obtained from DCLS program staff at Lab_Cert@dgs.virginia.gov)

DOCUMENTS INCORPORATED BY REFERENCE (1VAC30-45)

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 \(EL-V2-2009\)](#)
