1 VAC 30 CHAPTER 45

CERTIFICATION FOR NON-COMMERCIAL ENVIRONMENTAL LABORATORIES

PART I. GENERAL PROVISIONS

1 VAC 30-45-10. 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 by the Commonwealth's air, waste and water laws and regulations. This chapter sets out the required standards and the process by which owners or operators of non-commercial environmental laboratories may obtain certification for their laboratories. Chapter 46 of 1 VAC 30 covers commercial environmental laboratories and NELAC-accredited environmental laboratories located outside Virginia.

1 VAC 30-45-20. Establishment of certification program.

A. Once the certification program has been established, laboratory certification shall be required before any environmental analyses performed by a non-commercial environmental laboratory may be used for the purposes of the Virginia Air Pollution Control Law, the Virginia Waste Management Act or the State Water Control Law (§ 10.1-1300 *et seq.*, § 10.1-1400 *et seq.*, and § 62.1-44.2 *et seq.*, respectively of the *Code of Virginia*).

B. The certification program shall be established on the first day of the 25th month following the effective date of this chapter.

1 VAC 30-45-30. Applicability.

A. This chapter applies to any owner or operator of a non-commercial environmental laboratory.

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

1. by DGS-DCLS to the standards set out in this chapter, or

2. by a federal primary accrediting authority to the standards established by the National Environmental Laboratory Accreditation Conference.

1 VAC 30-45-40. Definitions.

"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 which are due to sampling and analytical operations. Accuracy is an indicator of data quality.

"Aliquot" means something that is contained an exact number of times in another, such as aliquot samples for testing or analysis.

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

"Analytical batch" means a batch composed of prepared environmental samples (extracts, digestates or concentrates) which are analyzed together as a group. An analytical batch can include prepared samples originating from various environmental matrices and can exceed 20 samples.

"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 who performs on-site assessments of laboratories' capability and capacity for meeting the requirements under this chapter by examining the records and other physical evidence for each one of the tests for which certification has been requested.

"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, Title 15.2, Chapter 15 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. See analytical batch.

"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.

"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.

"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.

"DGS-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 by 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 air, water or waste.

2. Field testing and measurement of air, water or waste, except when performed in an environmental laboratory rather than at the site where the sample was taken.

"Environmental laboratory" or "laboratory" means a facility or a defined area within a facility where environmental analysis is performed.

"Establishment date" means the date set for the accreditation program under 1 VAC 30, Chapter 46 and the certification program under 1 VAC 30, Chapter 45 to be established.

"Establishment of certification program" or "established program" means that DGS-DCLS has completed the initial accreditation of environmental laboratories covered by 1 VAC 30, Chapter 46, and the initial certification of environmental laboratories covered by 1 VAC 30, Chapter 45.

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

"Field of testing" means an approach to certifying laboratories by program, 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; on-line monitoring; flow monitoring; tests for pH, residual chlorine, temperature and dissolved oxygen; and field analysis for soil gas.

"Finding" means an assessment conclusion that identifies a condition having a significant effect on an item or activity. An assessment finding is normally a deficiency and is normally accompanied by specific examples of the observed condition.

"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 (or maximum allowable holding time)" means the maximum time that a sample may be held prior to analysis and still be considered valid or not compromised.

"Initial certification period" means the period during which DGS-DCLS is accepting and processing applications for the first time under this chapter as specified in 1 VAC 30-45-60.

"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.

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

"Matrix" means the component or substrate that may contain the analyte of interest. For purposes of batch and quality control requirement determinations, the following matrix types shall be used:

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

2. Non-potable water: any aqueous sample excluded from the definition of drinking water matrix. Includes surface water, groundwater, effluents, water treatment chemicals, and TCLP or other extracts.

3. Solid and chemical materials: includes soils, sediments, sludges, products and by-products of an industrial process that results in a matrix not previously defined.

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

5. Air and emissions: Whole gas or vapor samples including those contained in flexible or rigid wall containers and the extracted concentrated analytes of interest from a gas or vapor that are collected with a sorbent tube, impinger solution, filter or other device.

"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. A subset of NELAP.

"National Environmental Laboratory Accreditation Program (NELAP)" means the overall National Environmental Laboratory Accreditation Program of which NELAC is a part.

"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 to those laboratories testing drinking water and wastewater.

"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.

"Non-commercial 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 or operator of a small sewage treatment plant treating domestic sewage at a flow rate of less than or equal to 1000 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 sewage treatment facility or a waterworks.

c. Environmental analysis performed by an environmental laboratory owned by a corporation as part of the prequalification process for a potential customer as required by a hazardous waste management permit under 9 VAC 20, Chapter 60, Part XI.

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 9 VAC 25, Chapter 1, Part VII.

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" or "operator" means any person who owns or operates 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 accrediting authority" means the agency or department designated at the territory, state or federal level as the recognized authority with the responsibility and accountability for granting NELAC accreditation to a specific laboratory for a specific field 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) field of testing" means the approach to offer proficiency testing by regulatory or environmental program, matrix type, and analyte.

"Proficiency test (PT) sample" means a sample, the composition of which is unknown to the analyst, provided to test whether the analyst or laboratory or both 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 field testing or 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" means an integrated system of activities involving planning, quality control, quality assessment, reporting and quality improvement to ensure that a product or service meets defined standards of quality with a stated level of confidence.

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

"Quality control" means the overall system of technical activities whose purpose is to measure and control the quality of a product or service so that it meets the needs of users.

"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.

"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.

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

(i) If the laboratory is owned or operated by a private corporation, "responsible official" means (1) 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 (2) 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.

(ii) 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.

(iii) 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.

(iv) Any person designated as the responsible official by an individual described in (i), (ii) or (iii) above, 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 DGS-DCLS.

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

"Sanitation district" means a sanitation district created under the provisions of Title 21, Chapters 3 through 5 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" 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),

b) fecal coliform,

c) total coliform,

d) fecal streptococci,

e) settleable solids (SS),

f) total dissolved solids (TDS),

g) total solids (TS),

h) total suspended solids (TSS),

i) total volatile solids (TVS), and

j) total volatile suspended solids (TVSS).

"Standard operating procedure (SOP)" means a written document which details the method of an operation, analysis or action whose techniques and procedures are thoroughly prescribed and which is accepted as the method for performing certain routine or repetitive tasks.

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

"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 by 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 (9 VAC 5), including any method of analysis listed either in the definition of "reference method" in 9 VAC 5-10-20, or listed or

adopted by reference in 9 VAC 5, Chapters 30, 40, 50 or 60; or by any permit or order issued under and in accordance with this law and these regulations.

"Test, analysis, measurement or monitoring required by 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 (9 VAC 20), including any method of analysis listed or adopted by reference in 9 VAC 20, Chapters 60, 80, 101, or 120; or by any permit or order issued under and in accordance with this law and these regulations.

"Test, analysis, measurement or monitoring required by 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 (9 VAC 25), including any method of analysis listed or adopted by reference in 9 VAC 25, Chapters 31, 32, 110, 120, 151, 180, 190, 192, or 210; 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 a specific measurement problem, as documented in a laboratory standard operating procedure or published by a recognized authority.

"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" 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 §10.1-1300 of the *Code of Virginia* which is titled 'Air Pollution Control Board.'

"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.

1 VAC 30-45-50. Scope of certification.

A. Non-commercial environmental laboratories shall be certified based on the general laboratory standards set out in Part II 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. DGS-DCLS shall review alternative test methods and procedures for certification when these are proposed by the applicant laboratory. The provisions of 1 VAC 30-45-70 E and 1 VAC 30-45-90 B govern alternative test methods and procedures.

C. Certification shall be granted for a specific field or fields of testing, including the technology and methods used by the non-commercial environmental laboratory, and the individual analytes or analyte groups determined by the particular method.

1 VAC 30-45-60. 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 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 or operated 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.

1 VAC 30-45-70. Process to apply and obtain certification.

A. Duty to apply.

All owners or operators of non-commercial environmental laboratories shall apply for certification as specified by the provisions of this section.

B. Timely initial applications.

1. Owners or operators of non-commercial environmental laboratories in existence on the date this chapter becomes effective.

Owners or operators of non-commercial environmental laboratories applying for certification under this chapter for the first time shall submit an application to DGS-DCLS no later than 240 calendar days after the effective date of this chapter.

2. Owners or operators of non-commercial environmental laboratories that come into existence after this chapter becomes effective.

Owners or operators of non-commercial environmental laboratories that come into existence after this chapter becomes effective shall submit an initial application to DGS-DCLS no later than 180 calendar days prior to beginning operation.

C. Timely renewal applications.

The owner or operator of an certified non-commercial environmental laboratory shall submit an application for renewal of certification at least 90 calendar days prior to expiration of certification.

D. Responsibilities of the owner or operator.

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 DGS-DCLS may notify non-commercial environmental laboratories of the date their applications are due, failure of DGS-DCLS to notify does not relieve the owner or operator of his obligation to apply under this chapter.

E. Submission of applications for modifications to certification.

An owner or operator of a certified non-commercial environmental laboratory shall follow the process set out in 1 VAC 30-45-90 B to add a new technology, an analyte or a test method, modify a test method or institute use of a method not in the laboratory's standard operating procedures, including alternative test methods or procedures.

F. Contents of application.

1. Applications shall include 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 e-mail, as applicable, of responsible official;

h. name, address, telephone number, facsimile number and e-mail, as applicable, of laboratory manager;

i. name, address, telephone number, facsimile number and e-mail, 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 industrial (with type of industry indicated));

l. laboratory hours of operation;

m. fields of testing (program, test methods, and analytes) for which certification is sought;

n. methods employed, including analytes;

o. the results of the three most recent proficiency test studies;

p. quality assurance manual;

q. lab identification number (for renewal only); and

r. 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 1 VAC 30-45-130.

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 (1 VAC 30, Chapter 45) and is subject to the provisions of 1 VAC 30-45-100 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. DGS-DCLS shall determine whether an application is complete and notify the laboratory of the result of such determination. Except during the initial certification period,

DGS-DCLS shall provide this notice within 60 calendar days of DGS-DCLS's receipt of the application.

2. An application shall be determined complete if it contains all the information required pursuant to 1 VAC 30-45-70 F and is sufficient to evaluate the laboratory prior to the on-site assessment. Designating an application complete does not preclude DGS-DCLS from requesting or accepting additional information.

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

4. Except during the initial certification period, if no determination is made within 60 calendar days of DGS-DCLS's 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. DGS-DCLS may deny any application from a laboratory and require the laboratory to submit a new application if the laboratory does not submit additional information required by DGS-DCLS within 90 days of receiving a notice that requires additional information.

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

1. DGS-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. DGS-DCLS is unable to schedule the on-site assessment within 90 days of its determination that the application is complete and that the laboratory has satisfied all other requirements for certification.

2. A laboratory with interim certification shall have the same rights and status as a laboratory that has been granted certification by DGS-DCLS.

3. Interim certification expires when DGS-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 Part II, Article 2 of this chapter prior to issuance of a final determination on certification.

J. Final determination on certification.

1. Upon completion of the certification review process and corrective action, if any, DGS-DCLS shall grant certification in accordance with subsection K of this section or deny certification in accordance with subsection L of this section.

2. Except during the initial certification period, DGS-DCLS shall complete action on a laboratory's application within nine months from the time an application is determined to be complete.

K. Grant of certification.

1. When a laboratory meets the requirements specified for receiving certification, DGS-DCLS shall issue a certificate to the laboratory. The certificate shall be sent to the laboratory manager, and the responsible official shall be notified.

2. The certificate shall be signed by the director of DGS-DCLS and shall include the following information:

a. name of owner or operator of laboratory;

b. name of responsible official;

c. address and location of laboratory;

d. laboratory identification number;

e. fields of testing (program, method, analyte or other parameter) for which certification is granted;

f. any addenda or attachments; and

g. issuance date and expiration date.

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

4. Certification shall expire two years after date on which certification is granted.

L. Denial of certification.

1. DGS-DCLS shall deny certification to an environmental laboratory in total if the laboratory owner or an employee falsifies any data or provides false information to support certification.

2. Denial of certification in total or in part.

a. DGS-DCLS may deny certification to an environmental laboratory in total or in part if the laboratory owner or an employee 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 of this chapter.

(3) Successfully analyze and report proficiency testing samples as required by Part II of this chapter.

(4) Submit a corrective action report 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 report within the time frame specified by DGS-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. DGS-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 DGS-DCLS in accordance with this chapter.

c. DGS-DCLS may deny certification to an environmental laboratory in total or in part if the DGS-DCLS on-site assessment team is unable to carry out the on-site assessment pursuant to Part II, Article 2 of this chapter because an employee, owner, or other representative of the environmental laboratory denied the team entry during normal business hours.

3. To deny certification, DGS-DCLS shall provide by certified mail written notification of denial to the responsible official and manager of the laboratory, including a detailed explanation of the reason for denial and notice of the right to appeal such denial.

M. Reapplication following denial of certification.

1. Upon denial of certification, the laboratory shall wait six months before reapplying for certification.

2. DGS-DCLS shall not waive application fees for a laboratory reapplying for certification.

1 VAC 30-45-80. Maintaining certification

A. Certification remains in effect until withdrawn by DGS-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 1 VAC 30-45-90.

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 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 of Part II of this chapter.

D. Record keeping and retention.

All laboratory records associated with certification parameters shall be kept as provided by the requirements for records under Part II 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 DGS-DCLS upon request.

1 VAC 30-45-90. Changing certification status.

A. Changes to key certification criteria.

1. The certified laboratory shall notify DGS-DCLS as set out in subdivision A 3 of this section of any changes in key certification criteria within 30 calendar days of the change. Key certification criteria are laboratory ownership, location, key personnel, test methods, analytes, and major instrumentation.

2. The laboratory may initially notify DGS-DCLS of any change to key certification criteria by e-mail, facsimile or telephone. The notification by e-mail, facsimile or telephone subsequently shall be submitted in writing.

3. As specified in subsection B of this section, changes to key certification criteria that affect the laboratory's scope of certification require review and approval by DGS-DCLS in advance of the laboratory's making the change.

B. Changes to scope of certification.

1. DGS-DCLS shall review and approve the addition of a new technology, an analyte, or a test method to a laboratory's scope of certification.

2. To begin the process of review, the owner or operator of the certified laboratory that wants to add to the laboratory's scope of certification shall submit the following application materials to DGS-DCLS:

a. A letter signed by the owner or operator that briefly summarizes the addition to be made to the laboratory's scope of certification.

b. Pertinent information demonstrating that the laboratory is capable of performing the test method or using the technology to be added such as proficiency testing performance and quality control performance.

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

DGS-DCLS may request additional material to complete its review.

3. DGS-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. An addition of a new technology or test method requiring specific equipment may require an on-site assessment. Other reviews of performance and documentation may be carried out by DGS-DCLS, depending on the modification for which the laboratory applies.

4. If the proposed modification to the laboratory's scope of certification is approved, DGS-DCLS shall amend the laboratory's certificate of certification.

C. Change of ownership or location of laboratory.

1. The certified laboratory shall submit a written notification to DGS-DCLS of the change of ownership or location of the laboratory within 30 calendar days of the change.

2. Certification may be transferred when the legal status or ownership of an certified laboratory changes without affecting its personnel, equipment, and facilities.

3. DGS-DCLS may charge a transfer fee and may conduct an on-site assessment to verify the effects of such changes on laboratory performance.

4. When a laboratory changes ownership, the new laboratory owner shall assure that the history of the laboratory's ownership can be traced through laboratory identification numbers.

5. When there is a change in ownership, all records and analyses performed by the previous owner under his scope of certification shall be kept for a period of five years. As required under 1 VAC 30-45-80 D, all such records shall be made available to DGS-DCLS upon request.

D. Voluntary withdrawal.

Any environmental laboratory owner or operator who wishes to withdraw the laboratory from its certification status or from being certified, in total or in part, shall submit written notification to DGS-DCLS no later than 30 calendar days before the end of the laboratory's certification term. Within 30 calendar days, DGS-DCLS shall provide the laboratory with a written notice of withdrawal.

1 VAC 30-45-100. Decertification.

A. DGS-DCLS shall decertify an environmental laboratory in total for any of the following reasons:

1. Submittal by the laboratory owner or an employee of proficiency test sample results generated by another laboratory as its own.

2. Falsification by a laboratory owner or an employee of any data or the provision of false information by any laboratory owner or an employee to support certification.

3. Conviction of the laboratory owner or an employee of charges relating to the falsification of any report concerning a laboratory analysis.

B. DGS-DCLS may decertify an environmental laboratory in part or in total when the laboratory owner or an employee has failed to do any of the following:

1. Participate in the proficiency testing program as required by Article 3 of Part II of this chapter.

2. Complete proficiency testing studies and maintain a history of at least two successful proficiency testing studies for each affected certified field of testing out of the three most recent proficiency testing studies as defined in Part II, Article 3 of this chapter.

3. Maintain a quality system as defined in Part II, Article 4 of this chapter.

4. Employ staff that meet the personnel qualifications in Part II, Article 1 of this chapter.

5. Submit an acceptable corrective action report after two opportunities, as specified in 1 VAC 30-45-390.

6. Implement corrective action specified in the laboratory's corrective action report, as set out under 1 VAC 30-45-390.

7. Notify DGS-DCLS of any changes in key certification criteria, as set forth in 1 VAC 30-45-90.

8. Use accurate references to the laboratory's certification status in the laboratory's documentation.

C. To decertify an environmental laboratory, DGS-DCLS shall provide by certified mail written notification of the decertification to the responsible official and manager of the laboratory, including a detailed explanation of the reason for the decertification and notice of the right to appeal such decertification.

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

1. Laboratories that lose their certification in full shall return their certificate to DGS-DCLS.

2. If a laboratory loses certification in part, an addendum to the certificate shall be issued by DGS-DCLS to the laboratory.

E. After correcting the reason or cause for decertification under 1 VAC 30-45-100 A or B, the laboratory owner or operator may reapply for certification.

1 VAC 30-45-110. Appeal procedures.

A. DGS-DCLS shall notify an environmental laboratory in writing of its decision to deny certification or to decertify an environmental laboratory.

B. All appeals taken from actions of the DGS-DCLS director relative to the provisions of this chapter shall be governed by the Virginia Administrative Process Act (§2.2-4000 *et seq*. of the *Code of Virginia*).

1 VAC 30-45-120. Exemptions.

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

B. DGS-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, DGS-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. DGS-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 DGS-DCLS shall be for a period of no more than 24 months.

1 VAC 30-45-130. Fees.

A. General.

1. Fees shall be submitted with all applications for certification. Applications shall not be designated as complete until the fee is received by DGS-DCLS.

2. Fees shall be nonrefundable.

B. Fee computation.

1. Fees shall be computed based on the test methods for which a laboratory seeks certification and on the laboratory type. For the purpose of fee calculation, the designations for the laboratory type are (i) a general environmental laboratory or (ii) an environmental laboratory performing only simple test procedures.

2. The fee shall be the total of the base fee and the test category fees for the specific laboratory type to be certified.

3. The test category fees cover categories for the test methods to be certified as specified in the laboratory's application.

4. If the total of the base fee and the test category fees is more than the maximum fee designated for the specific laboratory type to be certified, the laboratory shall pay the maximum fee.

C. Laboratories performing only simple test procedures.

1. The base fee shall be $100.

2. The maximum fee shall be $400.

D. General environmental laboratories.

1. The base fee shall be $1700.

2. The maximum fee shall be $3800.

E. Test category fees.

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

2. The fee for each category includes one or more analytical methods unless otherwise specified. With the exception of the test categories labeled oxygen demand and physical, test categories related to test methods for water are defined by 40 CFR Part 136, § 136.3.

3. Fees.

TEST CATEGORY	FEE
Oxygen demand (BOD or COD)	$300
Bacteriology	$300
Inorganic chemistry, fewer than four methods	$300
Inorganic chemistry, four or more methods	$600
Chemistry metals, fewer than four methods	$300
Chemistry metals, four or more methods	$600
Organic chemistry, fewer than four methods	$350
Organic chemistry, four or more	$700
Whole effluent toxicity, acute methods only	$300
Whole effluent toxicity, acute and chronic methods	$600
Radiochemical	$900
Physical	$300

F. Additional fees.

1. General environmental laboratories applying for an exemption under 1 VAC 30-45-120 shall pay an application fee of $250 and if the exemption is granted, up to an additional $1000 depending on the scope of the exemption. Laboratories performing only simple test procedures applying for an exemption under 1 VAC 30-45-120 shall pay an application fee of $100 and if the exemption is granted, up to an additional $1000 depending on

the scope of the exemption. The fee assessed for the scope of the exemption shall be based on the actual time needed for DGS-DCLS to make the determination. The fee assessed shall be calculated using the method in subdivision F 4 of this section.

2. For any certified environmental laboratory that applies to modify its scope of certification as specified under 1 VAC 30-45-90 B, DGS-DCLS shall assess a fee determined by the method in subdivision F 4 of this section.

3. Under 1 VAC 30-45-90 C, DGS-DCLS may charge a transfer fee to a certified laboratory that transfers ownership. If DGS-DCLS determines that a fee should be charged, the fee shall be a minimum of $100 and a maximum of $1000. If DGS-DCLS determines that an on-site assessment is necessary to evaluate the effect of the transfer of ownership, DGS-DCLS shall assess a fee determined by the method in subdivision F 4 of this section.

4. Fee determination.

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

b. 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 1642 (number of annual hours established by Fiscal Services, DGS, for billing purposes).

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

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

G. On-site assessment fees.

When, with the concurrence of the applicant laboratory, DGS-DCLS uses approved, third-party on-site assessors, the cost of the on-site assessment shall be paid by the applicant.

1 VAC 30-45-140. 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 must 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 subsection. If the director continues to believe 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;

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 are subject to the provisions of Article 3 of the Virginia Administrative Process Act (§2-2-4000 *et seq*. of the *Code of Virginia*).

1 VAC 30-45-150 through 1 VAC 30-45-190. Reserved.

1 VAC 30 CHAPTER 45

CERTIFICATION FOR NON-COMMERCIAL ENVIRONMENTAL LABORATORIES

PART II. STANDARDS

ARTICLE 1. PERSONNEL

1 VAC 30-45-200. 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.

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, a laboratory manager shall be designated by the responsible official.

1 VAC 30-45-210. 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, 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.

1 VAC 30-45-220. 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, 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.

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.

1 VAC 30-45-230. Absence of laboratory manager or quality assurance officer.

The laboratory shall nominate deputies in the case of absence of the laboratory manager or the quality assurance officer.

1 VAC 30-45-240 through 1 VAC 30-45-290. Reserved.

ARTICLE 2. ON-SITE ASSESSMENT

1 VAC 30-45-300. Frequency of on-site assessment.

A. A comprehensive on-site assessment shall be conducted of each laboratory as a condition for granting certification.

B. On-site assessments may be conducted more frequently for cause.

1. Situations which might trigger more frequent on-site assessments include review of a previously deficient on-site assessment, poor performance on a proficiency testing sample, change in other certification elements, or other information concerning the capabilities or practices of the certified laboratory.

2. DGS-DCLS may reassess a laboratory prior to taking a regulatory or administrative action affecting the laboratory's certification.

3. An assessment may be conducted when a major change occurs in a laboratory's operations that might reasonably be expected to alter or impair analytical capability and quality.

1 VAC 30-45-310. Announced and unannounced on-site assessments.

A. DGS-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, DGS-DCLS, when necessary, shall work with the owner or operator of an environmental laboratory to obtain government security clearances

for assessment personnel as far in advance as possible. The owner or operator 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.

1 VAC 30-45-320. Request for records.

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

1 VAC 30-45-330. Areas to be assessed.

A. The areas evaluated in an on-site assessment shall include:

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.

B. These areas shall be evaluated against the standards set out in Article 4, Part II of this chapter and the appropriate reference methods.

1 VAC 30-45-340. 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 DGS-DCLS in writing of any information that is controlled for national security reasons and cannot be released to the public.

1 VAC 30-45-350. Arrival, admittance and opening conference.

A. Arrival.

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

B. Admittance of assessment personnel.

A laboratory's refusal to admit the assessment personnel for an on-site assessment shall result in an automatic failure of the laboratory to receive certification or loss of an existing certification by the laboratory, unless there are extenuating circumstances that are accepted and documented by DGS-DCLS. The team leader for the assessment personnel shall notify DGS-DCLS as soon as possible after refusal of entry.

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.

1 VAC 30-45-360. 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.

1 VAC 30-45-370. 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.

1 VAC 30-45-380. 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 DGS-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.

1 VAC 30-45-390. Follow-up and reporting procedures.

A. DGS-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 DGS-DCLS. This response shall be called a corrective action report.

C. An exception to the deadlines specified in subsections A and B may occur in appropriate circumstances. Two circumstances that may be considered appropriate by DGS-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 report 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. DGS-DCLS shall determine and shall notify the laboratory within 30 calendar days of receipt whether the corrective action report is an acceptable response to the deficiencies identified in the assessment report.

F. If the corrective action report (or a portion of the report) is determined to be unacceptable to remedy the deficiency, DGS-DCLS shall provide written notification to the responsible official and technical director 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 report acceptable to DGS-DCLS.

1 VAC 30-45-400. Documentation of on-site assessment.

A. Checklists.

The checklists used by assessment personnel during the assessment shall become a part of DGS-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 1 VAC 30-45-330.

2. Assessment reports shall contain:

a. name of owner or operator of the laboratory;

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 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 by DGS-DCLS to the laboratory supervisor. 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. Any documentation determined to be relevant to an ongoing enforcement investigation shall be considered exempt from release to the public.

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

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 DGS-DCLS five days prior to visiting DGS-DCLS. A laboratory may request copies of its documents without visiting DGS-DCLS. A reasonable fee may be charged for copying, mailing, and staff time.

1 VAC 30-45-410 through 1 VAC 30-45-490. Reserved.

ARTICLE 3. PROFICIENCY TESTING

1 VAC 30-45-500. 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 two single-blind, single-concentration PT studies, where available, per year for each PT field of testing for which it seeks or wants to maintain certification.

2. Laboratories shall obtain PT samples from NIST or another provider approved by DGS-DCLS.

3. Each laboratory shall participate in at least two PT studies for each PT field of testing per year unless DGS-DCLS approves a different frequency for a given program.

B. Requesting certification.

1. At the time each laboratory applies for certification, it shall notify DGS-DCLS which fields of testing it chooses to become certified for and shall participate in the appropriate PT studies.

2. For all fields of testing for which PT samples are not available, the laboratory shall ensure the reliability of its testing procedures by maintaining a quality system that meets all applicable requirements of Part II, Article 4 of this chapter.

C. Reporting results.

1. Each laboratory shall authorize the PT study provider to release all certification and remediation results and “acceptable” or “not acceptable” status directly to DGS-DCLS, in addition to the laboratory.

2. The results of all of the PT sample tests including “acceptable” or “not acceptable” status shall be part of the public record.

3. The result of a PT sample, “acceptable” or “not acceptable” status, shall apply to all certified methods within that matrix which a laboratory employs for an analyte.

1 VAC 30-45-510. Requirements for laboratory testing of PT study samples.

A. The samples shall be analyzed and the results returned to the PT study provider no later than 45 calendar days from the scheduled study shipment date.

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, facilities, and frequency of analysis.

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 intracompany 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 five 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 assessors of DGS-DCLS during on-site audits of the laboratory.

1 VAC 30-45-520. PT criteria for laboratory certification.

A. Result categories.

1. The criteria described in this section apply individually to each PT field of testing, 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 two PT studies for each requested PT field of testing within the most recent three rounds attempted.

2. Once a laboratory has been granted certification status, it shall continue to complete PT studies for each PT field of testing and maintain a history of at least two acceptable PT studies for each PT field of testing out of the most recent three.

3. For a laboratory seeking to obtain initial certification, the most recent three rounds attempted shall have occurred within 18 months of the laboratory’s application date.

4. For a laboratory seeking initial certification, or for a laboratory performing supplemental testing, the PT studies shall be at least 30 calendar days apart.

5. For a laboratory to maintain certification, completion dates of successive proficiency rounds for a given PT field of testing shall be approximately six months apart. Failure to meet the semiannual schedule is regarded as a failed study.

C. Supplemental studies.

1. A laboratory may elect to participate in PT studies more frequently than required by the semiannual schedule. This may be desirable, for example, when a laboratory first applies for certification or when a laboratory fails a study and wishes to quickly re-establish its history of successful performance.

2. These additional studies shall be reported and are counted and scored the same way as routinely scheduled studies and shall be at least 30 calendar days apart.

D. Failed studies and corrective action.

1. Whenever a laboratory fails a study, it shall determine the cause for the failure and take any necessary corrective action. It shall then document in its own records and provide to DGS-DCLS both the investigation and the action taken.

2. If a laboratory fails two out of the three most recent studies for a given field of testing, its performance is considered unacceptable for that field. The laboratory shall then meet the requirements of initial certification as described in subsection B of this section.

E. Second failed study.

1. The PT provider reports laboratory PT performance results to DGS-DCLS at the same time that it reports the results to the laboratory.

2. If a laboratory fails a second study out of the most recent three, as described in subsection D 2 of this section, DGS-DCLS shall take action within 60 calendar days to determine the certification status of all methods for the unacceptable analyte or analytes for that program and matrix.

F. Scheduling of PT studies.

1. DGS-DCLS may specify which months that laboratories within its authority are required to participate in PT study programs.

2. If DGS-DCLS chooses to specify the months, then it shall adhere to the required semiannual schedule. If DGS-DCLS does not specify the months, then the laboratory shall determine the schedule.

G. Withdrawal from PT studies.

A laboratory may withdraw from a PT study for an analyte or analytes or for the entire study if the laboratory notifies both the PT provider and DGS-DCLS before the closing date of the PT study. This does not exempt the laboratory from participating in the semiannual schedule.

1 VAC 30-45-530 through 1 VAC 30-45-590. Reserved.

ARTICLE 4. QUALITY SYSTEM

1 VAC 30-45-600. 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. Therefore, for technical or other reasons, some of the requirements of this article may not apply to every laboratory subject to this chapter. When in doubt as to the applicability of an Article 4 requirement, the applicant laboratory should consult DGS-DCLS.

C. 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 requirements are more stringent, the standard from the method or regulation is to be followed.

D. Provisions pertaining to the management of the quality system appear in 1 VAC 30-45-610 through 1 VAC 30-45-700. Provisions pertaining to the technical requirements for the quality system appear in 1 VAC 30-45-710 through 1 VAC 30-45-770.

1 VAC 30-45-610. 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 subsection B of this section.

B. Elements of a quality manual.

1. Title page.

The quality manual shall list the following items on the title page:

a. a document title;

b. the laboratory's full name and address;

c. the name, address (if different from above), and telephone number of the responsible official, laboratory manager, and quality assurance officer;

d. the laboratory facility or facilities covered by the quality manual;

e. signed and dated concurrence, with appropriate titles, of the responsible official, laboratory manager, and quality assurance officer; and

f. the effective date of the quality manual.

2. Table of contents.

3. A quality policy statement, including objectives and commitments, signed by top management.

4. The organization and management structure of the laboratory, its place in any parent organization and relevant organizational charts.

5. The relationship between management, technical operations, support services and the quality system.

6. The capabilities of the laboratory or scope of its operation.

7. 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 which ensures that all standard operating procedures, manuals, or documents clearly indicate the time period during which the procedure or document was in force.

8. Job descriptions of key staff and reference to the job descriptions of other staff.

9. The laboratory's procedures for achieving traceability of measurements, including standards.

10. A list of all test methods under which the laboratory performs its certified testing.

11. Mechanisms for ensuring that the laboratory reviews all new work to ensure that it has the appropriate facilities and resources before commencing such work.

12. Reference to the calibration and verification test procedures used.

13. Procedures for receiving, handling, storing, and disposing of submitted samples.

14. Reference to the major equipment and reference measurement standards used as well as the physical facility and environment used by the laboratory in conducting tests.

15. Reference to procedures for calibration, verification and maintenance of equipment.

16. Reference to verification practices which may include interlaboratory comparisons, proficiency testing programs, use of reference materials and internal quality control schemes.

17. Procedures to be followed for feedback and corrective action whenever testing discrepancies are detected, or departures from documented policies and procedures occur.

18. The laboratory management arrangements for permitting departures from documented policies and procedures or from standard specifications when the departures are planned and controlled.

19. Procedures for dealing with complaints.

20. Procedures for audits and data review.

21. 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.

22. Ethics policy statement developed by the laboratory. Processes and procedures for educating and training personnel in their ethical and legal responsibilities including the potential penalties for improper, unethical or illegal actions.

23. Reference to procedures for reporting analytical results.

C. 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 may significantly affect 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.

1 VAC 30-45-620. 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.

1 VAC 30-45-630. Records.

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

1 VAC 30-45-640. Record keeping system and design.

A. The record keeping system shall allow 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 interlaboratory transfers of samples or extracts or both.

B. The records shall include the identity of personnel involved in sampling, sample receipt, preparation, calibration or testing.

C. All information relating to the laboratory facilities equipment, analytical test methods, and related laboratory activities, such as sample receipt, sample preparation, or data verification shall be documented.

D. The record keeping system shall facilitate the retrieval of all working files and archived records for inspection and verification purposes, e.g., set format for naming electronic files.

E. All changes to records shall be signed or initialed by responsible staff. 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 record-keeping 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. Computer and electronic data records shall be kept in accordance with 1 VAC 30-45-650 C and 1 VAC 30-45-730 K.

1 VAC 30-45-650. Records management and storage.

A. All records, certificates and reports shall be kept as required by applicable state and federal recordkeeping laws and regulations and safely stored and held secure.

B. All records shall be retained 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. 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, shall be maintained by the laboratory.

C. Records which 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. These records shall be protected 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, appropriate regulatory and state legal requirements concerning laboratory records shall be followed.

1 VAC 30-45-660. Required records.

A. Sample handling.

1. A record of all procedures to which a sample is subjected while in the possession of the laboratory shall be maintained. These shall include but are not limited to all

records pertaining to sample preservation, identification, receipt, acceptance or rejection, log-in, storage and tracking.

2. The laboratory shall have documented procedures for the receipt and retention of test items.

B. Laboratory support activities.

The following documents and data shall be retained:

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 which 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 reports, audits and audit responses.

7. Proficiency test results and raw data.

8. Results of data review, verification, and cross checking procedures.

C. Analytical records.

Essential information associated with analytical documents, such as strip charts, tabular printouts, computer data files, analytical notebooks, and run logs, shall be retained. 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 following shall be maintained:

1. Personnel qualifications, experience and training records.

2. Records of demonstration of capability for each analyst.

3. A log of names, initials and signatures for all individuals who are responsible for signing or initialing any laboratory record.

1 VAC 30-45-670. 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. Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited. 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. Small laboratories 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 interlaboratory 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 time frame 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. Performance audits.

In addition to periodic audits, the laboratory shall ensure the quality of results by implementing checks to monitor the quality of the laboratory's analytical activities. The following are examples of such checks:

1. Internal quality control procedures using statistical techniques.

2. Participation in proficiency testing or other interlaboratory comparisons.

3. Use of certified reference materials and/or in-house quality control using secondary reference materials.

4. Replicate testings using the same or different test methods.

5. Re-testing of retained samples.

6. Correlation of results for different but related analysis of a sample (for example, total phosphorus should be greater than or equal to orthophosphate).

E. 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 reports.

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.

1 VAC 30-45-680. 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 Chapter 46 or under another state's NELAP-approved program.

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 above requirements have been met.

1 VAC 30-45-690. Outside support services and supplies.

A. Where the laboratory procures outside services and supplies in support of tests, the laboratory shall use only those outside support services and supplies that are of adequate quality to sustain confidence in the laboratory's tests.

B. Where no independent assurance of the quality of outside support services or supplies is available, the laboratory shall have procedures to ensure that purchased equipment, materials and services comply with specified requirements. 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 any standard specifications relevant to the calibrations or tests concerned.

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

1 VAC 30-45-700. 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 1 VAC 30-45-670 A. Records of the complaint and subsequent actions shall be maintained.

1 VAC 30-45-710. 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 may 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 testing areas when the activities in the testing areas are incompatible (i.e., microbiological culture or incubation and volatile organic chemicals).

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.

1 VAC 30-45-720. 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 which has been subjected to overloading or mishandling, or which gives suspect results, or has been shown by verification or otherwise to be defective, shall be taken out of service, clearly identified 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 shall be maintained of each major item of equipment significant to the tests performed. These records shall include documentation on all routine and non-routine maintenance activities. The laboratory shall maintain records of reference materials sufficient to provide proper performance of tests. The records may include:

1. the name of the item of equipment;

2. the manufacturer's name, type identification, and serial number or other unique identification;

3. date received and date placed in service (if available);

4. current location, where appropriate;

5. if available, condition when received (e.g. new, used, reconditioned);

6. copy of the manufacturer's instructions, where available;

7. dates and results of calibrations or verifications or both and date of the next calibration or verification;

8. details of maintenance carried out to date and planned for the future; and

9. history of any damage, malfunction, modification or repair.

1 VAC 30-45-730. 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 approving authority.

3. Copies of all SOPs shall be accessible to all personnel.

C. Laboratory methods manuals.

1. The laboratory shall have and maintain an in-house methods manual or manuals for each certified analyte or test method.

2. This manual may consists of copies of published or referenced methods or standard operating procedures that have been 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. method detection limit;

d. scope and application, including components 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. 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 Virginia 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 below).

E. Demonstration of capability.

1. Prior to acceptance and institution of any test method, satisfactory 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 matrix (a sample of a matrix in which no target analytes or interferences are present at concentrations that impact the results of a specific test method), e.g., water, solids, biological

tissue and air. For analytes which do not lend themselves to spiking, the demonstration of capability may be performed using quality control samples.

2. Thereafter, continuing 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 before July 1999, 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, a certification statement shall be completed and retained by the laboratory to be made available upon request. All associated supporting data necessary to reproduce the analytical results summarized in the certification statement shall be retained by the laboratory.

5. A demonstration of capability shall be completed each time there is a change in instrument type, personnel or test method.

F. Procedure for demonstration of capability.

1. The following steps (adapted from the EPA test methods published in 40 CFR part 136, Appendix A) shall be performed if required reagents/standards are available.

a. A quality control (QC) sample shall be obtained from an outside source. If not available, the QC sample may be prepared by the laboratory using stock standards that are prepared independently from those used in instrument calibration.

b. The analyte or analytes shall be diluted in a volume of clean matrix sufficient to prepare four aliquots at the concentration specified, or if unspecified, to a

concentration approximately 10 times the method-stated or laboratory-calculated method detection limit.

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

d. 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 must assess performance against established and documented criteria.

e. Compare the information from subdivision F 1 d of this section 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.

f. When one or more of the tested parameters fail at least one of the acceptance criteria, the analyst must proceed according to either subdivision (1) or (2) below.

(1) Locate and correct the source of the problem and repeat the test for all parameters of interest beginning with subdivision F 1 c.

(2) Beginning with subdivision F 1 c, 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 F 1 c.

2. It is the responsibility of the laboratory to document that other approaches to demonstrating capability are adequate. This documentation shall be included in the laboratory's quality assurance manual.

G. Certification statement.

The following certification statement shall be used to document the completion of each demonstration of capability. A copy of the certification statement shall be retained in the personnel records of each affected employee.

Demonstration of Capability
Certification Statement

Date: Page of
Laboratory Name:
Laboratory Address:
Analyst(s) Name(s):

Matrix:
(examples: laboratory pure water, soil, air, solid, biological tissue)
Method number, SOP#, Rev#, and Analyte, or Class of Analytes or Measured Parameters
(examples: barium by 200.7, trace metals by 6010, benzene by 8021, etc.)

We, the undersigned, CERTIFY that:

1. The analysts identified above, using the cited test method(s), which is in use at this facility for the analyses of samples under the Virginia Environmental Laboratory Certification Program, have met the Demonstration of Capability.

2. The test method(s) was performed by the analyst(s) identified on this certification.

3. A copy of the test method(s) and the laboratory-specific SOPs are available for all personnel on-site.

4. The data associated with the demonstration capability are true, accurate, complete and self-explanatory (1).

5. All raw data (including a copy of this certification form) necessary to reconstruct and validate these analyses have been retained at the facility, and that the associated information is well organized and available for review by authorized assessors.

Laboratory Manager's Name and Title Signature Date

Quality Assurance Officer's Name Signature Date

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, and to address 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 and media including the manufacturer/vendor, the manufacturer's Certificate of Analysis or purity (if supplied), 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.

3. Records shall be maintained on reagent and standard 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. All requirements of this article are complied with.

2. Computer software is tested and documented to be adequate for use, e.g. internal audits, personnel training, focus point of quality assurance and quality control.

3. 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.

4. 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.

5. 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.

1 VAC 30-45-740. Measurement traceability and calibration.

A. General requirements.

All measuring operations and testing equipment having an effect on the accuracy or validity of tests shall be calibrated or verified or both before being put into service and on a continuing basis. The laboratory shall have an established program for the calibration and verification of its measuring and test equipment. This includes balances, thermistors, thermometers and control standards.

B. Traceability of calibration.

1. 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 where available.

2. Calibration certificates shall indicate the traceability to national standards of measurement and shall provide the measurement results and associated uncertainty of measurement or a statement of compliance with an identified metrological specification or both. The laboratory shall maintain records of all such certifications.

3. Where traceability to national standards of measurement is not applicable, the laboratory shall provide satisfactory evidence of correlation of results, for example by participation in a suitable program of interlaboratory comparisons, proficiency testing, or independent analysis.

C. Reference standards.

1. Reference standards of measurement held by the laboratory (such as Class S or equivalent weights or traceable thermometers) shall be used for calibration only, unless it can be demonstrated that their performance as reference standards have not been invalidated. Reference standards of measurement shall be calibrated by a body that can provide traceability. Where possible, this traceability shall be to a national standard of measurement.

2. There shall be a program of calibration and verification for reference standards.

3. Where relevant, reference standards and measuring and testing equipment shall be subjected to in-service checks between calibrations and verifications. Reference materials shall be traceable. Where possible, traceability shall be to national or international standards of measurement, or to national or international standard reference materials.

D. Calibration.

Calibration requirements are divided into two parts: (1) requirements for analytical support equipment, and (2) 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. Prior to use on each working day, 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 details of the initial instrument calibration procedures, including calculations, integrations, acceptance criteria and associated statistics shall be included or referenced in the test method standard operating procedure. When initial instrument calibration procedures are referenced in the test method, then the referenced material shall be retained by the laboratory and be available for review.

2) Sufficient raw data records shall be retained 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.

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 appropriate to the technique employed.

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 details of the continuing instrument calibration procedure, calculations and associated statistics shall be included or referenced in the test method standard operating procedure.

(b) A continuing instrument calibration check shall be repeated at the beginning and end of each analytical batch. The concentrations of the calibration verification shall be varied within the established calibration range. If an internal standard is used, only one continuing instrument calibration verification shall be analyzed per analytical batch.

(c) Sufficient raw data records shall be retained to permit reconstruction of the continuing instrument calibration verification, e.g., 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.

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

(e) 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 performance after corrective action with two consecutive successful calibration verifications, or a new initial instrument calibration shall be performed. If the laboratory has not demonstrated acceptable performance, sample analyses shall not occur until a new initial calibration curve is established and verified. However, sample data associated with an unacceptable calibration verification may be reported as qualified data under the following special conditions:

(1) When the acceptance criteria for the continuing calibration verification are exceeded high, i.e., high bias, and there are associated samples that are non-detects, then those non-detects 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.

(2) 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.

1 VAC 30-45-750. Essential quality control procedures.

A. The general quality control principles in subsections B through E 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. The standards for any given test type shall assure that the applicable principles are addressed.

B. 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.

C. All quality control measures shall be assessed and evaluated on an on-going basis, and quality control acceptance criteria shall be used to determine the validity of the data.

D. The laboratory shall have procedures for the development of acceptance or rejection criteria where no method or regulatory criteria exist. (See 1 VAC 30-45-760 B)

E. The laboratory shall ensure that the essential quality control standards and protocols listed in subsection B of this section and specified by mandated methods or regulations are incorporated into the laboratory's method manual and followed.

1 VAC 30-45-760. 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.

A. 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.

B. 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 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.

C. Sample receipt protocols.

1. 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.

2. All samples which require thermal preservation shall be considered acceptable if the arrival temperature is either within 2 degrees C of the required temperature or the method specified range. For samples with a specified temperature of 4 degrees C, samples with a temperature of ranging from just above freezing temperature of water to 6 degrees C shall be acceptable. Samples that are hand delivered to the laboratory immediately after collection may not meet this 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.

3. 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.

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

D. Storage conditions.

1. 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.

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

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

b. 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.

3. Sample fractions, extracts, leachates and other sample preparation products shall be stored according to subdivision D 1 of this section or according to specifications in the test method.

4. Where a sample or portion of the sample is to be held secure (for example, 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.

E. Sample disposal.

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

1 VAC 30-45-770. 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 sub-contractors, 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.

1 VAC 30-45-780 through 1 VAC 30-45-800. Reserved.

1 VAC 30 CHAPTER 46

ACCREDITATION FOR COMMERCIAL ENVIRONMENTAL LABORATORIES

PART I. GENERAL PROVISIONS

1 VAC 30-46-10. Purpose.

Section 2.2-1105 of the *Code of Virginia* directs the Division of Consolidated Laboratory Services to establish a program to certify environmental laboratories that perform tests, analyses, measurements or monitoring required by the Commonwealth's air, waste and water laws and regulations. This chapter sets out the required standards and the process by which owners or operators of commercial environmental laboratories may obtain certification for their laboratories. Certification is referred to as accreditation in this chapter. Commercial environmental laboratories are accredited under the standards of the National Environmental Laboratory Accreditation Conference as approved in 2002. In addition, this chapter sets out the process that NELAC-accredited environmental laboratories located outside Virginia must use to receive accreditation in Virginia. Chapter 45 of 1 VAC 30 covers non-commercial environmental laboratories.

1 VAC 30-46-20. Establishment of accreditation program.

A. Once the accreditation program has been established, laboratory accreditation shall be required before any environmental analyses performed by a commercial environmental laboratory may be used for the purposes of the Virginia Air Pollution Control Law, the Virginia Waste Management Act or the State Water Control Law (§ 10.1-1300 et seq., § 10.1-1400 et seq., and § 62.1-44.2 et seq., respectively, of the *Code of Virginia*).

B. The accreditation program shall be established on the first day of the 25th month following the effective date of this chapter.

1 VAC 30-46-30. Applicability.

A. General applicability.

This chapter applies to the following:

1. any owner or operator of a commercial environmental laboratory.

2. any owner or operator of an environmental laboratory located in jurisdictions outside of Virginia who wishes to apply for reciprocal accreditation under 1 VAC 30-46-140.

B. DGS-DCLS.

1. NELAP-accredited laboratory.

DGS-DCLS shall meet the requirements of this chapter through review and accreditation by a NELAP-accredited federal or state accrediting authority. This process shall be completed before the program under this chapter and Chapter 45 is established.

2. Primary accrediting authority.

DGS-DCLS shall meet the requirements of the NELAC Standards to become the primary accrediting authority for the Commonwealth of Virginia. This review and approval by a NELAP accrediting team shall be completed no later than one year following the effective date of this chapter.

C. Voluntary accreditation.

Any owner or operator of an environmental laboratory may apply for accreditation under this chapter.

D. Environmental laboratories required to obtain drinking water certification under 1 VAC 30, Chapter 40.

Any owner or operator of an environmental laboratory who must meet the requirements of Chapter 40 of 1 VAC 30 pertaining to drinking water laboratory certification and

either Chapter 45 of 1 VAC 30 or this chapter may meet those requirements by obtaining accreditation under this chapter.

1 VAC 30-46-40. Definitions.

"Accreditation" means the term used as a substitute for the term 'certification' under this chapter.

"Accrediting authority" means the territorial, state, or federal agency having responsibility and accountability for environmental laboratory accreditation and which grants accreditation under NELAC.

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

"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 who performs on-site assessments of laboratories' capability and capacity for meeting the requirements under this chapter by examining the records and other physical evidence for each one of the tests for which accreditation has been requested.

"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, Title 15.2, Chapter 51 of the *Code of Virginia*.

"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.

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

"Environmental analysis" or "environmental analyses" means any test, analysis, measurement, or monitoring used for the purposes of the Virginia Air Pollution Control Law, the Virginia Waste Management Act or the State Water Control Law (§ 10.1-1300 et seq., § 10.1-1400 et seq., and § 62.1-44.2 et seq., respectively, of the *Code of Virginia*). For the purposes of these regulations, any test, analysis, measurement, or monitoring required by 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 air, water or waste.

2. Field testing and measurement of air, water or waste, except when performed in an environmental laboratory rather than at the site where the sample was taken.

"Environmental laboratory" or "laboratory" means a facility or a defined area within a facility where environmental analysis is performed.

"Establishment date" means the date set for the accreditation program under 1 VAC 30, Chapter 46 and the certification program under 1 VAC 30, Chapter 45 to be established.

"Establishment of accreditation program" or "established program" means that DGS-DCLS has completed the initial accreditation of environmental laboratories covered by 1 VAC 30, Chapter 46, and the initial certification of environmental laboratories covered by 1 VAC 30, Chapter 45.

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

"Field of accreditation" means an approach to accrediting laboratories by matrix, technology/method and analyte/analyte group.

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

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

2. Non-potable water: any aqueous sample excluded from the definition of drinking water matrix. Includes surface water, groundwater, effluents, water treatment chemicals, and TCLP or other extracts.

3. Solid and chemical materials: includes soils, sediments, sludges, products and by-products of an industrial process that results in a matrix not previously defined.

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

5. Air and emissions: Whole gas or vapor samples including those contained in flexible or rigid wall containers and the extracted concentrated analytes of interest from a gas or vapor that are collected with a sorbent tube, impinger solution, filter or other device.

"Field of proficiency testing" means an approach to offer proficiency testing by matrix, technology, and analyte/analyte group.

"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; on-line monitoring; flow monitoring; tests for pH, residual chlorine, temperature and dissolved oxygen; and field analysis for soil gas.

"Finding" means a conclusion reached during an on-site assessment that identifies a condition having a significant effect on an item or activity. An assessment finding is normally a deficiency and is normally accompanied by specific examples of the observed condition.

"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 (or maximum allowable holding time)" means the maximum time that a sample may be held prior to analysis and still be considered valid or not compromised.

"Initial accreditation period" means the period during which DGS-DCLS is accepting and processing applications for the first time under this chapter as specified in 1 VAC 30-46-70.

"Legal entity" means an entity, other than a natural person, who has sufficient existence in legal contemplation that it can function legally, be sued or sue and make decisions through agents as in the case of corporations.

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

"Matrix" means the component or substrate that contains the analyte of interest.

"National accreditation database" means the publicly accessible database listing the accreditation status of all laboratories participating in NELAP.

"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. A subset of NELAP.

"National Environmental Laboratory Accreditation Program (NELAP)" means the overall National Environmental Laboratory Accreditation Program of which NELAC is a part.

"Non-commercial 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 or operator of a small sewage treatment plant treating domestic sewage at a flow rate of less than or equal to 1000 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 sewage treatment facility or a waterworks.

c. Environmental analysis performed by an environmental laboratory owned by a corporation as part of the prequalification process for a potential customer as required by a hazardous waste management permit under 9 VAC 20, Chapter 60, Part XI.

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 9 VAC 25, Chapter 1, Part VII.

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" or "operator" means any person who owns or operates an environmental laboratory.

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

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

"Pretreatment requirements" means any requirements arising under Part VII of 9 VAC 25, Chapter 31 of the Virginia Administrative Code including the duty to allow or carry out inspections, entry or monitoring activities; any rules, regulations, or orders issued by the owner of a POTW; or any reporting requirements imposed by the owner of a POTW or by the regulations of the State Water Control Board. Pretreatment requirements do not include the requirements of a national pretreatment standard.

"Primary accrediting authority" means the agency or department designated at the territory, state or federal level as the recognized authority with the responsibility and

accountability for granting NELAC accreditation to a specific laboratory for a specific field 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 analyst, provided to test whether the analyst or laboratory or both 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.

"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" means an integrated system of activities involving planning, quality control, quality assessment, reporting and quality improvement to ensure that a product or service meets defined standards of quality with a stated level of confidence.

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

"Quality control" means the overall system of technical activities whose purpose is to measure and control the quality of a product or service so that it meets the needs of users.

"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.

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

1. 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.

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

3. Saline/estuarine: any aqueous sample from an ocean or estuary, or other salt water source such as the Great Salt Lake.

4. Non-aqueous liquid: any organic liquid with less than 15 percent settleable solids.

5. Biological tissue: any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origin, i.e., by species.

6. Solids: includes soils, sediments, sludges and other matrices with less than 15 percent settleable solids.

7. Chemical waste: a product or by-product of an industrial process that results in a matrix not previously defined.

8. 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.

"Recognition" means the mutual agreement of two or more accrediting authorities to accept each other's findings regarding the ability of environmental laboratories to meet NELAC standards.

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

(i) If the laboratory is owned or operated by a private corporation, "responsible official" means (1) 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 (2) 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.

(ii) 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.

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

(iv) Any person designated as the responsible official by an individual described in (i), (ii) or (iii) above, provided the designation is in writing, the designation specifies an individual or position with responsibility for the overall operation of the laboratory, and the designation is submitted to DGS-DCLS.

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

"Sanitation district" means a sanitation district created under the provisions of Title 21, Chapters 3 through 5 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.

"Standard operating procedure (SOP)" means a written document which details the method of an operation, analysis or action whose techniques and procedures are thoroughly prescribed and which is accepted as the method for performing certain routine or repetitive tasks.

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

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

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

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

"Test, analysis, measurement or monitoring required by 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 (9 VAC 5), including any method of analysis listed either in the definition of "reference method" in 9 VAC 5-10-20, or listed or adopted by reference in 9 VAC 5, Chapters 30, 40, 50 or 60; or by any permit or order issued under and in accordance with this law and these regulations.

"Test, analysis, measurement or monitoring required by 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 (9 VAC 20), including any method of analysis listed or adopted by reference in 9 VAC 20, Chapters 60, 80, 101, or 120; or by any permit or order issued under and in accordance with this law and these regulations.

"Test, analysis, measurement or monitoring required by 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 (9 VAC 25), including any method of analysis

listed or adopted by reference in 9 VAC 25, Chapters 31, 32, 110, 120, 151, 180, 190, 192, or 210; 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 a specific measurement problem, as documented in a laboratory standard operating procedure or published by a recognized authority.

"U.S. Environmental Protection Agency (U.S. EPA 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 §10.1-1300 of the *Code of Virginia* which is titled 'Air Pollution Control Board.'

"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.

1 VAC 30-46-50. Scope of accreditation.

A. Commercial environmental laboratories shall be accredited based on the general laboratory standards set out in Part II of this chapter and on the specific test methods or analysis, monitoring or measurement required by 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 and regulations.

B. DGS-DCLS shall review alternative test methods and procedures for accreditation when these are proposed by the applicant laboratory. The provisions of 1 VAC 30-46-70 E and 1 VAC 30-46-90 B govern alternative test methods and procedures.

C. Accreditation shall be granted for a specific field or fields of accreditation, including the technology and methods used by the commercial environmental laboratory, and the individual analytes or analyte groups determined by the particular method.

1 VAC 30-46-60. General: accreditation requirements.

A. Components of accreditation.

The components of accreditation include review of personnel qualifications, on-site assessment, proficiency testing and quality assurance and quality control standards. The criteria for these components, specified in Part II of this chapter, shall be fulfilled for accreditation.

B. Individual laboratory sites and mobile laboratories.

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

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

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

1 VAC 30-46-70. Process to apply and obtain accreditation.

A. Duty to apply.

All owners or operators of (i) commercial environmental laboratories and (ii) NELAC-accredited environmental laboratories located outside Virginia applying for reciprocal accreditation shall apply for accreditation as specified by the provisions of this section.

B. Timely initial applications.

1. Owners or operators of commercial environmental laboratories in existence on the date this chapter becomes effective.

Owners or operators of commercial environmental laboratories applying for accreditation under this chapter for the first time shall submit an application to DGS-DCLS no later than 180 calendar days after the effective date of this chapter.

2. Owners or operators of commercial environmental laboratories that come into existence after this chapter becomes effective.

Owners or operators of commercial environmental laboratories that come into existence after this chapter becomes effective shall submit an initial application to DGS-DCLS no later than 180 calendar days prior to initiating the provision of environmental laboratory services.

3. Owners or operators of NELAC-accredited environmental laboratories located outside Virginia.

a. During the initial accreditation period, NELAC-accredited environmental laboratories located outside Virginia shall submit an application to DGS-DCLS no later than 180 calendar days after the effective date of this chapter.

b. After the program is established, NELAC-accredited environmental laboratories located outside Virginia shall submit an application to DGS-DCLS no later than 180 calendar days prior to initiating the provision of environmental laboratory services.

C. Timely renewal applications.

The owner or operator of either an (i) accredited commercial environmental laboratory or an (ii) environmental laboratory holding reciprocal accreditation shall submit an application for renewal of accreditation at least 90 calendar days prior to expiration of accreditation.

D. Responsibilities of the owner or operator.

1. When an environmental laboratory is owned by one person but is operated by another person, the operator may submit the application for the owner.

2. If the operator fails to submit the application, the owner is not relieved of his responsibility to apply for accreditation.

3. While DGS-DCLS may notify environmental laboratories of the date their applications are due, failure of DGS-DCLS to notify does not relieve the owner or operator of his obligation to apply under this chapter.

E. Submission of applications for modifications to accreditation.

An owner or operator of an accredited environmental laboratory shall follow the process set out in 1 VAC 30-46-90 B to add a new technology, an analyte or a test method, modify a test method or institute use of a method not in the laboratory's standard operating procedures, including alternative test methods or procedures.

F. Contents of application.

1. Applications shall include 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 e-mail, as applicable, of responsible official;

h. name, address, telephone number, facsimile number and e-mail, as applicable, of technical director;

i. name, address, telephone number, facsimile number and e-mail, as applicable, of designated quality assurance officer;

j. name and telephone number of laboratory contact person;

k. laboratory type (e.g., commercial, public wastewater system, mobile);

l. laboratory hours of operation;

m. fields of accreditation for which the laboratory is seeking accreditation;

n. methods employed, including analytes;

o. the results of the three most recent proficiency test studies;

p. quality assurance manual;

q. lab identification number (for renewal only); and

r. 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 1 VAC 30-46-150.

3. Certification of compliance.

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

b. The certification of compliance shall state: "The applicant understands and acknowledges that the laboratory is required to be continually in compliance with the Virginia environmental laboratory accreditation program regulation (1 VAC 30, Chapter 46) and is subject to the provisions of 1 VAC 30-46-100 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 or withdrawal of accreditation. I further certify that I am authorized to sign this application."

G. Completeness determination.

1. DGS-DCLS shall determine whether an application is complete and notify the laboratory of the result of such determination. Except during the initial accreditation period, DGS-DCLS shall provide this notice within 60 calendar days of DGS-DCLS's receipt of the application.

2. An application shall be determined complete if it contains all the information required pursuant to 1 VAC 30-46-70 F and is sufficient to evaluate the laboratory prior to the on-site assessment. Designating an application complete does not preclude DGS-DCLS from requesting or accepting additional information.

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

4. Except during the initial accreditation period, if no determination is made within 60 calendar days of DGS-DCLS's 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. DGS-DCLS may deny any application from a laboratory and require the laboratory to submit a new application, if the laboratory does not submit additional information required by DGS-DCLS within 90 days of the mailing date of the notice that requires additional information.

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

1. DGS-DCLS shall grant a laboratory interim accreditation status under the following conditions:

a. the laboratory’s application is determined to be complete;

b. the laboratory has satisfied all the requirements for accreditation, including all requests for additional information, with the exception of on-site assessment; and

c. DGS-DCLS is unable to schedule the on-site assessment within 90 days of its determination that the application is complete and that the laboratory has satisfied all other requirements for accreditation.

2. A laboratory with interim accreditation shall have the same rights and status as a laboratory that has been granted accreditation by DGS-DCLS.

3. Interim accreditation expires when DGS-DCLS issues a final determination on accreditation.

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 Part II of this chapter prior to issuance of a final determination on accreditation.

J. Final determination on accreditation.

1. Upon completion of the accreditation review process and corrective action, if any, DGS-DCLS shall grant accreditation in accordance with subsection K of this section or deny accreditation in accordance with subsection L of this section.

2. Except during the initial accreditation period, DGS-DCLS shall complete action on a laboratory's application within nine months from the time an application is determined to be complete.

3. During the initial accreditation period, DGS-DCLS shall notify applicants of their interim accreditation status under subsection H of this section only after all applications have been reviewed and are determined to be complete.

4. During the final approval process of the initial accreditation period, DGS-DCLS shall notify applicants of their final accreditation status only after all timely and complete applications have been reviewed, all on-site assessments have been completed, and accreditation status has been determined for all applicant laboratories.

5. During the final approval process, DGS-DCLS shall release on-site assessment reports to applicants at the time that applicants are notified of their final accreditation status. If a laboratory is found to have deficiencies during the on-site assessment, DGS-DCLS may provide comments and recommendations aimed at helping the laboratory improve.

K. Grant of accreditation.

1. When a laboratory meets the requirements specified for receiving accreditation, DGS-DCLS shall issue a certificate to the laboratory. The certificate shall be sent to the technical director, and the responsible official shall be notified.

2. The certificate shall be signed by the director of DGS-DCLS. The certificate shall be transmitted as a sealed and dated document.

3. The certificate shall include the following information:

a. name of owner or operator of laboratory;

b. name of responsible official;

c. address and location of laboratory;

d. laboratory identification number;

e. fields of accreditation (matrix, technology/method and analyte/analyte group) for which accreditation is granted;

f. any addenda or attachments; and

g. issuance date and expiration date.

4. National Environmental Laboratory Accreditation Program (NELAP) status.

a. Laboratories accredited under this chapter are accredited under the standards of the National Environmental Laboratory Accreditation Conference.

b. The certificate of accreditation shall contain the NELAP insignia.

c. Accredited laboratories shall comply with the provisions of 1 VAC 30-46-130 with regard to the use of these certificates and their status as NELAP-accredited laboratories.

5. The laboratory shall post the most recent certificate of accreditation and any addenda to the certificate issued by DGS-DCLS in a prominent place in the laboratory facility.

6. Accreditation shall expire two years after date on which accreditation is granted.

L. Denial of accreditation.

1. DGS-DCLS shall deny accreditation to an environmental laboratory in total if the laboratory owner or an employee falsifies any data or provides false information to support accreditation.

2. Denial of accreditation in total or in part.

a. DGS-DCLS may deny accreditation to an environmental laboratory in total or in part if the laboratory owner or an employee 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 of this chapter;

(3) successfully analyze and report proficiency testing samples as required by Part II of this chapter;

(4) submit a corrective action report 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 report within the time frame specified by DGS-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. DGS-DCLS may deny accreditation to an environmental laboratory in total or in part if the laboratory's application is not determined to be complete within 90 days following notification of incompleteness because the laboratory is delinquent in submitting information required by DGS-DCLS in accordance with this chapter.

c. DGS-DCLS may deny accreditation to an environmental laboratory in total or in part if

the DGS-DCLS on-site assessment team is unable to carry out the on-site assessment pursuant to 1 VAC 30-46-210 B because an employee, owner, or other representative of the environmental laboratory denied the team entry during normal business hours.

3. To deny accreditation, DGS-DCLS shall provide by certified mail written notification of denial to the responsible officer and the technical director of the laboratory, including a detailed explanation of the reason for denial and notice of the right to appeal such denial.

M. Reapplication following denial of accreditation.

1. Upon denial of accreditation, the laboratory shall wait six months before reapplying for accreditation.

2. DGS-DCLS shall not waive application fees for a laboratory reapplying for accreditation.

1 VAC 30-46-80. Maintaining accreditation

A. Accreditation remains in effect until withdrawn by DGS-DCLS, withdrawn voluntarily at the written request of the accredited laboratory, or until expiration of the

accreditation period. To maintain accreditation, the accredited laboratory shall comply with the elements listed in this section and in 1 VAC 30-46-90.

B. Quality systems.

A laboratory seeking to maintain accreditation under this regulation shall assure consistency and promote the use of quality assurance and quality control procedures. Part II of this chapter specifies the quality assurance and quality control requirements that shall be met to maintain accreditation. The laboratory shall establish and maintain a quality system based on the required elements contained in Part II and appropriate to the type, range and volume of environmental testing activities it undertakes.

C. Proficiency tests.

Laboratories seeking to maintain accreditation under this regulation shall perform proficiency tests as required under Part II of this chapter.

D. Record keeping and retention.

All laboratory records associated with accreditation parameters shall be kept as provided by the requirements for records under Part II of this regulation. These records shall be maintained for a minimum of five years unless designated for a longer period by another regulation or authority. All such records shall be available to DGS-DCLS upon request.

1 VAC 30-46-90. Changing accreditation status.

A. Changes to key accreditation criteria.

1. The accredited laboratory shall notify DGS-DCLS as set out in subdivision A 3 of this section of any changes in key accreditation criteria within 30 calendar days of the change. Key accreditation criteria are laboratory ownership, location, key personnel, test methods, analytes, and major instrumentation.

2. The laboratory may initially notify DGS-DCLS of any change to key accreditation criteria by e-mail, facsimile or telephone. The notification by e-mail, facsimile or telephone subsequently shall be submitted in writing.

3. As specified in subsection B of this section, changes to key accreditation criteria that affect the laboratory's scope of accreditation require review and approval by DGS-DCLS in advance of the laboratory's making the change.

B. Changes to scope of accreditation.

1. DGS-DCLS shall review and approve the addition of a new technology, an analyte, or a test method to a laboratory's scope of accreditation.

2. To begin the process of review, the owner or operator of the accredited laboratory that wants to add to the laboratory's scope of accreditation shall submit the following application materials to DGS-DCLS:

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

b. Pertinent information demonstrating that the laboratory is capable of performing the test method or using the technology to be added such as proficiency testing performance and quality control performance.

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

DGS-DCLS may request additional material to complete its review.

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

documentation may be carried out by DGS-DCLS, depending on the modification for which the laboratory applies.

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

C. Change of ownership or location of laboratory.

1. The accredited laboratory shall submit a written notification to DGS-DCLS of the change of ownership or location of the laboratory within 30 calendar days of the change.

2. Accreditation may be transferred when the legal status or ownership of a accredited laboratory changes without affecting its personnel, equipment, and facilities.

3. DGS-DCLS may charge a transfer fee and may conduct an on-site assessment to verify the effects of such changes on laboratory performance.

4. When a laboratory changes ownership, the new laboratory owner shall assure that the history of the laboratory's ownership can be traced through laboratory identification numbers.

5. When there is a change in ownership, all records and analyses performed by the previous owner under his scope of accreditation shall be kept for a period of five years. As required under 1 VAC 30-46-80 D, all such records shall be made available to DGS-DCLS upon request.

D. Voluntary withdrawal.

Any environmental laboratory owner or operator who wishes to withdraw the laboratory from its accreditation status or from being accredited, in total or in part, shall submit written notification to DGS-DCLS no later than 30 calendar days before the end of the laboratory's accreditation term. Within 30 calendar days, DGS-DCLS shall provide the laboratory with a written notice of withdrawal.

1 VAC 30-46-100 Withdrawal of accreditation.

A. DGS-DCLS shall withdraw accreditation from an environmental laboratory in total for the following reasons:

1. Submittal by the laboratory owner or employee of proficiency test sample results generated by another laboratory as its own.

2. Falsification by a laboratory owner or employee of any data or the provision of false information by any laboratory owner or employee to support accreditation.

3. Conviction of the laboratory owner or employee of charges relating to the falsification of any report concerning a laboratory analysis.

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

1. Participate in the proficiency testing program as required by 1 VAC 30-46-210 C.

2. Complete proficiency testing studies and maintain a history of at least two successful proficiency testing studies for each affected accredited field of testing out of the three most recent proficiency testing studies as defined in 1 VAC 30-46-210 C.

3. Maintain a quality system as defined in 1 VAC 30-46-210 D.

4. Employ staff that meet the personnel qualifications of 1 VAC 30-46-210 A.

5. Submit an acceptable corrective action report after two opportunities, as specified in 1 VAC 30-46-210 B.

6. Implement corrective action specified in the laboratory’s corrective action report, as set out under 1 VAC 30-46-210 B.

7. Notify DGS-DCLS of any changes in key accreditation criteria, as set forth in 1 VAC 30-46-90.

8. Use correct and authorized references to the laboratory's accreditation status or that of DGS-DCLS in the laboratory's documentation and advertising, as set forth in 1 VAC 30-46-130.

C. Responsibilities of the environmental laboratory and DGS-DCLS when accreditation has been withdrawn.

1. Laboratories that lose their accreditation in full shall return their certificate to DGS-DCLS.

2. If a laboratory loses accreditation in part, an addendum to the certificate shall be issued by DGS-DCLS to the laboratory.

3. The laboratory shall discontinue the use of all materials that contain either a reference to the environmental laboratory's past accreditation status or that display the NELAC/NELAP logo. These materials may include catalogs, advertising, business solicitations, proposals, quotations, laboratory analytical results or other materials.

D. After correcting the reason or cause for the withdrawal of accreditation under 1 VAC 30-46-100 A or B, the laboratory owner or operator may reapply for accreditation.

1 VAC 30-46-110. Appeal procedures.

A. DGS-DCLS shall notify an environmental laboratory in writing of its decision to deny accreditation to or to withdraw accreditation from an environmental laboratory.

B. All appeals taken from actions of the DGS-DCLS director relative to the provisions of this chapter shall be governed by the Virginia Administrative Process Act (§2.2-4000 *et seq.* of the *Code of Virginia*).

1 VAC 30-46-120. National accreditation database.

DGS-DCLS shall provide to NELAP the following information about environmental laboratories accredited under this chapter: (i) technical director's name; (ii) ownership and

location of laboratory and any changes; (iii) key accreditation criteria and any changes; (iv) interim, as well as final, accreditation status; and (v) on-site assessment reports.

1 VAC 30-46-130. Use of accreditation status by environmental laboratories accredited under this chapter.

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

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

1. Post or display their most recent accreditation certificate or their fields of accreditation in a prominent place in the laboratory facility.

2. Make accurate statements concerning their fields of accreditation and accreditation status.

3. Accompany DGS-DCLS's name or the NELAC/NELAP logo or both with at least the phrase "NELAP-accredited" and the laboratory's identification number or other identifier when DGS-DCLS's name is used on general literature such as catalogs, advertising, business solicitations, proposals, quotations, laboratory analytical reports or other materials.

4. Not use their accreditation certificate, their accreditation status or the NELAC/NELAP logo to imply endorsement by DGS-DCLS.

C. The owners or operators of laboratories accredited under this chapter who choose (i) to use DGS-DCLS's name or (ii) to make reference to its NELAP accreditation status or (iii) to use the NELAC/NELAP logo in any catalogs, advertising, business solicitations,

proposals, quotations, laboratory analytical reports or other materials, shall comply with both of the following:

1. Distinguish between proposed testing for which the laboratory is accredited and the proposed testing for which the laboratory is not accredited.

2. Include the laboratory's identification number or other identifier.

1 VAC 30-46-140. Reciprocal accreditation.

A. DGS-DCLS, when recognized by NELAP as a primary accrediting authority, may grant reciprocal accreditation to an environmental laboratory located outside Virginia that holds a current accreditation from another NELAP-recognized primary accrediting authority.

B. The owner or operator of a NELAP-accredited environmental laboratory that seeks accreditation under this chapter shall apply as specified in 1 VAC 30-46-70.

C. The owner or operator of the applicant laboratory shall pay the fee required by 1 VAC 30-46-150.

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

E. DGS-DCLS shall consider only the current certificate of accreditation issued by the NELAP-recognized primary accrediting authority.

F. DGS-DCLS shall do the following:

1. Grant reciprocal accreditation for only the fields of accreditation for which the laboratory holds current primary NELAP accreditation.

2. Except during the initial accreditation period, grant reciprocal accreditation and issue certificates to an applicant laboratory within 30 calendar days of receipt of the laboratory's application.

G. Potential nonconformance issues.

1. If DGS-DCLS notes any potential nonconformance with the NELAC standards by a laboratory during the initial application process for reciprocal accreditation or for a laboratory that already has been granted NELAP accreditation through reciprocal accreditation, DGS-DCLS shall immediately notify, in writing, the applicable NELAP-recognized primary accrediting authority and the laboratory. The notification shall cite the applicable sections within the NELAC standards for which nonconformance by the laboratory has been noted.

2. If the alleged nonconformance is noted during the initial application process for reciprocal accreditation, final action on the application for reciprocal accreditation shall not be taken until the alleged nonconformance issue has been resolved.

3. If the alleged nonconformance is noted after reciprocal accreditation has been granted, the laboratory shall maintain its current accreditation status until the alleged nonconformance issue has been resolved.

4. If DGS-DCLS does not believe the primary accrediting authority has taken timely and appropriate action on the potential nonconformance, DGS-DCLS shall notify the NELAP director of its concerns.

1 VAC 30-46-150. Fees.

A. General.

1. Fees shall be submitted with all applications for accreditation. Applications shall not be designated as complete until the fee is received by DGS-DCLS.

2. Fees shall be nonrefundable.

3. An environmental laboratory applying for reciprocal accreditation under this chapter shall pay the same fee as other laboratories subject to this chapter.

B. Fee computation.

1. The fee shall be the total of the base fee and the test category fees.

2. The test category fees cover categories for the test methods to be accredited as specified in the laboratory's application.

3. If the total of the base fee and the test category fees is more than the maximum fee, the laboratory shall pay the maximum fee.

C. Maximum fee.

The maximum fee shall be $4200.

D. Base fee.

The base fee shall be $2100.

E. Test category fees.

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

2. The fee for each category includes one or more analytical methods unless otherwise specified. With the exception of the test categories labeled oxygen demand and physical, test categories related to test methods for water are defined by 40 CFR Part 136, § 136.3.

3. Fees.

TEST CATEGORY	FEE
Oxygen demand (BOD or COD)	$300
Bacteriology	$300
Inorganic chemistry, fewer than four methods	$300

Inorganic chemistry, four or more methods	$600
Chemistry metals, fewer than four methods	$300
Chemistry metals, four or more methods	$600
Organic chemistry, fewer than four methods	$350
Organic chemistry, four or more	$700
Whole effluent toxicity, acute methods only	$300
Whole effluent toxicity, acute and chronic methods	$600
Radiochemical	$900
Physical	$300

F. Additional fees.

1. For any accredited environmental laboratory that applies to modify its scope of accreditation as specified under 1 VAC 30-46-90 B, DGS-DCLS shall assess a fee determined by the method in subdivision F 3 of this section.

2. Under 1 VAC 30-46-90 C, DGS-DCLS may charge a transfer fee to a certified laboratory that transfers ownership. If DGS-DCLS determines that a fee should be charged, the fee shall be a minimum of $100 and a maximum of $1000. If DGS-DCLS determines that an on-site assessment is necessary to evaluate the effect of the transfer of ownership, DGS-DCLS shall assess a fee determined by the method in subdivision F 3 of this section.

3. Fee determination.

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

b. 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 1642 (number of annual hours established by Fiscal Services, DGS, for billing purposes).

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

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

G. On-site assessment fees.

When, with the concurrence of the applicant laboratory, DGS-DCLS uses approved, third-party on-site assessors, the cost of the on-site assessment shall be paid by the applicant.

1 VAC 30-46-160. Petitioning for a variance.

A. Any person regulated by this chapter may petition the director to grant a variance from any requirement of this chapter. Any person submitting a petition to the director must 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 subsection. If the director continues to believe 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;

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 are subject to the provisions of Article 3 of the Virginia Administrative Process Act (§2-2-4000 *et seq*. of the *Code of Virginia*).

1 VAC 30-46-170 through 1 VAC 30-46-190. Reserved.

1 VAC 30 CHAPTER 46
ACCREDITATION FOR COMMERCIAL ENVIRONMENTAL LABORATORIES

PART II. STANDARDS

1 VAC 30-46-200. Incorporation of NELAC standards.

A. The 2002 National Environmental Laboratory Accreditation Conference (NELAC) standards as specified in 1 VAC 30-46-210 are incorporated by reference into this chapter.

B. Laboratories applying for accreditation and accredited under this chapter shall comply with the 2002 NELAC standards incorporated by reference into 1 VAC 30-46-210.

1 VAC 30-46-210. Standards for accreditation.

A. Standards for personnel qualifications.

The standards for personnel qualifications are the following provisions of the National Environmental Laboratory Accreditation Conference (NELAC) standards as incorporated by reference into Part II, Chapter 46 of 1 VAC 30: Chapter 4, Accreditation Process, specifically, Components of Accreditation and Personnel Qualifications.

B. Standards for on-site assessment.

The standards for on-site assessment are the following provisions of the NELAC standards as incorporated by reference into Part II, Chapter 46 of 1 VAC 30:

1. Chapter 3, On-site Assessment: specifically, On-site Assessment Personnel; Frequency and Types of On-site Assessments; Pre-assessment Procedures; Assessment Procedures; Standards for Assessment; and Documentation of On-site Assessment, with one exception. Subsection 3.4.5, Confidential Business Information (CBI) Considerations, shall not be incorporated by reference into Part II, Chapter 46 of 1 VAC 30.

2. Chapter 4, Accreditation Process: specifically, On-site Assessments and Corrective Action Reports in Response to On-site Assessment.

C. Standards for proficiency testing.

The standards for proficiency testing are the following provisions of the NELAC standards as incorporated by reference into Part II, Chapter 46 of 1 VAC 30:

1. Chapter 2, Proficiency Testing: specifically, Major PT Groups and Their Responsibilities - Laboratories and Accrediting Authorities; Laboratory Enrollment in Proficiency Testing Programs; Requirements for Laboratory Testing of PT Study Samples; and PT Criteria for Laboratory Accreditation.

2. Chapter 4, Accreditation Process: specifically, Proficiency Testing Samples.

D. Standards for quality systems.

1. The standards for quality systems are the following provisions of the NELAC standards as incorporated by reference into Part II, Chapter 46 of 1 VAC 30: (i) Chapter 4, specifically, Accountability for Analytical Standards, and (ii) Chapter 5, Quality Systems.

2. Quality systems - scope.

Chapter 5 of the NELAC standards sets out the scope of quality systems requirements. These provisions provide an overview to major aspects of the accreditation process and are set out below for emphasis:

a. Chapter 5 includes all quality assurance policies and quality control procedures which shall be delineated in a quality manual and followed to ensure and document the quality of the analytical data. Laboratories seeking accreditation shall assure implementation of all quality assurance policies and the essential applicable quality control procedures specified in this chapter. The quality assurance policies, which establish essential

quality control procedures, are applicable to environmental laboratories regardless of size and complexity.

b. The intent of Chapter 5 is to provide sufficient detail concerning quality management requirements so that DGS-DCLS can evaluate environmental laboratories consistently and uniformly.

c. Chapter 5 sets out the general requirements that a laboratory has to successfully demonstrate to be recognized as competent to carry out specific environmental tests.

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 requirements are more stringent, the standard from the method or regulation is to be followed.

1 VAC 30-46-220 through 1 VAC 30-46-300. Reserved.