



Final Regulation Agency Background Document

Agency name	Department of General Services Division of Consolidated Laboratory Services
Virginia Administrative Code (VAC) citation	1 VAC 30, Chapters 45 and 46
Regulation title	Certification for Noncommercial Environmental Laboratories (Chapter 45) and Accreditation for Commercial Environmental Laboratories (Chapter 46)
Action title	Virginia Environmental Laboratory Certification Program
Date this document prepared	November 17, 2008

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation. Also, please include a brief description of changes to the regulation from publication of the proposed regulation to the final regulation.

The regulations establish the certification program required by §2.2-1105 of the Code of Virginia for environmental laboratories submitting data to the Department of Environmental Quality under the state's air, water and waste laws. There are two regulations, one for noncommercial environmental laboratories (1VAC30-45) and one for commercial environmental laboratories (1VAC30-46). Each regulation is organized into two parts. Part I of each regulation contains the provisions pertaining to the administration of the program. This part describes the process that owners or operators of environmental laboratories must use to be certified and to maintain certification under the program. Part II of each regulation contains the quality assurance and quality control standards that environmental laboratories must meet to be certified under the program. The standards in Part II of Chapter 45 have been developed for Virginia noncommercial environmental laboratories. The standards in Part II of Chapter 46 are the 2003 National Environmental Laboratory Accreditation Conference standards, which are incorporated by reference into the regulation.

Final regulations were published August 18, 2008 (24:25 VA.R. 3449-3523). The final stage of the regulations was suspended on September 17, 2008. A notice of suspension of the regulatory process was published on October 13, 2008 (25:3 VA.R. 340-342). The notice included additional proposed language, 1 VAC 30-45-30 C and D, in response to the public comments that triggered the suspension. 1 VAC 30-45-30 C addresses certification of laboratories owned by or affiliated with citizen water quality monitoring groups. This subsection allows these laboratories to meet the DEQ quality assurance and quality control requirements for citizen monitoring groups in lieu of the certification requirements of 1 VAC 30, Chapter 45 or Chapter 46. 1 VAC 30-45-30 D addresses environmental research performed by environmental laboratories owned by institutions of higher education. This subsection exempts research performed by these laboratories from the requirements of 1 VAC 30, Chapter 45 or Chapter 46, unless DEQ requires certification. This proposed additional language is included, without change, in the revised final regulations.

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.

The Director of the Department of General Services approved the final environmental laboratory certification regulations on November 18, 2008. The regulations are entitled Certification for Non-Commercial Environmental Laboratories (1 VAC 30, Chapter 45) and Accreditation for Commercial Environmental Laboratories (1 VAC 30, Chapter 46).

Legal basis

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

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

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

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

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

Section 2.2-1105 A of the *Code of Virginia* (Title 2.2, Chapter 11) requires that DCLS establish by regulation a program to certify laboratories conducting any tests, analyses, measurements, or monitoring required pursuant to the State Air Pollution Control Board (§10.1-1300 *et seq.*), the Virginia Waste Management Act (§10.1-1400 *et seq.*) or the State Water Control Law (§62.1-44.2 *et seq.*).

Section 2.2-1105 A requires that the program include minimum criteria for the following: (1) laboratory procedures; (2) performance evaluations; (3) supervisory and personnel requirements; (4) facilities and equipment; (5) analytical quality control and quality assurance; (6) certificate issuance and maintenance; (7) recertification and decertification; and (8) granting full and partial exemptions from the program based on compliance and performance. Other criteria may be included. Section 2.2-1105 A states further that regulations shall be proposed only after national accreditation standards are adopted by the National Environmental Laboratory Accreditation Conference. The last sentence of §2.2-1105 A specifies the purpose of the program: “to ensure that laboratories provide accurate and consistent tests, analyses, measurements and monitoring so that the goals and requirements of [Virginia’s air, waste and water laws] may be met.” Section 2.2-1105 B states that once the certification program is established, laboratory certification is required before any tests, analyses, measurements, or monitoring performed by a laboratory may be used for the purposes of Virginia’s air, waste or water laws. Section 2.2-1105 C requires that a fee system be established to pay for the costs of certifying laboratories under the program. Section 2.2-1105 D requires the program to include procedures for determining the qualifications of out-of-state laboratories to conduct tests, analyses, measurements or monitoring for use in Virginia. Environmental laboratories located outside Virginia that are certified or accredited under a program determined by DCLS to be equivalent to Virginia’s program must be deemed to meet the certification requirements established under §2.2-1105. Section 2.2-1105 E requires that DCLS must deny certification to or decertify laboratories found to be falsifying data or providing false information to support certification. Section 2.2-1105 F allows any laboratory subject to the regulations to petition the Director of DCLS for a reasonable variance from the requirements of the regulations. The director may grant a petition if the petitioner demonstrates to the Director’s satisfaction that the variance will meet the goals and purposes of the statute or the regulations and will not conflict with federal or state law or regulations.

Purpose

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

The proposed regulations fulfill the mandate of §2.2-1105 of the *Code of Virginia* to establish a program to certify laboratories conducting tests, analyses, measurements, or monitoring required pursuant to the State Air Pollution Control Board (§10.1-1300 *et seq.*), the Virginia Waste Management Act (§10.1-1400 *et seq.*) or the State Water Control Law (§62.1-44.2 *et seq.*). Section 2.2-1105 specifies that the purpose of the program is “to ensure that laboratories provide accurate and consistent tests, analyses, measurements and monitoring . . .” required by these laws.

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

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

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

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

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

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

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

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

may then use another commercial laboratory. The problematic commercial laboratory is still free, however, to provide analytical services to other permittees who are not aware of the problems at this laboratory.

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

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

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

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

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

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

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

The NELAC standards and individual state certification or accreditation programs for environmental laboratories use quality assurance and quality control measures to determine whether environmental laboratories operate uniformly and consistently. Quality assurance is defined by EPA’s Quality Assurance Management Group as “an integrated system of activities involving planning, quality control, quality assessment, reporting, and quality improvement to ensure that a product or service meets defined standards of quality with a stated level of confidence.” NELAC 2003 Standards, page 1A-9 of the Glossary, Appendix A, Chapter 1. Quality control is defined as “the overall system of technical activities whose purpose is to measure and control the quality of a product or service so that it meets the needs of users.” NELAC 2003 Standards, *ibid*.

The certification program will provide standards and requirements for all environmental laboratories providing data required by Virginia's environmental laws. The program initiates certification requirements for laboratories that analyze air and waste samples. It enhances laboratory audit and certification programs for water by increasing the frequency of on-site assessments of laboratory facilities for all but major wastewater facilities, and the frequency of proficiency testing for all laboratories analyzing water samples. By requiring environmental laboratories to meet standards to obtain certification, the program will encourage the production of environmental data that are consistent, accurate and comparable. The program will enhance the quality of all environmental laboratories by assisting and educating laboratories in their continuing development of good laboratory practice. In turn, the public health and environmental quality will be protected because public health and environmental management decisions will be based on data that are of high quality. Basing environmental and public health decisions on sound data is inherently cost efficient and best protects the quality of the Commonwealth's air, water and terrain.

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

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

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

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

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

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

As of July 2004, 146 major sources and 1018 minor sources have water program permits. The total number of minor sources does not include those holding general permits. These permittees generally are not required to provide data from laboratory analyses as part of their

permits. The proposed laboratory certification program will cover an estimated 773 wastewater permittees. This includes 123 major sources and 650 minor sources. The wastewater permit holders were reviewed to eliminate those sources that perform only field testing or contract out laboratory work. Field tests are not included in the proposed program except when the tests are performed in an environmental laboratory. These numbers have changed since originally provided in 2002; the number of permit holders does fluctuate over time. In 2002, there were 160 major sources and 1198 minor sources holding water program permits. The laboratory certification program was proposed to cover 915 wastewater permittees. This included all the major sources and 755 minor sources.

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

Substance

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

A summary of the regulations is set out below.

1 VAC 30, Chapter 45

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

1. Part I of the regulation addresses general requirements of the certification program for non-commercial environmental laboratories. The following are some of the general requirements covered by Part I: establishment of the program, applicability of environmental laboratories, definitions, the scope of certification, general requirements, the process to apply and obtain certification, the reasons why certification would be denied, how to maintain certification status, the process to change certification scope or status, the reasons why certification might be withdrawn and the process of withdrawal of certification, appeal procedures, exemptions, fees, and petitioning for a variance.
2. The regulation establishes the certification program on the first day of the 37th month following the regulation’s effective date [1 VAC 30-45-20 B]. Non-commercial environmental laboratories must be certified prior to this date. After this date, only data from certified environmental laboratories can be used for the purposes of Virginia’s air, waste and water laws. [1 VAC 30-45-20 A].
3. The regulation applies to any owner or operator of a non-commercial environmental laboratory [1 VAC 30-45-30 A].
4. An environmental laboratory is a facility or a defined place within a facility where environmental analysis is performed. Environmental analysis is any test, analysis, measurement

or monitoring used for or required by Virginia's air, waste or water laws, regulations, or any permit or order issued under those laws or regulations. Environmental analysis does not include sampling, field testing and measurement, or taxonomic identification of samples. [1 VAC 30-45-40]

5. A non-commercial environmental laboratory is one where environmental analysis is performed solely for the owner. Activities that might be seen as commercial but that are considered to be non-commercial in this regulation are listed in the definition. [1 VAC 30-45-40]

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

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

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

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

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

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

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

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

12. DCLS shall decertify an environmental laboratory if the laboratory is found to be falsifying any data or providing false information to support certification. DCLS may decertify an environmental laboratory when the laboratory fails to maintain the standards and quality system for

which it was certified. Decertification may be for all aspects of the certification or part of the certification. DCLS, if it believes it has grounds to decertify a laboratory, will provide a written notice to the environmental laboratory with a detailed explanation of the basis for the notice and of the process to follow. [1 VAC 30-45-100 and -110]

13. A laboratory may apply to DCLS for a partial or full exemption from the certification program requirements. The laboratory must have met all requirements for certification for four years before DCLS will consider granting an exemption. DCLS will provide a notice in the *Virginia Register* and take comments on the request before deciding to grant or deny the application for an exemption. The exemption shall be limited to 24 months. [1 VAC 30-45-120]

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

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

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

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

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

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

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

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

1 VAC 30, Chapter 46

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

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

2. Chapter 46 uses the term "accreditation" instead of the term "certification." Unlike Chapter 45, Chapter 46 uses the 2003 National Environmental Laboratory Accreditation Conference

(NELAC) standards as the standards to be met by commercial environmental laboratories. The term used by the National Environmental Laboratory Accreditation Program is “accreditation.”

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

4. An environmental laboratory is a facility or a defined place within a facility where environmental analysis is performed. Environmental analysis is any test, analysis, measurement or monitoring used for or required by Virginia’s air, waste or water laws, regulations, or any permit or order issued under those laws or regulations. Environmental analysis does not include sampling, field testing and measurement, or taxonomic identification of a sample. [1 VAC 30-46-40]

5. A commercial environmental laboratory is one where environmental analysis is performed for another person. A “person” is an individual, corporation, partnership, association, or other legal entity, including any government. [1 VAC 30-45-40]

6. The owner or operator of any environmental laboratory currently accredited under the NELAC standards who wishes to apply for reciprocal accreditation must apply under Chapter 46. [1 VAC 30-46-30 A]

7. The regulation applies to DCLS. DCLS will meet the requirements of the regulation through review and accreditation by a National Environmental Laboratory Accreditation Program (NELAP)-accredited federal or state accrediting authority. This process will be complete before the program is established. In addition, DCLS will meet the NELAC standards to become the primary accrediting authority for Virginia. This process shall be complete no later than one year after the effective date of the regulation. [1 VAC 30-46-30 B]

8. Any environmental laboratory owner or operator may voluntarily apply for accreditation under Chapter 46. When an environmental laboratory owner or operator must get drinking water certification under Chapter 40 of 1 VAC 30 and environmental laboratory certification under Chapter 45, the owner or operator may apply under Chapter 46 and meet the requirements of both regulations. [1 VAC 30-46-30 C and D]

9. Owners or operators of commercial environmental laboratories must submit applications for accreditation within six months after the regulation becomes effective. DCLS may determine more specific application deadlines and notify existing laboratories. Application requirements are listed and include an application fee and certification of compliance. Owners or operators of NELAC-accredited environmental laboratories must apply for reciprocal accreditation no later than six months after the regulation becomes effective. [1 VAC 30-46-70]

10. Information about accredited laboratories will be provided to the NELAP database. The information to be provided is basic information about the laboratory’s certification such as the technical director’s name, certification status and fields of testing for which the laboratory is accredited. [1 VAC 30-46-120]

11. The regulation lists requirements for owners or operators of laboratories accredited under Chapter 46 who wish to use the NELAP accreditation status and logo. [1 VAC 30-46-130]

12. DCLS, once it is recognized by NELAP as a primary accrediting authority, may grant reciprocal accreditation to environmental laboratories already accredited by another primary accrediting authority. The regulation describes the process that these laboratories need to use to apply for and receive reciprocal accreditation under the program. [1 VAC 30-46-140]

13. The term of accreditation is one year. Fees are paid at initial accreditation and every two years thereafter. In the interim year, the laboratory retains its accreditation status by maintaining compliance with Chapter 46 and attesting to that compliance by signing the certificate of compliance, and by reporting acceptable proficiency test values for the laboratory's fields of accreditation. [1 VAC 30-46-70 C]

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

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

Issues

Please identify the issues associated with the proposed regulatory action, including:

- 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*
 - 2) the primary advantages and disadvantages to the agency or the Commonwealth; and*
 - 3) other pertinent matters of interest to the regulated community, government officials, and the public.*
- If there are no disadvantages to the public or the Commonwealth, please indicate.*

General public

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

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

Regulated entities

Advantages. There are several advantages for regulated entities. First, DEQ and the customers of the commercial laboratories will be assured that the laboratories have been reviewed to standards

set by the program. This assurance should enhance the credibility of the data produced by the laboratories. Decisions that must be made using these data will be made with greater confidence. Second, an advantage for all laboratories subject to the proposed regulations and especially for small local government laboratories is the assistance and education that will be provided during the certification process. On-site assessments often provide teaching and learning opportunities for a certifying agency and the laboratory. Third, certification enhances the ability of commercial environmental laboratories to compete within the state and outside Virginia. Once accredited under Chapter 46, commercial laboratories in Virginia may apply for reciprocal accreditation in any state that has a NELAC program. The certification process under the proposed program will be the same for all commercial environmental laboratories. Each laboratory will have to meet the same general standards and pay the same costs relative to the commercial work done by the laboratory. The certification program enables the commercial laboratories to compete on an equivalent basis.

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

Agency

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

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

Other matters - Memorandum of Understanding between DCLS and DEQ

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

DCLS and DEQ discussed and developed an MOU in meetings during late February and March 2000. Representatives of both agencies signed the MOU in August 2000. The MOU addresses communication and coordination between the two agencies and the conflict of responsibilities mentioned earlier. The two agencies will form a workgroup to communicate on program implementation, certification and data issues. The MOU provides that DCLS will assume DEQ responsibilities for laboratory auditing under the VPDES program. This will be done after an interim transition period during which staff from the two agencies will work together. Prior to this time, DEQ will be responsible for laboratory audits under the VPDES program. After the

program is established, DCLS will be responsible for laboratory audits under the VPDES program. These audits will be a part of the certification program's review process. During the interim period, DEQ auditors will train DCLS auditors in all aspects of the requirements under VPDES. The certification program regulation, as proposed, does not include field testing; lab audits under VPDES cover field testing. To avoid duplication of tasks by the two agencies, DCLS will take over the audit of field testing at large minor and major sources.

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

Changes made since the proposed stage

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

Section number	Requirement at proposed (final) stage	What has changed	Rationale for change
1 VAC 30-45-20 B; 1 VAC 30-46-20 B	Establishment of the program should be three years following the effective date of the regulation, or October 1, 2011.	The specific calendar date has been substituted for the requirement that uses the effective date to trigger the establishment date. The calendar date has been revised to January 1, 2012.	To set the correct calendar date in the final regulation.
1 VAC 30-45-30 C*	None	Language has been added to the regulation to allow citizen monitoring group laboratories to meet the Department of Environmental Quality's (DEQ's) program of quality assurance/quality control requirements specifically devised for citizen monitoring groups in lieu of the requirements of either 1 VAC 30, Chapter 45 or Chapter 46.	DEQ's QA/QC program for citizen water quality monitoring (CMG) labs has been developed in the intervening years since the environmental laboratory certification program (ELCP) regulations were proposed in 2004. There are several reasons why the QA/QC review of CMG laboratories should remain with DEQ. The ELCP and the DEQ QA/QC program for CMG labs conflict. CMGs are funded by grant money from DEQ, which is limited. Currently, only two CMGs provide data from laboratory analysis rather than field testing data to DEQ that is used for the purposes of the state's water quality law and regulations. These laboratories meet DEQ's QA/QC requirements for Tier III laboratories: a QA plan, SOPs, laboratory audits, and calibration and QC information to DEQ along with any data submittal.
1 VAC 30-45-30 D*	None	Language has been added to the regulation concerning environmental laboratories owned	DEQ works with many environmental laboratories at institutions of higher education. The work of these laboratories often serves multiple purposes.

		by institutions of higher education that perform environmental research for DEQ at DEQ's request. These laboratories shall not have to meet the requirements of either 1 VAC 30, Chapter 45 or Chapter 46. These laboratories will have to meet the QA/QC requirements set by DEQ.	<p>Where the work of these university laboratories is used, for example, to assess impaired waters, determine VPDES waste load allocations, or set effluent limits and other standards, the laboratories must meet the requirements of the ELCP regulations. These laboratories are no different than other environmental laboratories in Virginia. They must meet the ELCP requirements if their analyses are submitted to DEQ to meet permit or other compliance conditions.</p> <p>The language added to 1 VAC 30-45-30 in subsection D provides that laboratories at institutions of higher education performing research for DEQ at its request do not have to meet the requirements of either 1 VAC 30, Chapter 45 or 46, unless DEQ requires the laboratory to do so. An example of this research is analysis to determine the cause of fish kills by comparing fish kill areas versus areas where fish kills do not seem to occur.</p> <p>If these laboratories are doing additional analyses that meet the criterion set out in the first paragraph, these laboratories would need to be certified for that work but not for the research work.</p>
1 VAC 30-45-70 B 1	The application due date set in the August 18, 2008, final regulation was May 29, 2009.	The application due date for noncommercial laboratories has been revised to September 29, 2009.	To set the correct calendar date in the final regulation.
1 VAC 30-45-70 B 2, 1 VAC 30-45-70 B 2	The effective date set in the August 18, 2008 final regulation was October 1, 2008.	The effective date has been revised to January 1, 2009.	To set the correct calendar date in the final regulation.
1 VAC 30-46-30 B 1	The deadline for DCLS to become a NELAP accredited laboratory set in the August 18, 2008 final regulation was October 1, 2011.	The deadline has been revised to January 1, 2012.	To set the correct calendar date in the final regulation.
1 VAC 30-46-30 B 2	The deadline for DCLS to become a NELAP accrediting authority set in the August 18, 2008 final regulation was October 1, 2009.	The deadline has been revised to January 1, 2010.	To set the correct calendar date in the final regulation.
1 VAC 30-46-70 B 1 and B 3	The application due date set in the August 18, 2008, final regulation was March 30, 2009.	The application due date for commercial laboratories has been revised to July 1, 2009.	To set the correct calendar date in the final regulation.

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate.

Commenter	Comment	Agency response
<ol style="list-style-type: none"> 1. Amherst County Service Authority 2. Buena Vista (City of), Division of Wastewater Treatment 3. Campbell County Utilities and Service Authority 4. Chesterfield County, Division of Utilities 5. Culpeper, Town of 6. Hampton Roads Sanitation District 7. Harrisonburg-Rockingham Regional Sewer Authority 8. Peppers Ferry Regional Wastewater Treatment Authority 9. Rapidan Service Authority 10. Rivanna Water & Sewer Authority 11. Tappahannock, Town of 12. Upper Occoquan Sewage Authority 13. VA Rural Water Association 14. Virginia Association of Municipal Wastewater Agencies (VAMWA) 	<p>The regulations should clarify that field tests are excluded regardless of who performs the test and of whether the field test is performed outdoors (currently excluded) or performed inside for convenience. All commenters support VAMWA's suggested language for a new subsection, 1 VAC 30-45-30 E: "This chapter does not apply to any environmental laboratory performing only field testing or measurements by or for citizen monitoring groups, institutions of higher education located in Virginia, and federal, state or local governmental entities." VAMWA states "The foregoing sentence will clarify that field tests do not fall within the scope of the laboratory certification program when a citizen group, higher education institution or governmental entity performs these particular field analyses (and only these tests) in a small outbuilding or other structure for convenience."</p>	<p>DCLS, in its Notice of Suspension of Regulatory Process (25:3 VA.R. 340-342, October 13, 2008), stated under "Additional Public Comment" that DGS-DCLS will only take comments on the issues that were raised and the specific regulatory provisions set out below."</p> <p>The comments offered by VAMWA and some of its members, along with the VA Rural Water Association, are not pertinent to the issues raised in the notice or the specific regulatory provisions on which DCLS requested comments.</p> <p>DCLS is aware of the commenters' concerns about field testing and the definition of an environmental laboratory. DCLS believes the regulations have defined the scope of environmental analysis sufficiently. Where there is a question of what constitutes an environmental laboratory, the owner and DCLS will need to address the question by looking at the structure used in the field.</p> <p>No change has been made to the regulations as a result of this comment.</p>
<p>Virginia Association of Municipal Wastewater Agencies (VAMWA) and others, above</p>	<p>Proposed 1 VAC 30-45-30 C 1 should be clarified to specify it applies only to a noncommercial laboratory owned by a citizen monitoring group, as follows: "Laboratories owned by citizen monitoring groups, <u>unless the laboratory is subject to 1 VAC 30, Chapter 45 or 46.</u>"</p>	<p>An environmental laboratory owned by a citizen monitoring group or affiliated with the group should only be doing work for that group. If the laboratory is doing other work as a noncommercial or commercial environmental laboratory as defined in the regulations, then it must meet the requirements of the certification program. The definitions make this clear.</p> <p>No change has been made to the regulations as a result of this comment.</p>
<p>Virginia Association of Municipal Wastewater Agencies (VAMWA) and others, above</p>	<p>The proposed language does not make it clear that an environmental laboratory at an institution of higher education must be certified if its data are used for the purposes of Virginia's air, waste, and</p>	<p>The proposed new 1 VAC 30-45-30 D addresses environmental research performed at labs owned by institutions of higher education. No clarification is</p>

	<p>water programs. VAMWA suggests adding the following language to subsection 1 VAC 30-45-30 D: "However this chapter applies to any environmental laboratory owned by an institution of higher education to the extent that the laboratory performs analyses used for the purposes of the Virginia Air Pollution Control Act, the Virginia Waste Management Act, or the State Water Control Law." Otherwise college or university labs might misconstrue the language of the regulation and believe that DEQ must affirmatively tell these labs to be certified.</p>	<p>needed to require these laboratories to meet the requirements of Chapter 45 or 46, if the laboratory is doing environmental analyses that meet the tests of the regulations as the commenters suggest. See the discussion on the addition of 1 VAC 30-45-30 D in the "Changes Made . . ." section above.</p> <p>No change has been made to the regulations as a result of this comment.</p>
<p>VAMWA and Upper Occoquan Sewage Authority</p>	<p>"DCLS' proposed exemption will present universities and DEQ with the issue that data generated by non-certified labs will by operation of law be excluded from future use in regulatory programs such as water quality standards regulation development, 303(d) listings (whether based on chemical, biological, or physical properties), TMDL development, and effluent and other compliance determinations. Furthermore, data from non-certified laboratories will likely be suspect compared to, and presumably trumped by, data from certified laboratories."</p>	<p>See the comments of the Chesapeake Bay program and the agency's response below.</p> <p>No change has been made to the regulations as a result of this comment.</p>
<p>US EPA Chesapeake Bay Program</p>	<p>We believe that laboratories owned by Virginia institutions of higher education that generate data for Chesapeake Bay Program tidal and non-tidal water quality monitoring programs must be certified under 1 VAC 30, Chapter 45. Chesapeake Bay and watershed water quality data from these laboratories are not intended for research purposes; rather they serve multiple purposes such as the assessment of impaired waters and the determination (through calibration of TMDL models) of VPDES waste load allocations and effluent limits for nitrogen, phosphorus and sediment.</p> <p>It is uncertain whether or not the Old Dominion University and VA Institute of Marine Sciences labs will be required to be certified for Chesapeake Bay Program analyses. We are concerned that DEQ could consider the work to be non-regulatory and exempt these labs from the certification requirements because 1 VAC 30, Chapter 45 does not explicitly state which monitoring programs are covered under the regulation.</p> <p>Labs at institutions of higher education must be certified under Chapter 45 if they generate data used in making decisions on listing and delisting of impaired water bodies under section 303(d) of the CWA.</p>	<p>DEQ has reviewed the comments of the Chesapeake Bay Program. DEQ intends that laboratories at institutions of higher education providing analyses used to assess impaired waters, determine VPDES waste load allocations, or set effluent limits and other standards, must meet the requirements of the ELCP regulations. These laboratories are no different than other environmental laboratories in Virginia. They must meet the ELCP requirements if their analyses are submitted to DEQ to meet permit or other compliance conditions. DEQ believes that the definitions cover environmental laboratories at institutions of higher education when they are performing analyses as described above.</p> <p>DEQ wants to provide an exemption only for those laboratories doing research such as analyses to determine the cause of fish kills by comparing fish kill areas versus areas where fish kills do not seem to occur. Laboratories doing only research are limited in number. Laboratories performing analyses as described in the paragraph above as well as research as described in this paragraph must meet the certification requirements for all analyses other than research analyses.</p> <p>No change has been made to the regulations as a result of this comment.</p>
<p>Old Dominion University, Chesapeake Bay Water</p>	<p>The commenter asks whether Virginia will be the only state in the Chesapeake Bay Initiative Program</p>	<p>Pennsylvania is a NELAP accrediting body and requires accreditation of environmental</p>

<p>Quality Laboratory</p>	<p>that requires certification of environmental laboratories. The commenter also asks whether DEQ or EPA will provide funds to support certification at these labs.</p>	<p>laboratories performing analyses of nonpotable water. There are no plans to provide funds to environmental laboratories to meet their certification requirements.</p> <p>No change has been made to the regulations as a result of this comment.</p>
<p>Old Dominion University, Chesapeake Bay Water Quality Laboratory</p>	<p>In the recent past, CBP has added parameters for one year or one sampling cycle which are funded and requested by scientists. A recent example was Colored Dissolved Organic Material (CDOM), for which the procedure was given to us by the Smithsonian Research Center. How will the laboratories approach becoming certified for these analyses which occur in short time frames?</p>	<p>DCLS will need to work with Chesapeake Bay Program (CBP) laboratories on issues such as the one described by the commenter.</p> <p>No change has been made to the regulations as a result of this comment.</p>
<p>Old Dominion University, Chesapeake Bay Water Quality Laboratory</p>	<p>For the CBP, many methods were developed over 20 years ago. Changes in these methods have been discouraged to avoid affecting the integrity of long term data sets with respect to their ability to track long term environmental trends. Will methods need to be updated to meet current requirements? Where methods are modified by agreement with other partners, will these need to be changed to the current methods?</p>	<p>DCLS will need to work with Chesapeake Bay Program (CBP) laboratories on issues such as the one described by the commenter.</p> <p>No change has been made to the regulations as a result of this comment.</p>
<p>Old Dominion University, Chesapeake Bay Water Quality Laboratory</p>	<p>University laboratories that have not been certified will probably need a longer time to be ready to apply for the certification. In the original document there was a 5 to 7 month window for applying for certification. Once a laboratory applies, all aspects of that laboratory's operations are to be in full compliance with the regulation. Will university laboratories be assisted in understanding the regulations so they can become certified? Who will assist them?</p>	<p>The effective date of the program will now be January 1, 2009. The commenter's laboratory will have until September 29, 2009, to submit an application. Seminars are being offered in Virginia through the commercial laboratory group, LAVA, and other opportunities may become available.</p> <p>No change has been made to the regulations as a result of this comment.</p>
<p>Old Dominion University, Chesapeake Bay Water Quality Laboratory</p>	<p>Much of the sample preparation is performed in the field on a research vessel. Will research vessels be considered mobile laboratories and therefore need to be certified?</p>	<p>DCLS will need to work with Chesapeake Bay Program (CBP) laboratories on issues such as the one described by the commenter. Sampling is exempt from the program. Field testing and measurement are exempt from the program unless this testing is performed in an environmental laboratory. Field testing is defined by the holding time of the sample.</p> <p>No change has been made to the regulations as a result of this comment.</p>
<p>Old Dominion University, Chesapeake Bay Water Quality Laboratory</p>	<p>Proficiency Testing Standards (PTS) are required to be performed semi-annually. There are no PTSs available for several routine CBP analyses, such as particulate carbon, particulate nitrogen, particulate phosphorus, chlorophyll a and pheophytin. The PTSs which are available for other parameters are non-saline, and have much higher concentrations than those that exist naturally in the Chesapeake Bay. Will new PTSs be developed or will there be waivers for analyses of those parameters for which there are not appropriate PTSs?</p>	<p>If PTs are not available for specific Fields of Proficiency Testing, then the PTs are not required.</p> <p>No change has been made to the regulations as a result of this comment.</p>

All changes made in this regulatory action

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

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

Regulatory flexibility analysis

Please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

The agency considered alternatives to the standards to be used to certify environmental laboratories. The agency considered using the National Environmental Laboratory Accreditation Conference (NELAC) standards for all the laboratories applicable under the proposed regulations. These standards are the national standards developed by the states and the federal agencies, including the Environmental Protection Agency. The agency determined that using the NELAC standards for all environmental laboratories was not feasible given the opposition to this approach from many of the non-commercial laboratories affected by the program. The agency after working with an *ad hoc* advisory group on various options for the standards to be used decided on two separate sets of standards for the program, one for commercial laboratories (the NELAC standards) and one for noncommercial laboratories. The standards for the noncommercial laboratories have most of the elements contained in the NELAC standards. They do not however contain as many documentation requirements as do the NELAC standards. This two-tier system of standards appears to be the least burdensome alternative.

Family impact

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

It is not anticipated that these regulations will have a direct impact on families. However, there will be a positive indirect impact. The regulations will ensure that data used to comply with the Commonwealth's environmental laws and regulations have been derived in an accurate, precise and consistent fashion. As a result, the environmental health and welfare of the Commonwealth, including its families, will be protected.