



## **Economic Impact Analysis Virginia Department of Planning and Budget**

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### **1 VAC 30-45 and 1 VAC 30-46 – Regulations Governing the Certification of Noncommercial and Commercial Environmental Laboratories**

**Department of General Services**

January 20, 2004

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The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with Section 2.2-4007.G of the Administrative Process Act and Executive Order Number 21 (02). Section 2.2-4007.G requires that such economic impact analyses include, but need not be limited to, the projected number of businesses or other entities to whom the regulation would apply, the identity of any localities and types of businesses or other entities particularly affected, the projected number of persons and employment positions to be affected, the projected costs to affected businesses or entities to implement or comply with the regulation, and the impact on the use and value of private property. The analysis presented below represents DPB's best estimate of these economic impacts.

### **Summary of the Proposed Regulation**

The General Assembly mandates in §2.2-1105 of the Code of Virginia that the Division Consolidated Laboratory Services (DCLS) establish a program for the certification of laboratories conducting tests, analyses, measurements, or monitoring required by the State Air Pollution Control Board, the Virginia Waste Management Act, and the State Water Control Law. For laboratories located in jurisdictions outside Virginia, the Code of Virginia requires that DCLS develop procedures for determining the qualifications of these laboratories to perform tests, analyses, measurements, or monitoring required under the Virginia's air, waste, and water laws. Once the certification program is established, the law mandates that all laboratories be certified before being allowed to submit data under the state's environmental laws. Laboratories falsifying data or providing false information to support certification are to be decertified or

denied certification. §2.2-1105 of the Code of Virginia also authorizes DCLS to set up a fee system to offset the costs of running the certification program.

In order to fulfill the mandate of §2.2-1105 of the Code of Virginia, DCLS has proposed two regulations: (1) *Chapter 46* applies to commercial environmental laboratories. The regulation incorporates the 2002 National Environmental Laboratory Accreditation Conference (NELAC) standards as the minimum standards of operation for commercial environmental laboratories. It establishes DCLS as the primary accrediting authority and requires that DCLS be recognized by NELAC as the primary accrediting authority in Virginia within one year of the effective date of the regulation. Chapter 46 also lays out the general requirements of the accreditation program for commercial laboratories, including the process by which laboratories can apply and obtain accreditation, the process by which laboratories can change accreditation status, the requirements for the petitioning and granting of variances, and the appeals procedure to be followed in case of denial or withdrawal of accreditation. The regulation establishes the procedure to be followed by laboratories accredited in other states and seeking reciprocal accreditation in Virginia. It also establishes the fees to be charged from commercial laboratories for accreditation (including reciprocal accreditation). (2) *Chapter 45* applies to noncommercial environmental laboratories. The regulation establishes minimum standards of operation for non-commercial environmental laboratories that are less stringent than the NELAC standards proposed in Chapter 46. The regulation describes the general requirements of the certification program for noncommercial laboratories, including the process to apply and obtain certification, how to change certification status or scope, the requirements for the petitioning and granting of variances, and the appeals procedure when certification is denied or withdrawn. The regulation allows noncommercial laboratories to apply for and be granted exemptions from the certification program based on compliance and performance. The regulation also establishes fees to be charged from noncommercial laboratories for certification. Fees vary depending on whether the laboratory performs only simple test procedures or more complex tests and analyses.

The proposed regulations permit all noncommercial environmental laboratories to voluntarily get accreditation under the NELAC standards incorporated in Chapter 46. For example, laboratories that require to be certified under the Safe Drinking Water Act and the National Primary Drinking Water Regulations and under Chapter 45 of the proposed regulations can meet both requirements by getting accredited under the NELAC standards in Chapter 46.

## **Estimated Economic Impact**

### *Need for a Certification Program:*

The purpose of the proposed regulations is to improve the quality of data being reported to the Department of Environmental Quality (DEQ) as part of the air, water, and waste permitting programs. Compliance is dependent in many instances, especially in the case of water permits, on source-reported data and analysis. Currently, Virginia has no minimum requirements and no process for certifying laboratories that conduct tests, analyses, measurements, or monitoring required to determine a facility's compliance with its air, water, and waste permit.

According to DCLS, adequate enforcement of the state's environmental laws has been problematic when source-reported data are the primary means of ensuring compliance. This is especially true in the case of the state water laws where the principal method of determining compliance with a water permit is through data provided by the permittee in Discharge Monitoring Reports (DMR) submitted as part of the permit requirements. The Discharge Monitoring Report-Quality Assurance (DMR-QA) Program run in conjunction with the Environmental Protection Agency (EPA) evaluates the quality of source-reported DMR data. Under the DMR-QA program, performance evaluation samples are sent to laboratories that provide data and analysis included in DMRs submitted by permitted facilities. The samples, usually emulating possible effluent samples from the permitted facility, are analyzed at the laboratories and the results are sent back to EPA for comparison with the actual make up of the samples. The states are evaluated on the permitted facility's (and hence the laboratory's) ability to analyze all parameters correctly and on the overall level of correct analysis. Currently, the DMR-QA program is administered to all major sources and to some minor sources based on DEQ's determination.

Apart from the DMR-QA program, some water permits such as the Virginia Pollutant Discharge Elimination System (VPDES) permits allow for laboratory inspections for both noncommercial (source-run) and commercial environmental laboratories. DEQ's current policy is to conduct laboratory inspections whenever technical inspections are conducted at VPDES permitted facilities. Inspection frequency varies depending on the size of the facility and the potential for harm to the environment. In case of problems at a laboratory, DEQ is authorized to take corrective action against the VPDES permitted facility, but not the laboratory itself.

Despite these checks, a 1997 Joint Legislative Audit and Review Commission (JLARC) report reviewing DEQ's performance found that water quality indicators were mixed about any improvement in the state of Virginia's waters since DEQ's creation in 1993. The U.S. Geological Survey found that while water quality in some specific areas was improving, it was getting worse in others. In fact, the percentage of waterways identified as impaired rose from 3% in 1994 to 5% in 1996. The DMR-QA program has pointed to problems with the DMR data reported to DEQ. In 1995, only 46% of permitted facilities in Virginia were able to analyze all parameters correctly, the lowest percentage in seven years. Moreover, the overall percentage of correct analysis among permitted facilities in 1995 was also the lowest in seven years at 86%. In a 1993 nationwide comparison, Virginia ranked twenty-second in terms of the percentage of permittees able to analyze all parameters correctly and forty-third in terms of the overall percentage of correct analysis. According to the 1997 JLARC report, there have also been a number of cases of DMR falsification in the past 10 years.

Enforcement of standards for source-reported data and analysis has suffered as budgetary constraints have led to inadequate oversight of the DMR process and a decline in inspections of laboratories providing analysis to environmental permit holders. The cancellation of the mobile laboratory program in 1994 for budgetary reasons has hampered DEQ's ability to test permittees' discharges and enforce the state's water laws. Prior to 1994, DEQ had mobile laboratories that would travel to VPDES permitted sources and conduct complete environmental site audits of the facilities. By conducting its own analysis of the effluent being discharged, the mobile laboratories served as a check on source-reported DMRs. In cases of deliberate falsification of DMRs, lack of a consistent and effective procedure in detecting falsified DMRs (currently done by DEQ staff through a visual review of the report) and the large time gap between the first alleged falsification and the launch of a criminal investigation have been identified in the 1997 JLARC report as some of the reasons why DEQ's current check for DMR falsification is not adequate. Current budget problems have only further hindered DEQ's ability to detect and investigate cases of DMR falsification. Laboratory inspections, the most potent tool in enforcing quality control standards on source-reported data, have been declining over the past few years. Limited staff and budgetary resources have led to a decline in the frequency of DEQ's inspections of environmental laboratories (commercial and noncommercial) and have been able to do little to stem the overall decline in the quality of source-reported DMR data.

The lack of effective enforcement has been of particular concern in the case of commercial environmental laboratories. Under current policy, if DEQ finds a problem with the data reported by a permitted facility, it can only take action against the permitted facility, not the laboratory that conducted the tests and analysis. In the case of facilities using commercial environmental laboratories to perform tests and analysis, DEQ can only take corrective action against the permitted facility, such as requiring that the facility stop using the laboratory in question for future testing and analysis. Thus, a commercial laboratory that serves multiple clients remains free to serve the rest of its clients despite producing substandard results in at least one instance. If DEQ had sufficient resources to conduct inspections and verify the accuracy of data being reported by all permitted facilities in Virginia, it would be able to identify and prevent permittees from using unqualified commercial laboratories. However, budget constraints limit the extent to which DEQ can audit and verify the accuracy of data reported by permitted facilities and hence the extent to which DEQ can evaluate the performance of commercial environmental laboratories.

The lack of effectiveness in enforcing environmental laws, especially state water laws, led the 1997 JLARC report to conclude that a state certification program for environmental laboratories would provide DEQ with more direct control over analytical activity and data used to enforce state environmental laws, provide greater assurance that the reported data is accurate and representative of the discharge, ensure minimum standards of quality, and allow for improved control over factors influencing the quality of the environment. The JLARC report recommended that the cost of running the certification program be met by fees paid by laboratories seeking certification.

Establishing a state environmental laboratory certification program has a number of economic advantages. First, to the extent that it improves the quality of data being reported and leads to more effective enforcement of environmental laws, it will ensure that potentially harmful activities are conducted in a manner that is protective of public health and the environment. As the 1997 JLARC report demonstrated, the current enforcement policy (limited by the lack of budgetary resources) is inadequate for ensuring minimum standards for source-reported data. A certification program is likely to be more effective in ensuring that source-reported data are more accurate and reliable. Second, transferring some or all of the cost of ensuring compliance with environmental laws from DEQ (and hence the taxpayer) to the environmental laboratories

themselves or to the permitted facilities using the environmental laboratories for the purpose of analysis will lead to a more efficient allocation of resources. Currently, DEQ bears the cost of conducting inspections and verifying the accuracy of the data being reported. Cost of certification can be viewed as part of the cost of ensuring the safe operation of facilities discharging pollutants into the environment. In this case, the cost of certification is the cost to DEQ of ensuring that laboratories conducting tests, analyses, measurements, or monitoring required by air, water, and waste permits are doing so in accordance with certain minimum standards that are protective of public health and of the air, water, and soil quality in Virginia. If, as under current policy, the cost is being paid by taxpayers, environmental laboratories and facilities that use their services are not paying costs commensurate with the risk posed to the environment from their activities. This could potentially result in the overuse of environmental resources. For example, the lower costs may result in more facilities and larger amounts of pollutants being discharged into the environment than if costs were higher and better reflected the actual cost of ensuring that the quality of data being provided by environmental laboratories and facilities that use their services meets certain standards.

*Description of the Proposed Regulation:*

In establishing a certification program for environmental laboratories, DCLS has chosen to distinguish between laboratories on the basis of whether they are classified as commercial or noncommercial. Commercial laboratories are defined as laboratories that perform environmental analysis for an outside person or entity. Noncommercial environmental laboratories include laboratories that perform environmental analysis solely for the owner of the laboratory and certain types of laboratories that perform environmental analysis for an outside person or entity. For example, an environmental laboratory owned by Publicly Owned Treatment Works (POTW) that performs analysis for an industrial source of wastewater under a permit issued by the POTW is considered a noncommercial environmental laboratory even though it performs analysis for an entity other than itself.

Commercial environmental laboratories are required to follow procedures and meet minimum standards established under the nationally recognized NELAC accreditation program as specified in Chapter 46. For environmental laboratories accredited under NELAC in another state, Chapter 46 also establishes requirements for seeking and receiving reciprocal accreditation.

Noncommercial environmental laboratories are required to follow procedures and meet minimum standards established under a state-run certification program as specified in Chapter 45. Noncommercial laboratories can also choose to get accredited under Chapter 46. Both Chapters 45 and 46 are divided into two parts: Part I contains provisions pertaining to the administration of the program and Part II contains provisions pertaining to quality assurance and quality control standards such as those dealing with personnel qualifications, on-site assessments, proficiency testing, and quality systems.

The proposed regulations impose less stringent requirements and standards on noncommercial environmental laboratories than on commercial environmental laboratories. For example: (a) In Part I of Chapter 45, noncommercial environmental laboratories are allowed to apply for and may be granted a partial or full exemption from the requirements of Chapter 45 for a period of up to two years if they have met all certification requirements for the prior four consecutive years. This provision is in accordance with §2.2-1105 of the Code of Virginia that requires any proposed environmental laboratory certification program include provisions for granting partial or full exemptions from the requirements of the program to laboratories based on compliance and performance. Under the proposed regulations, DCLS makes the determination regarding the granting of exemptions based on the laboratory's previous performance and compliance record. However, there are no such similar provisions for commercial environmental laboratories under Chapter 46. All commercial environmental laboratories are required to get accredited every two years. (b) In Part I of Chapter 45, noncommercial environmental laboratories are required to retain records associated with certification parameters for a minimum of three years. The record-keeping and retention requirement for commercial environmental laboratories is five years under Chapter 46.

There also exist significant differences in the minimum performance standards to be met under Part II of Chapter 45 and Part II of Chapter 46. While the on-site assessment and proficiency testing requirements are not significantly different for commercial and noncommercial environmental laboratories, differences arise in the personnel and quality system requirements. (a) Under NELAC standards adopted in Chapter 46, a laboratory manager/technical director is required to meet certain specific educational requirements depending on the type of testing conducted at the laboratory. For instance, NELAC standards require that a laboratory manager/technical director of a laboratory engaged in microbiological

analysis limited to fecal coliform, total coliform, and standard plate count (defined as simple test procedures in these regulations) have an associate's degree in an appropriate field of science or applied science with a minimum of four college semester credit hours in general microbiology. NELAC standards provide for exceptions from the educational requirements in just two cases: for laboratories at drinking water or sewage treatment facilities analyzing samples taken within that facility and for laboratories at industrial waste treatment facilities analyzing samples taken within that facility. In the case of noncommercial laboratories, Chapter 45 establishes no minimum education requirement for laboratory managers/technical directors. In fact, for laboratories performing only simple test procedures, an individual is not required to have any specific educational qualifications or experience in order to be appointed the laboratory manager/technical director. (b) Differences also exist in the quality system requirements for commercial and noncommercial environmental laboratories. In establishing procedures and requirements for noncommercial laboratories, Chapter 45 appropriately does not incorporate certain parts of the NELAC standards that pertain to commercial laboratory work. For example, Chapter 45 does not include a provision under NELAC that specifies the procedure for the review of requests, tenders, and contracts. However, even with respect to NELAC provisions that apply to both commercial and noncommercial laboratories, Chapter 45 establishes less specific requirements than those required under NELAC standards. For instance, both Chapter 45 and Chapter 46 establish essential quality control requirements such as positive and negative test controls, test variability/reproducibility, method evaluation, and data reduction. However, NELAC standards specify the methods by which these quality control requirements are to be met for each type of testing. For example, NELAC standards define the various methods for positive and negative test controls for chemical testing, toxicity testing, microbiology testing, radiochemical testing, air testing, and asbestos testing. On the other hand, Chapter 45 lays out the general principles of quality control and requires that the laboratories create and maintain detailed written protocols to monitor essential quality control requirements.

Commercial laboratories are also required to pay higher fees in order to get accredited. Because commercial laboratories are required to meet more stringent standards, DCLS expects that accrediting a laboratory under NELAC will take up more resources than certifying a laboratory under the state program. Commercial environmental laboratories are required to pay a base fee of \$2,100 and test category fees depending on the number and type of tests being



performed (test category fees range from \$300 to \$900 per test category), up to a maximum of \$4,200, for a two-year accreditation. Noncommercial environmental laboratories are divided into two categories: general environmental laboratories and laboratories that only perform simple test procedures. General environmental laboratories are required to pay a base fee of \$1,700 and the relevant test category fees, up to a maximum of \$3,800, for a two-year certification. Laboratories performing simple tests are required to pay a base fee of \$100 and the relevant test category fees, up to a maximum of \$400, for a two-year certification. According to DCLS, the higher fees paid by commercial environmental laboratories reflect the fact that it takes more time and resources to review applications for accreditation.

Apart from fees for certification/accreditation, the regulations also establish fees for commercial laboratories seeking reciprocal accreditation in Virginia. §2.2-1105 of the Code of Virginia mandates that laboratories located outside of Virginia that are certified or accredited under a program determined by DCLS to be equivalent to the environmental laboratory certification program in Virginia should be deemed to meet the certification requirements. The proposed regulation allows DCLS to grant reciprocal accreditation to an out-of-state environmental laboratory holding a current accreditation from another state. The fees charged to laboratories seeking reciprocal accreditation is the same as that charged to all other laboratories applying under Chapter 46 even though DCLS faces minimal accreditation costs.

The regulations propose to charge a fee from noncommercial environmental laboratories applying for an exemption under Chapter 45. Noncommercial environmental laboratories performing only simple test procedures are required to pay a \$100 application fee. Noncommercial general environmental laboratories are required to pay a \$250 application fee. If the exemption is granted, noncommercial environmental laboratories are required to pay up to \$1,000 more depending on the scope of the exemption. The regulation also allows DCLS to charge fees for all environmental laboratories changing or transferring ownership.

*Economic Impact:*

The distinction being made between commercial and noncommercial environmental laboratories in the proposed regulations does not have a rational basis in either economics or policy. First, the difference between laboratories classified as commercial environmental laboratories and those classified as noncommercial environmental laboratories is not based on

characteristics that are relevant to the maintenance of minimum quality standards for certain classes of laboratory procedures. While some laboratories performing tests and analyses for outside sources are classified as commercial, others are classified as noncommercial. A commercial environmental laboratory, as defined in these regulations, includes laboratories of various sizes, conducting tests of varying degrees of complexity, and analyzing samples from a number of different sources. The definition of a noncommercial environmental laboratory also includes laboratories of various sizes, conducting tests of varying degrees of complexity, and analyzing samples from a number of different sources. The only difference is that while the former is run as an independent profit-making operation, the latter does not operate solely on a profits basis. Second, the potential environmental consequences of inaccurate testing and analysis are the same whether a test is conducted at a commercial laboratory or at a noncommercial laboratory. There is not data to indicate that tests and analysis conducted at a commercial laboratory are done any better or worse than if the same tests and analyses were conducted at a noncommercial environmental laboratory.

However, under the proposed regulations, environmental laboratories conducting the same tests and analysis would need to meet different standards based on whether they are classified as commercial or noncommercial. Commercial environmental laboratories are also required to pay higher fees for accreditation than those paid by noncommercial environmental laboratories seeking certification to conduct similar tests. Other differences between Chapter 45 and 46, such as the provision allowing exemptions to be granted to noncommercial laboratories under Chapter 45, also do not appear to have any economic basis and would make it harder for commercial laboratories to operate and compete with noncommercial laboratories in Virginia.

Establishing different standards and requirements for environmental laboratories based on whether they are classified as commercial or noncommercial is likely to have a negative net economic impact. If the standards established in Chapter 45 are deemed adequate to produce data of a certain level of accuracy and reliability at all noncommercial laboratories, they should be adequate to enforce data quality standards at commercial laboratories conducting similar tests. Requiring commercial laboratories to meet higher standards is likely to increase the cost of operation for commercial environmental laboratories relative to noncommercial environmental laboratories while providing no significant additional protection to the environment or to public health. Higher costs are likely to translate into higher fees charged by commercial environmental

laboratories for their services. This, in turn, would increase costs for permitted facilities using outside laboratories for testing and analysis compared to facilities with in-house laboratories. If, on the other hand, for a certain class of tests standards and requirements established in Chapter 46 are deemed necessary to ensure adequate protection of the environment and public health, noncommercial laboratories should be required to meet these standards for that class of tests. Requiring noncommercial laboratories to meet less stringent standards could result in substandard testing and analysis, leading to an increased risk to public health and increased degradation of the environment. Thus, the proposed regulations are likely to have a negative net economic impact either by unnecessarily increasing the cost of operation of commercial environmental laboratories in Virginia or by increasing the cost to public health and the environment by applying inadequate standards to noncommercial laboratories.

To avoid this negative economic impact, the regulations should be designed such that they establish similar standards and requirements for environmental laboratories conducting similar tests. The fees charged for accreditation/certification should also be consistent across laboratories conducting similar tests. The standards should be designed such that they provide a level of accuracy, reliability, and consistency deemed necessary to produce environmental data of a certain quality, regardless whether the tests are conducted at a commercial laboratory or at a noncommercial laboratory. If DCLS believes that less stringent standards are appropriate for laboratories conducting certain simple tests where nonperformance or sub-par performance does not pose as much of a public health or environmental hazard, the regulation could be written such that less stringent standards apply to these laboratories. However, the less stringent standards should apply to all such laboratories regardless of whether they are classified as commercial or noncommercial. NELAC accreditation is always available as a voluntary option for those environmental laboratories that, while not required to meet NELAC standards, may find it in their interest to do so.

The fees being proposed for reciprocal accreditation for commercial environmental laboratories accredited under NELAC in another state do not have an economic basis and are not representative of the actual costs incurred by the agency in reviewing and granting reciprocal accreditation. The proposed regulation states that DCLS will not require a NELAC-accredited environmental laboratory that seeks reciprocal accreditation in Virginia to meet any additional proficiency testing, quality assurance, or on-site assessment requirements for fields of

accreditation for which the laboratory holds primary NELAC accreditation. For example, if an out-of-state environmental laboratory applies for reciprocal accreditation in the same fields for which it already holds NELAC accreditation, the costs incurred by DCLS in reviewing and granting accreditation will be much lower than the review process for a non-NELAC-accredited laboratory applying for accreditation. However, a laboratory applying for reciprocal accreditation is required to the same fees as any other commercial environmental laboratory applying for accreditation under Chapter 46.

The proposed fee for reciprocal accreditation is likely to have a negative economic impact by discouraging the entry and operation of out-of-state laboratories in Virginia. The purpose of the accreditation fees is to defray the cost incurred by DCLS in ensuring a desired level of accuracy and reliability in data produced by environmental laboratories. Charging out-of-state laboratories fees higher than the actual cost incurred by DCLS in accrediting these laboratories will lead to fewer out-of-state laboratories operating in Virginia than if fees were lower and reflected the actual cost of reciprocal accreditation. By restricting competition from outside, the proposed regulation is likely to result in higher costs of services provided by environmental laboratories in Virginia.

A more appropriate fee structure would be one that covers DCLS's cost of reviewing and granting accreditation but does not exceed the maximum fees charged for accrediting other environmental laboratories applying under Chapter 46. In response to DCLS concerns that lower fees for reciprocal accreditation might put in-state laboratories at a disadvantage with respect to out-of-state laboratories, the regulations could set lower fees for laboratories accredited in states that charge similarly discounted fees for reciprocal accreditation. For example, a laboratory accredited under NELAC in another state would pay fees that cover the agency's actual cost of reviewing and granting reciprocal accreditation as long as laboratories accredited in Virginia pay similar fees when seeking reciprocal accreditation in that state. For states not having similar provisions regarding reciprocal accreditation, environmental laboratories accredited in those states would have to pay the regular fees charged under Chapter 46. Apart from encouraging competition from out-of-state laboratories and potentially lowering the price of these services in Virginia, reciprocal accreditation fees established along these lines will have the additional benefit of providing Virginia laboratories the opportunity to expand their business in to other states by making it cheaper to get accredited and operate in those states. This provision has the

attractive property that it will only become effective if other states reciprocate, otherwise it does not. If other states do reciprocate then there could be a significant net benefit to both consumers and environmental laboratories based in Virginia. DCLS should be encouraged to contact other states to persuade them to join a reciprocal fee regime. States such as California and New York have incorporated provisions into their environmental laboratory accreditation program that allow for fee reciprocity.

The exemption fees being proposed for laboratories applying and receiving an exemption under Chapter 45 could have negative economic consequences. All noncommercial environmental laboratories applying for exemptions are required to pay an application fee, \$100 for laboratories performing only simple test procedures and \$250 for noncommercial general environmental laboratories. Upon the exemption being granted, additional fees of up to \$1,000 will be charged depending on the scope of the exemption. However, the fee structure being proposed is such that applying for an exemption would be worthwhile for larger noncommercial environmental laboratories (defined as general environmental laboratories) and some noncommercial laboratories conducting simple tests. All noncommercial environmental laboratories are required to pay a fee to obtain certification for a two-year period (general laboratories pay a \$1,700 base fee and relevant test category fees, up to a maximum of \$3,800 and simple test laboratories pay a \$100 base fee and relevant test category fees, up to a maximum of \$400). Only those laboratories that would pay less for an exemption than they would pay for certification would choose to apply for an exemption. Given the current fee structure, all general laboratories would prefer to pay the \$1,250 maximum for an exemption than the \$1,700 base fee and the relevant test category fees in order to get certified. Simple test laboratories will find it worthwhile to apply for an exemption only if the total fees (the \$100 application fee and additional fees of up to \$1,000) are less than the \$100 base fee and the relevant test category fees they would pay for certification.

DCLS has not provided any rationale for the proposed fees for the application and granting of exemptions, especially the exemption fees for noncommercial environmental laboratories conducting simple tests. The fees appear to be inconsistent insofar that it implies that it would cost less, under some circumstances, to review and grant certification to certain simple test laboratories than it would to review and grant them exemptions. If, as appears to be the case, the exemption fees are not an accurate reflection of DCLS resources required to review and grant

exemptions, the proposed regulation, by encouraging only general laboratories and some simple test laboratories to apply for and receive exemptions, may significantly increase the risk to public health and the environment. General laboratories are more likely to conduct complex tests where nonperformance or sub-par performance poses a serious public health or environmental threat than simple test laboratories. Thus, one could argue that these laboratories are more likely to require monitoring than laboratories conducting simple tests, and should be granted exemptions on a less frequent basis.

Chapters 45 and 46 allow DCLS to charge fees in the case of a transfer of ownership of a commercial or a noncommercial environmental laboratory. The transfer fee is set at a minimum of \$100 and a maximum of \$1,000. However, the regulations are unclear about when transfer fees will apply, stating only that when the legal status or ownership of a certified laboratory changes without affecting its personnel, equipment, and facilities DCLS is allowed to charge a transfer fee.

The regulations need to clarify the circumstances under which fees will be assessed for a transfer or change in ownership of an environmental laboratory. The lack of clarity is especially problematic in the case of laboratories owned by corporations and partnerships. The regulations do not address the issue of whether a fee would be charged if a partner in a partnership that owned an environmental laboratory transferred her/his stake or if the controlling stake in a publicly owned corporation that owned an environmental laboratory changed hands.

The proposed regulations establish standards and requirements that, if adhered to, would ensure that data being submitted under Virginia's air, water, and waste laws are of a certain quality. The enforcement of these standards is carried out through on-site assessments conducted during certification or renewal of certification, quality system requirements such as document control and the handling of samples that are required for certification, and proficiency tests administered twice a year. Under current policy, budgetary resources permitting, DEQ conducts complete site audits of environmental laboratories in order to detect instances of fraud. The effectiveness of current policy compared to the policy being proposed in these regulations in detecting cases of fraud is not clear. It is quite possible that the proposed regulations do not provide for as thorough a process for detecting data falsifications as the site audits conducted by DEQ. However, the number of such audits that DEQ conducts is severely limited by budgetary

constraints. It remains to be seen if the proposed regulations are more or less effective than current policy in detecting and preventing cases of data falsification and misreporting.

*DCLS Rationale:*

The following were given by DCLS as a rationale for keeping the regulations in their current form:

- a. According to DCLS, separate standards for commercial and noncommercial environmental laboratories are necessary as most noncommercial laboratories conduct relatively simple test procedures that do not pose a significant threat to public health and the environment. Such laboratories do not need to meet all NELAC standards in order to produce accurate and reliable test results. Thus, the distinction between commercial and noncommercial environmental laboratories is intended to act as a proxy for distinguishing between laboratories that are small and conduct simple tests and those that are larger and conduct more complex tests and analyses. However, an unintended consequence of this distinction is that it penalizes commercial environmental laboratories that perform simple test procedures. Such laboratories would be at a significant economic disadvantage (in terms of standards that they need to meet and the fees they need to pay) compared to noncommercial environmental laboratories conducting the same tests. Thus, even though there are currently few, if any, commercial environmental laboratories that conduct only simple tests, these regulations are likely to inhibit the establishment and operation of such laboratories. Moreover, if Chapter 46 standards are considered necessary to meet accuracy and reliability standards at laboratories conducting complex tests and analyses, they should apply to all such environmental laboratories regardless of whether they are commercial or noncommercial. Requiring all large noncommercial laboratories to be certified under Chapter 45 rather than Chapter 46 could result in substandard test performance and analyses at these facilities.
- b. DCLS also believes that the distinction between commercial and noncommercial environmental laboratories is appropriate as each operate under different incentives. According to DCLS, “commercial environmental laboratories have no direct personal interest in ensuring that a client’s permit requirements are met” and “non-performance or poor performance on the part of these laboratories does not immediately or directly affect

them”. “Their only incentive is economic.” On the other hand, “non-commercial environmental laboratories have a different incentive for ensuring that permit requirements are met.” as “they are part of the entity that holds the permit”. DPB believes this to be an erroneous assumption. Non-performance or poor performance by commercial environmental laboratories will have a direct and substantial impact on these laboratories. Such laboratories would lose business as clients’ permits are withdrawn or they choose to get their tests done at another facility. On the other hand, noncommercial environmental laboratories will not necessarily produce more reliable results just because they are part of the permitted facility. In fact, one might even argue that the economic incentives of commercial laboratories would be a more powerful inducement to maintain high standards of performance than the incentives of noncommercial environmental laboratories. Commercial environmental laboratories serve multiple clients and loss of any clients through poor performance would hurt their business, not just directly through the loss of those clients, but also indirectly by damaging their overall business prospects (in terms of retaining the remaining clients and attracting new clients). As it is not possible to determine which set of incentives is likely to result in more accurate results, distinguishing between commercial and noncommercial environmental laboratories based on this argument is not appropriate.

- c. DCLS contends that the potential for harm to the environment from the activities of commercial environmental laboratories is higher than that from noncommercial environmental laboratories. As commercial laboratories serve many clients, non-performance or poor performance may affect samples from many clients and may result in severe environmental consequences over a wide geographic area. On the other hand, while samples analyzed by noncommercial environmental laboratories may be as diverse as the samples analyzed by commercial environmental laboratories, the former is not performing the analyses for multiple clients. Non-performance or poor performance on the part of these laboratories has a local impact, and the environmental consequences are limited.

This is not an adequate basis for applying different standards to commercial and noncommercial environmental laboratories. Standard should be established to ensure a sufficient level of accuracy and reliability each time a test is conducted. It should not vary



with the number of times the test is conducted or the number of different clients for whom it is conducted. Moreover, noncommercial environmental laboratories, as defined in these regulations, also include laboratories serving multiple sources. For example, an environmental laboratory owned by an authority or sanitation district that performs analysis for participating local governments is classified as noncommercial as long as the analysis pertains to the purpose for which the authority or sanitation district was established. If NELAC standards are considered appropriate for laboratories serving multiple clients, they should also be applied to noncommercial laboratories analyzing samples from a variety of sources.

- d. DCLS also refers to the 1997 JLARC report in justifying the difference in standards applied to commercial and noncommercial environmental laboratories, saying

“JLARC noted the special need to certify commercial environmental laboratories [see TH-02, 9/20/02, page 4]. The JLARC report stated that one of the problems faced by DEQ was the agency’s lack of authority over commercial environmental laboratories. DEQ can hold permittees responsible whose in-house laboratories are not performing to standard. DEQ cannot require commercial environmental laboratories to improve their performance or accuracy. They can only ask the permittees not to use the commercial laboratories that perform poorly or inaccurately.”

As mentioned previously, the 1997 JLARC report identifies DEQ’s inability to ban permittees from using certain unqualified laboratories as a flaw in current enforcement of accuracy and reliability standards for source-reported data. While the report suggests that a certification/accreditation program for environmental laboratories would allow DEQ to better enforce these standards, it does not suggest separate standards for commercial and noncommercial environmental laboratories. The report states,

“The General Assembly could require that a laboratory certification program be designed to meet program costs and ensure a higher level of accuracy among laboratories doing business in Virginia. Interviews with laboratories and DEQ staff have indicated that a national certification program could be developed in the future. If such a program is developed, and would meet the needs identified for

Virginia, the General Assembly may wish to require inclusion in the national program instead of implementing a separate state certification program”.

A certification/accreditation program designed in a different way (such as having the same set of standards for all laboratories or having different standards based on the types of tests they conduct) would allow DEQ to adequately enforce standards for source-reported data and address the deficiencies in the current enforcement policy mentioned in the 1997 JLARC report.

- e. According to DCLS and the 1997 JLARC report, some commercial environmental laboratories have indicated that they would prefer NELAC accreditation to certification under a state program as it could be used as a marketing tool to attract clients within Virginia and allow them to seek reciprocal accreditation and operate in other states with a NELAC accrediting program. However, the proposed regulations make NELAC accreditation mandatory for all commercial environmental laboratories. If NELAC standards are considered essential for the accuracy and reliability of tests performed at commercial laboratories, it should be applied to all noncommercial environmental laboratories performing similar tests. If NELAC standards are not considered essential, laboratories should be required to meet only those standards considered essential by DCLS and NELAC accreditation should be made voluntary. This would allow commercial laboratories that want NELAC accreditation to get it, while allowing the rest to operate under the state certification program.
- f. Industrial and municipal laboratories that send samples for analysis to commercial environmental laboratories, represented on the ad hoc committee set up to advise DCLS of the proposed regulations, indicated that they wanted commercial laboratories to meet NELAC standards even if they themselves did not meet those standards. According to DCLS, this was yet another consideration in establishing separate standards for commercial and noncommercial environmental laboratories. Allowing laboratories (commercial or noncommercial) to be voluntarily accredited under NELAC standards would address this issue. Industrial and municipal facilities concerned about the quality of commercial environmental laboratories could choose to patronize only NELAC

accredited laboratories. Others could choose to send their samples for analysis to laboratories that are certified under the state program.

- g. Regarding the fees for reciprocal accreditation, DCLS believes that charging lower fees to laboratories accredited in states providing similar reciprocity in fees would put in-state laboratories at a disadvantage compared to out-of-state laboratories. However, as suggested above, lower reciprocal accreditation fees would encourage competition and lower the price of environmental laboratory services in Virginia and provide Virginia laboratories with an opportunity to expand their business to other states.

*Comparison to Other States:*

There are state agencies in 11 states that are currently qualified to be NELAC accrediting authorities. The participation of these states in NELAC varies from state to state. Different states adopt NELAC standards for different areas of testing. For example, New York and New Jersey require all environmental laboratories submitting data under the state's environmental programs to be NELAC accredited. On the other hand, California has adopted NELAC standards for environmental laboratories providing data under the state's food, drinking water, wastewater, shellfish, and hazardous waste programs and Pennsylvania has adopted NELAC standards only for laboratories submitting data under the state's drinking water regulations. States also differ in the whether NELAC standards are mandatory or voluntary. While some states such as Florida require all environmental laboratories submitting data under the state's environmental laws to be NELAC- accredited, most states do not require environmental laboratories to be accredited under NELAC. They provide laboratories with the option of getting certified under a state-run program or getting accredited under NELAC. However, none of these 11 states require commercial laboratories to meet NELAC standards and noncommercial laboratories to meet the state standards. Fees charged usually include a certain base fee and additional fees depending on the number of fields of testing for which the laboratory is getting accredited regardless of whether the laboratory does analysis for itself or for outside sources. Some states have only a state-run certification program and do not offer NELAC accreditation. While a few of these states, such as Wisconsin and North Carolina, do distinguish between types of environmental laboratories in terms of the fees charged, most make no such distinction.

*The Regulated Community:*

Conversations with the regulated community have reinforced perceptions about the flaws in the proposed regulations identified above. The Laboratory Association of Virginia (representing the interests of commercial environmental laboratories) believes there is no basis for establishing separate standards and requirements for commercial and noncommercial laboratories. Moreover, they voiced concerns about the proposed accreditation fee structure, saying that it would put undue burden on smaller environmental laboratories. The Virginia Manufacturers Association (representing the interests of environmental laboratories owned by industrial sources of pollution) believes that the regulations impose unduly high standards on small laboratories. They believe that the standards proposed under Chapter 45 are more stringent than required for laboratories conducting simple tests where failure or sub-par performance is not likely to have a significant impact on public health and the environment. They believed that regulations establishing standards appropriate to the tests conducted at these smaller laboratories would be more appropriate.

*Conclusion:*

While there is a compelling case for a certification program for environmental laboratories, the current regulations have serious flaws.

First, the distinction between commercial and noncommercial environmental laboratories in the proposed regulations is likely to have a significant negative economic impact. It is likely to either increase the cost operating a commercial environmental laboratory in Virginia by requiring them to meet minimum standards that are too stringent or increase the cost to public health and the environment by establishing minimum standards for noncommercial environmental laboratories that are not stringent enough. Second, the proposed reciprocal accreditation fees are likely to have a negative economic impact. They are likely to discourage competition from out-of-state laboratories and lead to higher prices for services of commercial environmental laboratories than would have been the case if fees reflected the actual cost incurred by DCLS in reviewing and granting reciprocal accreditation. Third, to the extent that the exemption fees encourage the laboratories conducting more complex and environmentally sensitive tests to apply and receive exemptions, the regulations could increase the risk to public health and the environment than if exemptions were reserved for laboratories conducting less environmentally sensitive tests. Fourth, the regulations' lack of clarity regarding when fees are to be charged for a

transfer of ownership is likely to have a small negative economic impact by increasing the uncertainty faced by environmental laboratories when applying for an exemption or transferring ownership. Fifth, it is not clear that the proposed regulations will prove more effective than current policy in detecting and preventing cases of data falsification and misreporting.

In general, these regulations do not appear to be rationally designed to meet the stated objective of protecting public health and safety.

## **Businesses and Entities Affected**

The proposed regulations affect approximately 915 noncommercial environmental laboratories (250 are classified as simple test laboratories and 665 are classified as general environmental laboratories) and 60 commercial environmental laboratories operating in Virginia. Approximately 40 of the 60 commercial environmental laboratories operate solely in Virginia whereas approximately 20 also operate in states other than Virginia.

The proposed regulations are likely to increase the cost of operation for commercial and noncommercial environmental laboratories in Virginia. Environmental laboratories are now required to meet certain minimum standards and requirements in order to be certified to operate in the state. However, the additional costs have to be weighed against the benefit to public health and the environment in Virginia from requiring environmental laboratories to meet certain minimum standards for data reported as part of Virginia's air, water, and waste laws. The proposed regulations impose a higher cost on commercial laboratories than on noncommercial laboratories as the former are required to meet more stringent standards and requirements. The regulations also impose costs on commercial laboratories seeking reciprocal accreditation greater than the cost incurred by DCLS in reviewing and granting reciprocal accreditation. Even though these laboratories are accredited under NELAC in another state, they are still required to pay the same accreditation fee as any laboratory seeking to get accredited for the first time.

The additional costs being imposed on commercial laboratories are likely to raise the cost of services provided by commercial environmental laboratories in Virginia. Moreover, the fees being proposed for laboratories applying for reciprocal accreditation are likely to discourage competition from out-of-state laboratories and push the price of these services even higher. The higher prices would place permittees without in-house laboratories that use commercial laboratories at a disadvantage compared to permittees with in-house laboratory facilities.

## **Localities Particularly Affected**

The proposed regulations affect all localities in the Commonwealth.

## **Projected Impact on Employment**

The proposed regulations are likely to have a negative impact on employment in Virginia. To the extent that the higher costs faced by commercial environmental laboratories to operate in Virginia discourages the establishment of such laboratories, the proposed regulations are going to have a negative impact on employment.

## **Effects on the Use and Value of Private Property**

The proposed regulations are likely to increase the cost of operation for all environmental laboratories in Virginia. However, the more stringent standards being imposed on commercial environmental laboratories are likely to raise their costs the most. The higher standards coupled with the restriction on competition from out-of-state laboratories is likely to raise the cost of the services provided by commercial environmental laboratories. This, in turn, will raise the cost of operation of permitted facilities using commercial laboratories for tests and analysis compared to permitted facilities with in-house laboratories. Overall, by raising their costs of operation, these regulations lower the asset value of private firms (commercial environmental laboratories and the firms buying their services) engaged in this business.