Virginia Department of General Services, Division of Consolidated Laboratory Services

Response to Department of Planning and Budget's Economic Impact Analysis on the Draft Proposed Environmental Laboratory Certification Program (1 VAC 30, Chapters 45 and 46)

January 20, 2004

The Department of Planning and Budget (DPB) completed its Economic Impact Analysis (EIA) on the draft proposed regulations for the certification of noncommercial environmental laboratories and the accreditation of commercial environmental laboratories (1 VAC 30, Chapters 45 and 46) on January 14, 2003. The Division of Consolidated Laboratory Services (DCLS) is providing its response to the EIA in this document.

Issue 1 - Distinction between commercial and noncommercial laboratories

DPB states in its conclusion on page 20 of the EIA that

> 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.

DCLS Response to Issue 1

The distinction between commercial and noncommercial environmental laboratories in the proposed regulations should not have a significant negative economic impact. The core standards that both commercial and noncommercial environmental laboratories must meet to be certified are essentially equivalent. The costs to the affected laboratories are spread fairly evenly among those laboratories, and include not just the fees but the costs of meeting the requirements of the proposed regulations.

DCLS intended, at the beginning of this rulemaking, to use one set of standards for all laboratories affected by the program. The National Environmental Laboratory Accreditation Conference (NELAC) standards were being developed by the states, federal government, and others as a national model. DCLS thought these standards were appropriate for Virginia

environmental laboratories. DCLS discovered however in the process of working with the government, industrial, and commercial laboratories which will be affected by this rulemaking that using one standard for all laboratories operating in Virginia was not politically defensible. The agency and the affected parties set about deciding how to differentiate between laboratories in order to use the NELAC standards for one group and a standard developed for Virginia laboratories for another group. The discussions tended to center around laboratories that work only for themselves in the corporate sense and those that provide laboratory services for others. This distinction became the foundation for the two regulations proposed by the agency. In the proposed regulations, the laboratories designated as “commercial” are those that perform substantial laboratory services for others. Noncommercial laboratories in some instances may perform such services for others but their work is done in a limited way and in a narrow context, generally within the corporate boundaries of the company or governmental entity of which they are a part. This distinction has merit beyond the political realities discussed here.

The 1997 General Assembly passed the statute requiring the establishment of the environmental laboratory certification program in response to the findings of the Joint Legislative Audit and Review Commission’s January 1997 report reviewing the Department of Environmental Quality (DEQ) [JLARC report]. In its discussion of the water quality program, JLARC found that the ability of environmental laboratories audited as part of the Virginia Permit Discharge Elimination System program to accurately analyze samples was seriously diminishing. JLARC noted the special need to certify commercial environmental laboratories. 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 enforce against permittees whose in-house laboratories are not performing to standard but not against commercial laboratories. DEQ cannot require commercial environmental laboratories to improve their performance or accuracy. DEQ can ask the permittees not to use the commercial laboratories that perform poorly or inaccurately, and can reject any data these laboratories have provided to their clients, if DEQ can make the connection. There is a clear need to require commercial laboratories to meet quality assurance/quality control standards established for the purpose in Virginia. There is also a need to provide information to consumers about which of these laboratories meet those standards and to keep non-performing laboratories from providing environmental data to DEQ.

Commercial environmental laboratories work for multiple clients and perform multiple tasks. They must have a system in place to manage receiving and analyzing samples from many clients in a limited amount of time. Commercial environmental laboratories typically analyze a broad spectrum of substances in various media. Non-performance or poor performance by a commercial laboratory may affect samples from many clients and may result in severe environmental consequences over a wide geographic area.

Noncommercial environmental laboratories may analyze samples as diverse as the samples a commercial laboratory analyzes. The noncommercial laboratory however does not perform 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 geographically.

Commercial environmental laboratories by and large want to be accredited under the NELAC standards. This accreditation enables them to get reciprocal accreditation in states that have NELAC accrediting authority. Getting NELAC accreditation provides the commercial laboratories with opportunities to work elsewhere in the country with a relatively low cost of accreditation. The NELAC standards were developed in part to do away with multiple accreditations across the country. The cost of getting accredited under a system of multiple state programs includes not just the cost of the fees but also the cost of going through the on-site accreditation process and accommodating the variety of approaches to accreditation.

While the distinction between commercial and noncommercial environmental laboratories is real, the tests and analyses the laboratories perform are the same across the spectrum of laboratories. Any laboratory, commercial or noncommercial, should meet the same core quality standards. The core standards that both commercial and noncommercial environmental laboratories must meet under the proposed regulations are essentially the same. The requirements for proficiency testing and on-site certification are the same for both. The requirements for quality systems remain essentially the same with less prescriptive provisions in Chapter 45 in some cases. Chapter 45 provides more flexibility than Chapter 46 in provisions that are less critical for a good quality environmental laboratory. The quality system standards for noncommercial laboratories do not include requirements that are pertinent only to commercial laboratories such as provisions dealing with the review of requests, tenders and contracts.

The requirements for personnel differ considerably between Chapter 45 for noncommercial environmental laboratories and Chapter 46 for commercial environmental laboratories. The Chapter 45 personnel requirements focus on work experience in the case of general laboratories. The approach taken in Chapter 46 is to rely on education as well as work experience. In the case of the Chapter 45 laboratories that perform only simple test procedures, the proposed regulation provides that these laboratories may designate personnel for the key jobs at the laboratory with no other requirement. The small laboratories expressed significant concern about meeting any higher standard. The agency believes that if the small laboratories meet their proficiency testing and quality systems requirements, the personnel requirements should not matter. If after some experience with the program, the agency finds that this assumption was wrong, changes to the program can be made.

DCLS would characterize the standards for noncommercial environmental laboratories in Chapter 45 as different than those for commercial environmental laboratories in Chapter 46, rather than less stringent. These two sets of standards both provide the same core requirements resulting in sound quality systems structures to be met by all environmental laboratories.

The costs to the affected laboratories are spread fairly evenly among those laboratories, and include not just the fees but the costs of meeting the requirements of the proposed regulations. The approach used to require commercial environmental laboratories to meet the NELAC standards should not increase the cost of having tests done at commercial laboratories. The cost for a commercial laboratory of becoming accredited is not significantly higher than the cost for a noncommercial laboratory.

Commercial environmental laboratories work within a market environment in Virginia and nationally. The prices charged for the same test by various commercial laboratories tend to be within a fairly small range. The ability to serve their clients - to do all the analyses needed for the client - and to provide that service with efficiency is what keeps commercial laboratories in business.

As proposed, fees will be charged as part of the application or renewal for certification or accreditation every two years. Fees are calculated using a base fee and adding test category fees. Laboratories pay no more than a designated maximum fee. For all laboratories, the fees

are lower if they do less extensive testing. The fees were based on the cost of the program to DCLS, including the time it would take to review the laboratories.

The base fees charged are derived from the estimated time it will take the agency to review a laboratory's application package. This differs depending on the complexity of the laboratory's operation and the pertinent requirements. The agency has assumed a hierarchy of complexity with the commercial laboratories being the most complex. The test category fees are the same for noncommercial and commercial laboratories.

The base fee for commercial environmental laboratories is $400 higher every two years or $200 annually than the base fee for general noncommercial laboratories. Another way to view this difference is to look at the hours the base fees represent, using $35 per hour as the labor rate. The base fee for general noncommercial laboratories is equivalent to 49 hours of review time. The base fee for commercial laboratories is equivalent to 60 hours, 11 hours more of review time. A difference of $200 annually for a commercial laboratory becomes significant only if the commercial laboratory is close to failing for reasons unrelated to the certification program.

The cost of becoming certified or accredited is more than the fees alone. There are other costs. Proficiency tests must be purchased and analyzed twice a year to determine the ability of the lab to accurately perform the tests for which they are certified or accredited. The laboratories must ensure that they have and maintain a system that produces quality at all levels of laboratory operation. Commercial environmental laboratories should already have the ability to meet any set of standards, including the NELAC standards. Many of them already hold national certifications for categories of testing not covered under this program. Their increased costs due to the certification program should be fairly low. Noncommercial laboratories, on the other hand, especially those owned by local governments, will have to spend resources to meet the standards of Chapter 45. Their initial costs may be higher than those of commercial laboratories.

DCLS anticipates that small, noncommercial environmental laboratories performing only simple test procedures are currently less prepared to meet laboratory certification standards. DCLS has limited their fees to allow these laboratories to absorb these other costs of becoming certified. DCLS will assist these small laboratories through educational programs so that they can succeed in meeting the program's goals. Some of the costs of reviewing the application

packages for these laboratories have been shifted to the other laboratories covered by the program.

There are two categories of costs that can be estimated, fees and proficiency tests.

Fees consist of a base fee and test category fees. The test category fees range from $300 to $900 per category. For fee purposes, there are two categories of noncommercial environmental laboratories under Chapter 45: general environmental laboratories and environmental laboratories that perform only simple test procedures. The table below gives the fee amounts for Chapter 45 and Chapter 46 laboratories.

Laboratory Category	Base Fee	Maximum Fee	Max. Annual Fee
Chapter 45 laboratory			
Simple test procedure	$100	$400	$200
General	$1700	$3800	$1900
Chapter 46 laboratory	$2100	$4200	$2100

Proficiency test samples cost between $50 and $310 per sample. Sets of samples can save money. One provider's current price for sets of samples required by the DMR-QA program range from $185 to $595 per set. For each laboratory, the cost of each round of proficiency test samples depends on the number of analytes for which the laboratory wants to be certified. Two rounds of proficiencies are required annually. The proficiency tests are sold by private providers approved by national standards bodies. One round of proficiencies is already required under the federal and Virginia water permit regulations. Proficiency tests are available for all media except air.

Examples of estimated annual costs of administrative fees and proficiency test studies follow:

- $350 for a simple test procedure, noncommercial laboratory (maximum fee annualized)
- $2075 for an average noncommercial laboratory (estimated annual fee of $1325)
- $2381 for a noncommercial laboratory with some metals tests requirements (estimated annual fee of $1475)
- $2881 for a commercial laboratory with a limited range of services (estimated annual fee of $1975)
- $3506 for a full-service commercial laboratory (maximum fee annualized)

> DPB suggests that the provisions of Chapter 45 would be appropriate for all laboratories, including commercial laboratories. Those that want to meet the NELAC standards incorporated into Chapter 46 could voluntarily apply under that chapter. The provisions of Chapter 45, as presently written, are not appropriate for commercial environmental laboratories. The changes needed to be made to make Chapter 45 work for commercial laboratories would be significant.

First, the Chapter 45 personnel requirements, as currently written, are inadequate for commercial laboratories. DCLS could include in Chapter 45 personnel provisions specifically for commercial laboratories or could require commercial laboratories under Chapter 45 to meet the NELAC personnel standards. Laboratories that wish to be accredited under the NELAC standards would still need to meet the NELAC personnel requirements.

Second, the NELAC standards include requirements pertinent to commercial laboratory operation that are not included in the noncommercial laboratory standards in Chapter 45. These requirements would have to be added to Chapter 45 but limited to commercial laboratories.

Third, providing laboratories with the opportunity for exemptions is required by the governing statute but not allowed under the NELAC standards. Section 2.2-1105 of the *Code of Virginia* requires that the program provide an opportunity for an exemption to applicant laboratories in circumstances determined by the agency during the rulemaking. DCLS would need to determine whether providing an exemption to those commercial laboratories getting certified under Chapter 45 would be appropriate.

Fourth, any change to the proposed regulatory scheme which would remove the distinction between commercial and noncommercial environmental laboratories would require DCLS to revisit the proposed fees to create a system that would fit the new regulatory approach. The fees would still need to pay for the cost of the program. Fees now charged to commercial laboratories would have to be spread among all laboratories. Making the program in Chapter 46 voluntary would mean that DCLS would not have any way to estimate its costs for the laboratories which would opt into Chapter 46. It is unclear what a new system might look like.

Issue 2 - Reciprocal accreditation fees

DPB states in its conclusion on page 20 of the EIA that

> 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.

DCLS Response to Issue 2

The proposed reciprocal accreditation fees are unlikely to have a negative economic impact, discourage competition from out-of-state commercial laboratories, or lead to higher prices for commercial laboratory services. The fees charged under the program are only one component of cost for commercial laboratories. Lower fees for out-of-state laboratories will not lower the prices these laboratories charge for their services. DPB's proposal for reciprocal accreditation creates a disadvantage for Virginia commercial environmental laboratories. The proposal would also shift costs for the program to the other applicant laboratories.

The fees charged by DCLS to any commercial environmental laboratory should be the same. The program should not create a bias in favor of out-of-state commercial laboratories and, in effect, against Virginia commercial environmental laboratories. This approach would give a competitive disadvantage to commercial laboratories located within Virginia.

The prices charged by commercial laboratories for their services are based on the marketplace. As stated earlier, the prices charged for the same test by various commercial laboratories tend to be within a fairly small range. The ability to serve their clients - to do all the analyses needed for the client - and to provide that service with efficiency is what keeps commercial laboratories in business. Costs incurred through accreditation affect the commercial laboratory's profit but not its prices. At some point when costs increase, the prices a commercial laboratory charge may go up but only if the market can bear the increase. Otherwise, the laboratory would price itself out of the market.

There is no statutory mandate for the agency to use actual cost in determining fees. The statute requires the agency to "establish a fee system to offset the costs of the certification program." §2.2-1105 C of the *Code of Virginia.*

DPB suggests that DCLS pursue a program of lowering fees "for laboratories accredited in states that charge similarly discounted fees for reciprocal accreditation." (EIA at page 12) DPB states that "California and New York have incorporated provisions in their environmental laboratory accreditation program that allow for fee reciprocity." In fact, neither state has such provisions (see Errors of Fact, below). Reciprocal fee accreditation does not, to DCLS' knowledge, exist in state programs.

Reciprocal fee accreditation would change the fee structure for the program. The costs would be the same but the income could not be estimated accurately. The costs of reviewing laboratories for certification or accreditation must be counted in the costs of the program, even for laboratories applying for reciprocal accreditation. If not, in-state laboratories pay the cost of the program that out-of-state laboratories would otherwise pay, thus raising their fees.

Issue 3 - Effectiveness of regulations in detecting and preventing data falsification and misreporting

DPB states in its conclusion on page 21 of the EIA that "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."

DCLS Response to Issue 3

DCLS agrees with DPB that the detection and prevention of cases of data falsification and misreporting may not be more effective in the case of this new program versus current policy. However, to the extent that the new program covers more laboratories, including the additional air and waste laboratories and the smaller water laboratories that are seldom reviewed by DEQ, it is more likely that these problems will be found. Fraud is difficult to detect. Performing data audits of laboratory work is the best way to detect it.

Under the governing statute, the program's purpose is to certify or accredit laboratories to quality assurance and quality control standards set out in regulation. The goal of this program is to ensure that those laboratories providing data under Virginia's air, waste and water laws and regulations are able to perform analyses and testing accurately and consistently. By initiating this program and broadening the scope of review of such laboratories, data falsification and misreporting may be prevented.

Comments from the regulated community

DCLS has worked with the regulated community since April 1998 on the development of these proposed regulations. The structure of the regulations as proposed is based on the discussions with the affected laboratories. They are agreeable to and support the commercial and noncommercial distinction. All the laboratories, large and small, and DCLS have been concerned about the smaller laboratories. Every effort has been made and will be made to lessen their burden.

On page 20 of the EIA, DPB describes conversations its analyst had with representatives of the Laboratory Association of Virginia and the Virginia Manufacturers Association. The description of the conversation with the representative of the Laboratory Association, according to that representative, does not reflect the conversation he had with the DPB representative. He did say that the conversation was an extended one. See Errors of Fact below. DCLS did not ask the VMA representative for his reaction to the summary of the discussion he had with DPB.

Significant Errors Of Fact

1. The New York and California Environmental Laboratory Accreditation Programs.

With regard to reciprocity agreements, § 55-2.8 entitled “Reciprocity Agreements” of the New York regulations states the following:

> The department may enter into agreements with any other state for the purpose of recognizing, on the basis of reciprocity, laboratory inspections performed or laboratory approvals granted by such other state, provided that the program of the other state is satisfactory to the department. Reciprocal approval may be granted to laboratories located in states with which the department has concluded agreements of reciprocity, provided that candidate laboratories in such other states pay all applicable approval fees and additional costs incurred in the performance of inspections conducted pursuant to this Subpart.

There is no reciprocal fee arrangement set out in the New York regulations.

With regard to California’s program, DPB tells DCLS that the program information available on the website includes information on the reciprocity agreements with states. The website also states that “reciprocity saves considerable resources and still meets the needs of the program.” As discussed above, one of the benefits of reciprocal accreditation is the cost savings to

commercial laboratories that wish to operate in several states. However, this information is not indicative of a reciprocal fee agreement that allows discounting between states.

2. Laboratory Association of Virginia (LAVA) comments.

DPB states on page 20 of the EIA that the Laboratory Association of Virginia "believes there is no basis for establishing separate standards and requirements for commercial and noncommercial laboratories." The LAVA representative has told DCLS that this is not a true statement. According to the LAVA representative, he told DPB that the current proposed structure of the regulations should go forward to public comment as is.