



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

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**1 VAC 30-45 Certification for Noncommercial Environmental Laboratories**

**1 VAC 30-46 Accreditation for Commercial Environmental Laboratories**

**Department of General Services**

**Town Hall Action/Stage: 5400 / 8962**

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## **Summary of the Proposed Amendments to Regulation**

The Division of Consolidated Laboratory Services (DCLS) of the Department of General Services (DGS) proposes to amend 1 VAC 30-45 *Certification for Noncommercial Environmental Laboratories* and 1 VAC 30-46 *Accreditation for Commercial Environmental Laboratories* to reflect the most recent revision<sup>1</sup> of the standards of the National Environmental Laboratory Accreditation Conference, now known as The NELAC Institute (TNI). Additionally, DCLS proposes a new fee covering the cost of compliance determination when the division has suspended accreditation or certification in total and the laboratory wishes to demonstrate that the reasons for suspension have been resolved. DCLS' proposal also includes adding violations to the lists of causes that could result in suspension or withdrawal of certification and accreditation.

## **Background**

Code of Virginia § 2.2-1105<sup>2</sup> requires DCLS to “by regulation establish a program for the certification of laboratories conducting any tests, analyses, measurements, or monitoring required pursuant to” Air Pollution Control Board statutes,<sup>3</sup> the Virginia Waste Management Act,<sup>4</sup> or the State Water Control Law.<sup>5</sup> Such a program for noncommercial environmental laboratories is established in 1 VAC 30-45 *Certification for Noncommercial Environmental Laboratories*. A program for commercial environmental laboratories is established in 1 VAC 30-

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<sup>1</sup> The current regulations reflect the 2009 TNI Standards. The proposed regulation would reflect the 2016 TNI Standards.

<sup>2</sup> See <https://law.lis.virginia.gov/vacode/title2.2/chapter11/section2.2-1105/>

<sup>3</sup> See <https://law.lis.virginia.gov/vacode/title10.1/chapter13/>

<sup>4</sup> See <https://law.lis.virginia.gov/vacode/title10.1/chapter14/>

<sup>5</sup> See <https://law.lis.virginia.gov/vacode/title62.1/chapter3.1/>

46 *Accreditation for Commercial Environmental Laboratories* (certification is referred to as accreditation throughout 1 VAC 30-46).<sup>6</sup> Code of Virginia § 2.2-1105 further requires that “The regulations shall be promulgated only after adoption of national accreditation standards by the National Environmental Laboratory Accreditation Conference sponsored by the United States Environmental Protection Agency.”

For both regulations, “commercial environmental laboratory” and “noncommercial environmental laboratory” are defined as follows. “Commercial environmental laboratory” means an environmental laboratory where environmental analysis is performed for another person. “Noncommercial environmental laboratory” means either of the following:

1. An environmental laboratory where environmental analysis is performed solely for the owner of the laboratory.
2. An environmental laboratory where the only performance of environmental analysis for another person is one of the following:
  - a. Environmental analysis performed by an environmental laboratory owned by a local government for an owner of a small wastewater treatment system treating domestic sewage at a flow rate of less than or equal to 1,000 gallons per day.
  - b. Environmental analysis performed by an environmental laboratory operated by a corporation as part of a general contract issued by a local government to operate and maintain a wastewater treatment system or a waterworks.
  - c. Environmental analysis performed by an environmental laboratory owned by a corporation as part of the prequalification process or to confirm the identity or characteristics of material supplied by a potential or existing customer or generator as required by a hazardous waste management permit under 9VAC20-60.
  - d. Environmental analysis performed by an environmental laboratory owned by a Publicly Owned Treatment Works (POTW) for an industrial source of wastewater under a permit issued by the POTW to the industrial source as part of the requirements of a pretreatment program under Part VII (9VAC25-31-730 et seq.) of 9VAC25-31.

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<sup>6</sup> See <https://law.lis.virginia.gov/admincode/title1/agency30/chapter46/section10/>

e. Environmental analysis performed by an environmental laboratory owned by a county authority for any municipality within the county's geographic jurisdiction when the environmental analysis pertains solely to the purpose for which the authority was created.

f. Environmental analysis performed by an environmental laboratory owned by an authority or a sanitation district for any participating local government of the authority or sanitation district when the environmental analysis pertains solely to the purpose for which the authority or sanitation district was created.

Generally speaking, noncommercial laboratories provide limited analytical services either for their own organization or for other entities (such as wastewater treatment facilities).<sup>7</sup> Moreover, in contrast to commercial laboratories, noncommercial laboratories generally use a more limited number and complexity of methods.

Although the noncommercial laboratories meet similar standards to those met by the commercial laboratories, according to DGS the differences are sufficient to require separate regulations. In addition, the TNI Standards include provisions that do not pertain to the noncommercial laboratories' work. For example, the TNI Standards include provisions related to the commercial provision of laboratory services such as contracting. Further, the TNI Standards cover asbestos, radiochemical, and toxicity testing which the noncommercial laboratories do not perform. The commercial laboratories typically want to meet the nationally-recognized TNI Standards<sup>8</sup> because this provides them with accreditation credentials that can be used to market their services.

### **Estimated Benefits and Costs**

DCLS' proposed amendments include numerous changes in testing specifics to comply with the latest TNI Standards, as well as changes in definitions and changes to improve clarity. Amending the regulations to match the most up-to-date TNI Standards may improve the quality and reliability of environmental testing. According to DGS, all of these amendments would have minimal impact on lab staff time and the cost of any needed materials would be negligible.

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<sup>7</sup> Source: DGS

<sup>8</sup> Ibid

### *Suspension and Withdrawal*

Both regulations have a list of violations for which certification (noncommercial) or accreditation (commercial) can be suspended in part or in total. For the most part these violations can be identified either during annual proficiency tests or from reassessments (discussed in the next section). Environmental laboratories may not continue to analyze samples or report analysis for the fields of certification/accreditation for which DCLS has suspended certification or accreditation. The term of suspension is six months or the remaining period of certification/accreditation, whichever is longer. If the laboratory demonstrates to DCLS that it has corrected the deficiency or deficiencies for which its certification or accreditation was suspended within the term of the suspension, the laboratory's suspended status changes to certified or accredited and it may resume analyzing samples and reporting analysis. If the laboratory fails to correct the causes of suspension within the term of suspension, DCLS withdraws<sup>9</sup> the laboratory's certification or accreditation in total or in part. In order to resume operations, the lab would have to file a new application. DCLS has 90 days to determine if applications are complete, then another 120 days to schedule an on-site assessment before granting, if merited, certification or accreditation. Application fees are the same as renewal fees. The fees vary greatly depending on the number of methods of analysis, the categories of the methods of analysis, and the number of components to be analyzed for each method.<sup>10</sup> Both regulations also have a list of violations for which certification (noncommercial) or accreditation (commercial) can be withdrawn directly.

### *Providing for Suspension in Addition to Withdrawal*

DCLS reassesses each noncommercial laboratory at least once every three years or more often under specified circumstances, and each commercial laboratory every two years. If in its assessment the division finds deficiencies, the laboratory has 30 days to provide a response. This response is called a corrective action plan. Under the current regulations if a laboratory fails to submit an acceptable corrective action plan after two opportunities, DCLS may withdraw accreditation or certification, but suspension is not an option. DCLS proposes to add this

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<sup>9</sup> 1 VAC 30-45 uses the term “decertification,” while 1 VAC 30-46 uses “withdrawal of accreditation.” For ease of reading, this document uses “withdrawal” for both certification and accreditation.

<sup>10</sup> For detail on fee calculation, see <https://law.lis.virginia.gov/admincode/title1/agency30/chapter45/section130/> and <https://law.lis.virginia.gov/admincode/title1/agency30/chapter46/section150/>

violation to the lists of causes for which a lab can be suspended in part or in total, in addition to withdrawal of accreditation or certification. By expanding the enforcement options, this proposal is beneficial in that it provides the division with a less onerous option for when that is deemed most appropriate. Affected labs that are suspended, rather than having their certification or accreditation withdrawn, and that are able to rectify their deficiencies in a timely manner would be able to resume operations much sooner. Once a suspended lab demonstrates to DCLS that it has corrected the deficiency or deficiencies for which its certification or accreditation was suspended within the term of the suspension, it may essentially resume operations immediately. In contrast, it can take seven months or more for a reapplication after withdrawal to be approved.

#### *Expanding Reasons for Withdrawal*

*Certification for Noncommercial Environmental Laboratories* currently includes failure to successfully complete three consecutive proficiency tests as a cause for which DCLS may withdraw certification in part or total. Proficiency tests are defined as a process to evaluate a laboratory's performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by an external source. This cause for withdrawal is not currently in *Accreditation for Commercial Environmental Laboratories*. DCLS proposes to add it to the list of causes for which the division may withdraw accreditation of commercial labs in part or total. To the extent that this proposed amendment helps prevent inaccurate testing or analyses of the safety of air, waste, and water in the Commonwealth from being conducted and communicated to the public and environmental regulators, it may be beneficial.

The regulations include prohibitions on communicating with any individual at another laboratory concerning the labs' proficiency testing sample prior to the time the results of the study are released. Exchanging information with other labs or asking other labs about running proficiency test samples violates the rules for running proficiency tests. The current regulations do not include explicit repercussions if this is violated. DCLS proposes to add this violation to the causes for which it may withdraw certification or accreditation in part or in total. To the extent that this proposed amendment helps maintain the integrity of proficiency testing by creating a strong deterrent to biasing the results, it may be beneficial.

### *New Fee*

Pursuant to Code of Virginia § 2.2-1105, the certification and accreditation programs are funded through fees charged to the laboratories. DCLS proposes to add a provision in both regulations requiring a laboratory to pay a fee covering the cost of compliance determination when the division has suspended accreditation or certification in total and the laboratory wishes to demonstrate that the reasons for suspension have been resolved. The laboratory would be charged the cost of any necessary follow-up on-site assessments or data review or both. Depending on the laboratory's overall scope of certification or accreditation and the number and complexity of the non-compliances causing the suspension, DCLS estimates that the fee could range from approximately \$400 to approximately \$4,000. Currently the general pool of fees charged to all laboratories pays for these costs. By charging this proposed fee to the lab that causes the cost to be incurred, the cost would no longer be subsidized by other labs that had no involvement in creating the cost. Though laboratories would not intentionally have their operations suspended in total, this extra cost could provide some extra incentive to avoid violations.

### *Documentation*

The current 1 VAC 30-45 *Certification for Noncommercial Environmental Laboratories* requires that access to archived information be documented with an access log. DCLS has determined that the access log does not serve a useful purpose in practice. Thus, the division proposes to eliminate this requirement. This should save some staff time for noncommercial labs.

### **Businesses and Other Entities Affected**

The proposal affects the 85 noncommercial certified environmental laboratories that are subject to 1 VAC 30-45 *Certification for Noncommercial Environmental Laboratories*: which consist of 64 public utilities, 11 industrial laboratories, five laboratories associated with educational institutions, four laboratories run by the federal government, and one laboratory at a state correctional facility. The proposal affects the 48 commercial accredited environmental laboratories that are subject to 1 VAC 30-46 *Accreditation for Commercial Environmental Laboratories*: which consist of 33 small businesses, 11 industrial laboratories, three public

utilities, and one university.<sup>11</sup> The proposed new fee would adversely impact<sup>12</sup> labs that have their accreditation or certification suspended in total that wish to demonstrate that the reasons for suspension have been resolved.

### **Small Businesses<sup>13</sup> Affected:**

#### Types and Estimated Number of Small Businesses Affected

The proposed amendments affect 33 small commercial environmental laboratories.<sup>14</sup>

#### Costs and Other Effects

If any of the 33 small commercial environmental laboratories were to be suspended in total and wishes to demonstrate that the reasons for suspension have been resolved, the proposed new fee would increase their costs from approximately \$400 to approximately \$4,000, depending on the laboratory's overall scope of certification or accreditation and the number and complexity of the non-compliances causing the suspension.

#### Alternative Method that Minimizes Adverse Impact

There are no clear alternative methods that both reduce adverse impact and meet the intended policy goals.

### **Localities<sup>15</sup> Affected<sup>16</sup>**

The proposal affects 133 environmental laboratories that test for air and water quality and contaminated waste throughout the Commonwealth. No particular localities are known to be disproportionately affected. The proposal does not appear to directly introduce costs for local governments.

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<sup>11</sup> Data source: DGS

<sup>12</sup> Adverse impact is indicated if there is any increase in net cost or reduction in net revenue for any entity, even if the benefits exceed the costs for all entities combined.

<sup>13</sup> Pursuant to § 2.2-4007.04 of the Code of Virginia, small business is defined as "a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million."

<sup>14</sup> Data source: DGS

<sup>15</sup> "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulatory change are most likely to occur.

<sup>16</sup> § 2.2-4007.04 defines "particularly affected" as bearing disproportionate material impact.

## Projected Impact on Employment

The proposed amendments are unlikely to substantively affect total employment.

## Effects on the Use and Value of Private Property

For private labs that may have substantial difficulty demonstrating proficiency or who may participate in unethical communication, the proposed additions to causes for potential withdrawal of certification or accreditation would potentially have a large negative impact on their firm value. If DCLS did choose to withdraw their certification or accreditation, the labs would be prevented from analyzing samples or reporting analyses for customers for possibly seven months or longer.

The proposed addition of failure to submit an acceptable corrective action plan after two opportunities to the list of causes for which DCLS may suspend certification or accreditation, may have a positive impact on the value of private labs in this situation if suspension is used instead of withdrawal by the division. As described earlier, a lab rectifying this deficiency could potentially resume operations many months earlier if its certification or accreditation is suspended rather than withdrawn.

The proposal does not appear to affect real estate development costs.

## Legal Mandates

**General:** The Department of Planning and Budget has analyzed the economic impact of this proposed regulation in accordance with § 2.2-4007.04 of the Code of Virginia (Code) and Executive Order 14 (as amended, July 16, 2018). Code § 2.2-4007.04 requires that such economic impact analyses determine the public benefits and costs of the proposed amendments. Further the report should include but not be limited to: (1) the projected number of businesses or other entities to whom the proposed regulatory action would apply, (2) the identity of any localities and types of businesses or other entities particularly affected, (3) the projected number of persons and employment positions to be affected, (4) the projected costs to affected businesses or entities to implement or comply with the regulation, and (5) the impact on the use and value of private property.

**Adverse impacts:** Pursuant to Code § 2.2-4007.04(D): In the event this economic impact analysis reveals that the proposed regulation would have an adverse economic impact on businesses or would impose a significant adverse economic impact on a locality, business, or entity particularly affected, the Department of Planning and Budget shall advise the Joint Commission on Administrative Rules, the House Committee on Appropriations, and the Senate Committee on Finance within the 45-day period.

If the proposed regulatory action may have an adverse effect on small businesses, Code § 2.2-4007.04 requires that such economic impact analyses include: (1) an identification and estimate of the number of small businesses subject to the proposed regulation, (2) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the proposed regulation, including the type of professional skills necessary for preparing required reports and other documents, (3) a statement of the probable effect of the proposed regulation on affected small businesses, and (4) a description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation. Additionally, pursuant to Code § 2.2-4007.1, if there is a finding that a



proposed regulation may have an adverse impact on small business, the Joint Commission on Administrative Rules shall be notified.