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Exempt Action Final Regulation Agency Background Document

Agency name	Department of General Services, Division of Consolidated Laboratory Services
Virginia Administrative Code (VAC) citation(s)	1VAC30-45-130 and 1VAC30-46-150
Regulation title(s)	Certification for Noncommercial Environmental Laboratories (1VAC30-45) and Accreditation for Commercial Environmental Laboratories (1VAC30-46)
Action title	Revision to VELAP Fees
Final agency action date	August 28, 2019
Date this document prepared	August 9, 2019

While a regulatory action may be exempt from executive branch review pursuant to § 2.2-4002 or § 2.2-4006 of the *Code of Virginia*, the agency is still encouraged to provide information to the public on the Regulatory Town Hall using this form. However, the agency may still be required to comply with the Virginia Register Act, Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1 VAC7-10), and the *Virginia Register Form, Style, and Procedure Manual for Publication of Virginia Regulations*.

Brief Summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.

The Division of Consolidated Laboratory Services (DCLS) is revising fees charged for certifying laboratories under 1VAC30-45 and accrediting environmental laboratories under 1VAC30-46.

Section 2.2-1105 C of the *Code of Virginia*, the law authorizing this program, requires DCLS to establish a fee system to offset the costs of the program. The current fees are inadequate to offset the costs of the program and must be revised.

The revised fees are exempt from the requirements of the Administrative Process Act (APA). The Budget of the Commonwealth of Virginia (Chapter 854, effective July 1, 2019) in Item 74, at C 3a provides that revised fees are exempt from the requirements of the APA as long as DCLS provides notice and an opportunity to submit written comments on the revised fees.

Mandate and Impetus

Please identify the mandate for this regulatory change, and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, internal staff review, petition for rulemaking, periodic review, board decision, etc.). "Mandate" is defined as "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

This is only the second update to the fees since the regulations first became effective in 2009. It has been six years since the current fees were developed based on an analysis in mid-2013 of the financial costs of the program. These fees were proposed in August 2013 for 1VAC30-46 and in September 2015 for 1VAC30-45 after being reviewed by the Department of Planning and Budget and the Governor's Office. The requirements of the APA review take time and so by the effective date of these two rules, the fees were already somewhat inadequate in offsetting the program costs. The current fees became effective for 1VAC30-46 on November 1, 2015, and for 1VAC30-45 on September 1, 2016.

During the intervening six years since the current fees were developed, the cost of living has increased. As an indication of how costs have changed, the Consumer Price Index Inflation Calculator indicates the cost of living has increased ten percent since January 2013. This is reflected in the increased cost of both labor and non-labor items for the program's operation.

The program's current staffing needs and the current number of laboratories accredited by the program are reflected in the revised fees. The revised fees also include the statewide salary adjustments for FY2020.

Statement of Final Agency Action

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

The Director of the Department of General Services approved this revision to the VELAP fees on August 28, 2019.

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate. Please distinguish between comments received on Town Hall versus those made in a public hearing or submitted directly to the agency or board.

1. B&B Consultants, Laboratory Division, Chase City, VA (primary C46 lab)
Laboratory expenses have increased over the years, not only for DCLS but also for small labs. B&B Consultants stated that it is a small lab with 4 employees running 15 methods. The commenter stated that increases in laboratory expenses over time have meant that lab

employees do not get annual salary adjustments. The VELAP fee revisions will make this situation more difficult. The commenter stated that the laboratory cannot increase prices to cover the VELAP fee increases because of the risk of losing customers to larger labs that can afford to keep prices low. The commenter requested considering reduction of the requirement for proficiency testing (PT) studies from two studies per year to one study per year.

Response: DCLS is sensitive to the expenses of small laboratories. DCLS held the current fees constant without increases for six years, however DCLS can no longer absorb increased operational costs another year without an impact to the mandated services it is to provide. As an indication of how costs have changed, the Consumer Price Index Inflation Calculator indicates the cost of living has increased ten percent since January 2013. This is reflected in the increased cost of both labor and non-labor items for the program's operation.

The program's current staffing needs and the current number of laboratories accredited by the program are reflected in the revised fees. The revised fees also include the statewide salary adjustments for FY2020.

2. Resolution Analytics, Fuquay-Varina, NC (secondary C46 lab)

This commercial lab maintains secondary accreditation with DCLS. The fees for their primary accreditations have risen dramatically over the last 10 years. The commenter stated that the DCLS increase in fees adds substantially to this financial burden. The commenter does not understand why they should be charged the same as a lab obtaining primary accreditation. Secondary accreditation requires only a paperwork review. The commenter also stated that the fee the lab would pay to DCLS is "much higher" than other states with which the laboratory maintains secondary accreditations. The commenter stated that fee increases should occur only for labs obtaining primary accreditation.

Response: There is no difference in the fees charged for primary and secondary laboratories by all the NELAP accreditation bodies (ABs) with two exceptions. Two accreditation bodies charge slightly lower fees for secondary accreditation. Commercial laboratories with primary accreditation from one AB may seek to provide commercial services in another state by applying for secondary accreditation. These fees paid for secondary accreditation are a part of the cost of doing business in multiple states.

While citing how much his total fees have increased over the past 10 years, the commenter attributed the majority of the increase to the laboratory's primary accreditation by another state accrediting body. While citing the total increase in the laboratory's fees over the past 10 years, the commenter did not provide information on what services or accreditations were held 10 years ago. The commenter's laboratory did not hold VELAP accreditation 10 years ago. The commenter has not provided information about the level of fees charged by the other ABs where this lab holds secondary accreditation so DCLS cannot comment on whether the revised fees are "much higher" than the other states with which the laboratory maintains secondary accreditation. The revised DCLS fees are in line with the other ABs' fee programs. See the specific fee levels for organic chemistry and radiochemistry and calculation of full laboratory fees by fee schedules from three states in the response to Comment #3, below, as examples.

3. Eurofins Eaton Analytical, LLC, South Bend, IN (secondary C46)

Based on a review of the latest invoice from DCLS, the commenter states that there would be a 45% increase in accreditation fees for his lab. The commenter stated that the increase seems unreasonably high since DCLS stated that the cost of living has risen only 10% since the last

revision to the fees. The commenter requested that DCLS consider lowering the proposed increase.

Response: The commenter provided the lab's latest invoice and adjusted it for the revised 1VAC30-46 fees. He noted that the proposed increase for his lab is an additional 45%.

The background document that accompanied the proposed fees lists three motivating factors for proposing the revised fees:

- The program's current staffing needs and the current number of laboratories accredited by the program.
- The statewide salary adjustments for FY2020.
- The increase in the cost of living since January 2013.

DCLS also increased fees for some categories over the general percentage increase for the base and other test categories. DCLS had underestimated the cost of evaluating these test categories which require more specialized assessor training as well as more time for data review and assessments than other categories. In addition to revisions to the organics and radiochemical testing fees described below, the proposed revisions include updates to the asbestos and aquatic toxicity fee categories. These updates were made in addition to the percentage increases applied across the fee tables to offset program costs.

Along with 21 other methods, this lab is accredited for 12 organic chemistry methods and 5 radiochemical methods for the same matrix. Organic chemistry and radiochemistry methods are complex. The increase in the fees for organic chemistry and radiochemistry were made to offset fees above the 25% increase per category for the remainder of the test categories for Chapter 46 laboratories. This accounts for the overall 45% increase in the fees for this laboratory.

The revised DCLS test category fee for organic chemistry with 1 matrix and 12 methods is \$1145. The revised DCLS test category fee for radiochemistry with 1 matrix and 5 methods is \$990.

Other accreditation bodies charge comparable fees for organic chemistry and radiochemistry.

ACCREDITATION BODY	FEES FOR ORGANIC CHEMISTRY	FEES FOR RADIOCHEMISTRY
Illinois	\$1000	\$1000
Kansas	\$1000 for each scope of accreditation	\$1000 for each scope of accreditation
Minnesota	\$1000-volatile organics; \$1000 other organics	\$750
New Jersey	\$235-NPW prep. Methods; \$840 each – chromatography, chromatography/MS	\$840
Pennsylvania	1 st matrix: \$850-purgeable VOCs; \$1750-extractable and semivolatile organic chemistry	\$950

A rough calculation of this laboratory's full program fees under the Pennsylvania program is \$8900 and under New Jersey's program is \$10,215. Fee systems among the TNI programs

vary considerably. For instance, New Jersey charges a supplemental fee of \$3500 for TNI accreditation in addition to its other fees. This laboratory's full program fee under the proposed VELAP revisions is \$5311.

DCLS based its revised fees on a close review of the cost of the program. For more on this review see the response to Comment #4 below. The program's statute requires DCLS to establish fees to offset the program's costs (Section 2.2-1105 C of the Code of Virginia). *Also see below for more information about the program's current scope.*

4. HRSD, Virginia Beach, VA (C46 primary lab)

"HRSD supports changes to the regulation that improve program effectiveness and efficiency, and ensure program sustainability, which may include adjustments to fees." HRSD notes that the fee increases are greater than 10% across the Board and vary from 15 to over 150 percent. The commenter stated that supporting information is lacking. The commenter stated that this precludes the development of meaningful comment and significantly diminishes the intended value of the requested review. The commenter stated that DCLS must develop text specifying how fee adjustments were made and then release this text with the proposed regulation for an additional comment period. "In addition, a system for adjusting fees should be developed and included in the regulation to ensure sustainability of the program and affordability for environmental laboratories moving forward."

Response: DCLS continues to appreciate HRSD's support of the environmental laboratory accreditation program. The program's statutory authority directs that the fees charged must cover the costs of this program. The purpose of the proposed fees is to offset these costs.

As noted in the response to Comment #3, the revised fees are not a 10% increase for the base and test category fees. Rather DCLS indicated in its background document that the cost of living in general had risen 10% since the last revision to the fees. This increase in the cost of living has affected everyone. DCLS had indicated in its background document that the fee revisions also accounted for the increase in salaries for its staff for Fiscal Year 2020 and the increase in the expenses to meet current staffing needs and expenses related to the current number of accredited laboratories. See the response to Comment #3 for the motivating factors for proposing the revised fees and the additional percentage increases to fees for complex test categories.

Other factors have contributed as well to the need for fee revisions. The program workload and the program staff had been evolving in size for a long while. The staff is now at a level that allows for the program to be managed appropriately for its size and scope. *See below for more information about the program's scope.* DCLS indicated in its background document that by the effective date (November 2015) of the 2013 revision of 1VAC30-46, for example, the fees were already somewhat inadequate in offsetting program costs, and that the current staffing needs and number of accredited laboratories for the programs are reflected in the revised fees.

DCLS has performed a budget analysis based on current program income vs. current program expenses. The proposed revised fees address the income to expense analysis. The proposed revised fees cover that portion of the scope below pertaining to the programs governed by 1VAC30-45 and 1VAC30-46.

Having provided the information above on the development of the fee revisions and the information below on the scope of the program, DCLS believes a second public comment period is unnecessary.

DCLS agrees that it is beneficial to both the agency and the accredited laboratories to revise fees as appropriate on a more frequent basis, perhaps every two years. The budget is reviewed at least on this frequency. This review would indicate whether a revision to the fees is necessary.

**CURRENT SCOPE OF THE
VIRGINIA ENVIRONMENTAL LABORATORY ACCREDITATION,
DRINKING WATER LABORATORY CERTIFICATION,
AND TUNING FORK CERTIFICATION PROGRAMS**

Staff: 7 laboratory certification officers, 1 administrative assistant, 1 manager

Number of Laboratories

Regulation/Program	No. of Laboratories
1VAC30-45 (noncommercial environmental)	88
1VAC30-46 (commercial)	140
• Primary	• 48
• Secondary	• 92
1VAC30-41 (drinking water)	91
• Primary	• 74
• Secondary	• 17
Tuning Fork laboratories	24
TOTAL	343

Workload

100 site visits per year, on average
 50 laboratories assigned to each assessor, on average
 Approximately 17,000 PT results received and logged per year

Scope of program offerings

625 methods
 1100 analytes
 7500 unique fields of certification (method+analyte+matrix)

All the public comments were sent directly to DCLS.

Changes made since the proposed stage

*Please list all changes that made to the text of the proposed regulation and the rationale for the changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. *Please put an asterisk next to any substantive changes.*

No changes to the proposed fees are being made as a result of the public comments received.