THOMAS P. DiNAPOLI
COMPTROLLER

110 STATE STREET
ALBANY, NEW YORK 12236

STATE OF NEW YORK
OFFICE OF THE STATE COMPTROLLER

December 9, 2019

Howard Zucker, M.D., J.D.
Commissioner
Department of Health
Corning Tower Building
Empire State Plaza
Albany, NY 12237

Re: Environmental Laboratory Approval Program
Report 2018-S-1

Dear Dr. Zucker:

Pursuant to the State Comptroller's authority as set forth in Article V, Section 1 of the State Constitution and Article II, Section 8 of the State Finance Law, we conducted an audit of selected aspects of the Department of Health's (Department) Wadsworth Center Environmental Laboratory Approval Program. The audit covered the period April 1, 2015 through July 16, 2019.

Background

The Environmental Laboratory Approval Program (ELAP) of the Wadsworth Center (Wadsworth) was established in 1984 and is responsible for the certification of laboratories performing environmental analyses on samples originating from New York State (NYS), thus ensuring the accuracy and reliability of these analyses. Accurate laboratory test results are essential to health assessment and disease or environmental exposure prevention.

ELAP issues certificates of approval/accreditation based on a combination of category-analyte-method/technology: *category* refers to the type of sample being tested (e.g., potable water), *analyte* refers to what is being measured (e.g., lead), and *method/ technology* refers to the kind of assessment used to test for an analyte. Currently, ELAP grants certification to commercial, self-monitoring, and government-operated environmental laboratories in the following fields of accreditation:

- Drinking (Potable) Water
- Non-Potable Water

- Solid and Chemical Materials (Solid and Hazardous Waste)
- Air and Emissions
- Medical Marijuana

Laboratories may only use testing methods for which they have ELAP approval.

ELAP is an approved accrediting authority under the National Environmental Laboratory Accreditation Conference Institute (NELAC/TNI), an independent non-profit organization, and its National Environmental Laboratory Accreditation Program (NELAP). ELAP standards conform to standards NELAC adopted for implementation in July 2003.

Most laboratories are granted either primary or secondary accreditation from ELAP. Primary accreditation is granted to all laboratories located in NYS and to out-of-state laboratories that do not hold NELAP/TNI accreditation from another NELAP-recognized accreditation body. Secondary accreditation is granted to laboratories located outside NYS and accredited by a NELAP/TNI-recognized state accreditation body. Accepting the accreditation status of a laboratory issued by another NELAP accreditation body is a condition of membership in NELAP. At times, NYS may serve as a second primary accreditation body for a laboratory whose home state may not accredit for a particular analyte (e.g., legionella), resulting in dual accreditation. In these cases, ELAP will review and provide accreditation for only the particular field of accreditation being sought.

As of July 2019, ELAP had 468 approved laboratories (287 in NYS, 168 in other states, and 13 outside of the United States). These laboratories were approved in the following fields: 176 for the analysis of air and emissions, 249 for the analysis of non-potable water, 247 for the analysis of potable water, 156 for the analysis of solid and hazardous waste, and 4 for the analysis of medical marijuana (labs can be approved for more than one category).

Results of Audit

We identified opportunities to improve documentation of on-site assessments for which Wadsworth has taken corrective action. However, we did not find a significant amount of other non-compliance with ELAP procedures and protocols in the areas reviewed that would cause us to question the sufficiency of Wadsworth's processes for certifying, monitoring, and enforcing regulations over environmental laboratories.

Approval Process

Laboratories seeking approval for a particular category must file an application with ELAP. Applications must also be submitted whenever there is a change in ownership or laboratory address or when applying for new technical personnel. Application packages for primary approval must include, at a minimum:

- An application form, which includes applicable qualifications for the Technical Director and Quality Assurance Manager and related documentation;

- A quality manual demonstrating that the laboratory has a quality system that meets the requirements of the program (new applicants only);
- Appropriate categorical application form(s); and
- Proficiency Test (PT) scores or a demonstration of capability when a PT is not available for the category-analyte-method/technology applied for (discussed below).

Laboratories applying to test medical marijuana must also obtain a controlled substance license from the Department's Bureau of Narcotic Enforcement. ELAP officials could not say how long it takes to obtain this license, but stated they will not accept an application without it.

Applications free of significant issues are marked for entry into the ELAP database, which assigns each laboratory a sequential ELAP identification number. Entry of a new laboratory's application into the database automatically initiates required on-site assessment scheduling. Applications for primary accreditation are required to be processed and approved as soon as possible, and no more than nine months from receipt. Delays can occur if all required documentation is not submitted, there are timing delays with scheduling an on-site assessment, or any prior administrative actions have been taken toward the applicant's owner and technical staff. For secondary accreditation, once a complete application package has been received, ELAP will issue certificates within 30 days. Once accredited, a laboratory maintains its status in that category for one year, April 1 through March 31.

To complete PTs, laboratories must obtain and analyze PT samples and report the results by method via the Department's Health Commerce System. Samples can be obtained from the Department or another approved PT provider. After a PT opens, laboratories have 45 days to report their results before the study closes.

In cases where a PT is not available, demonstrations of capability are required and must be submitted as part of the application. To complete demonstrations of capability, laboratory management spikes samples with known amounts of an analyte and laboratory analysts must calculate the amount of the analyte within an acceptable range of the known amount. Analysts must pass at least four spiked samples or they have to repeat the demonstration of capability.

We reviewed a judgmental sample of 10 of the 53 newly accredited laboratories and found that, prior to receiving accreditation, all 10 laboratories met the requirements cited above.

Maintaining Accreditation

Proficiency Testing

To maintain accreditation, laboratories must participate in two PTs per year for each accreditation they maintain (category-analyte-method/technology; fields of PT). The laboratory must achieve a passing score, on an ongoing basis, in two out of three

successive PTs. The U.S. Environmental Protection Agency's (EPA) Office of Water imposes additional requirements for potable water PTs. Laboratories failing to maintain a passing score on an ongoing basis in two out of three successive PTs will be suspended on an individual analyte basis. Laboratory accreditation can be reinstated by successfully analyzing PTs.

We obtained PT data covering tests from February 15, 2016 through April 23, 2019. In total, we identified 21 exceptions (failed PT tests that the Department did not identify) out of 39,520 fields of PT reviewed (.05 percent). (This includes a review of 30,738 fields of PT applicable to all analytes and 8,782 specific to requirements for potable water.) For each exception identified, ELAP has made changes within its database to identify and prevent these issues going forward. However, because the data we obtained largely pre-dated these changes, we still identified some exceptions.

On-Site Assessments

On-site assessments of ELAP-accredited laboratories take place approximately every two years, and are one of the primary means of determining a laboratory's capabilities, qualifications, and compliance with ELAP regulations and NELAC/TNI standards. On-site assessments are performed by ELAP Environmental Laboratory Consultants or Department-employed Technical Support Staff. Assessments are normally announced and are set up one to three months in advance on mutually agreeable dates.

To complete assessments, the consultants and Technical Support Staff follow the 55-page ELAP Quality Systems checklist to help determine if environmental laboratories are complying with applicable standards in a uniform manner. In addition to this checklist, ELAP has developed more specific checklists based on the laboratory being reviewed, including chemistry, microbiology, radon, and critical agents.

The consultants and Technical Support Staff are responsible for entering all deficiencies cited on the assessment checklists into the ELAP database. The deficiency report and all hard copy documentation are reviewed and approved by ELAP's quality assurance officer using an assessment review form. As part of this review, the quality assurance officer cross-walks the deficiencies listed in the checklists to a summary printout of the deficiencies entered into the ELAP database (deficiency review report). The quality assurance officer stated she may make changes during her review and, if so, includes an updated deficiency review report that reflects these changes (and should match the final deficiency report). She may also mark changes on the assessment review form and deficiency review report.

Within 35 days of receipt, the laboratory is required to respond to the deficiency report with a corrective action plan, including evidence of completed corrective actions. The assessment will not be closed until all deficiencies are completely addressed. To identify and track "at-risk" laboratories, a deficiency grading system is used to rate laboratories' conformance to the NELAC/TNI quality system.

According to ELAP officials, any laboratory with repeat deficiencies or large-scale gross quality system failures receives a proposal for suspension with the deficiency report. Laboratories must respond to the proposal for suspension within ten calendar days and must also complete a corrective action plan. Laboratories that receive a suspension also receive a follow-up visit in six to nine months.

We reviewed a judgmental sample of 50 assessments as well as the 3 remaining unreviewed Wadsworth general assessments (2 from the Florida accreditation body and 1 from the American Association for Laboratory Accreditation bodies, which are referenced in more detail later under Outside Audits) with deficiencies cited (53 total), selected from a list of the on-site assessments completed by ELAP officials for the period April 1, 2016 through April 23, 2019. For 50 of 53 assessments reviewed, we found the quality systems checklist was fully completed. Full completion of the checklist was not required on the remaining three reviews, as two checklists were completed by the Florida accreditation body as part of its review of Wadsworth laboratories and the remaining review was for dual accreditation. We found all 53 assessments showed evidence of management review. However, for seven assessments, the deficiencies cited in the final report and assessment checklists did not match, and officials were unable to support these changes. We identified 9 deficiencies on the checklist that were not on the initial deficiency report or final assessment report (of 822 deficiencies cited on the checklists, or 1.09 percent). We also identified 4 deficiencies on the initial deficiency report and final assessment report that did not appear on the checklist (of 800 deficiencies cited on the final assessment reports, or .50 percent). For one additional review, we identified an incorrect deficiency code cited in the report. As a result of our review, ELAP's quality assurance officer adjusted her assessment review form to show where changes were made as a result of her review. The form now shows both the preliminary and final number of suggestions cited, findings cited, and whether any of the findings were repeat findings.

We also reviewed the non-supplemental inspections (routine assessments that count toward the biennial inspection requirement) from the list of on-site assessments and found no laboratories were missing an assessment and only 17 of 416 (4.1 percent) laboratories did not receive a timely assessment (within 2.5 years); 2.51 to 2.87 years had passed between these assessments.

Finally, we reviewed all 560 inspections on the list of on-site assessments to examine the timeliness of the deficiency reporting process. Overall, we found that the assessment deficiency reporting process is occurring on time.

Outside Audits

We found ELAP and Wadsworth regularly receive assessments from outside organizations, including the following:

- As a certified accreditation body of NELAP, ELAP receives evaluations every three years. NELAP's most recent report dated September 13, 2017 reviewed compliance with 2009 TNI standards and maintained ELAP's accreditation in the areas of potable water, non-potable water, solid and chemical materials, and air/

emissions. NELAP identified four findings of non-conformity and two concerns. ELAP submitted adequate documentation to address all of the non-conformities identified. As part of our review, we found evidence to show two of the non-conformities had been corrected. The remaining non-conformities were not part of our review. Regarding the two concerns, ELAP was not required to address these matters.

- The EPA also conducts an assessment of ELAP every three years to review and evaluate its conformance to the requirements of the EPA Drinking Water Laboratory Certification Program. The assessment concluded that the Department continues to operate an acceptable Drinking Water Laboratory Certification Program.

- In May 2017 and January 2019, the Florida accreditation body reviewed the three Wadsworth environmental testing laboratories' accreditations against the standards in place at that time (2003 NELAC and 2009 TNI standards). These assessments take place every two years. Accreditations reviewed included drinking water (including for the chemicals PFOA and PFOS), non-potable water, solid/chemical material, and air/emissions. In total, 24 deficiencies were cited in 2017 and 8 deficiencies were cited in 2019. For each deficiency, the Wadsworth laboratories identified a root cause and developed an adequate corrective action plan with expected implementation dates. All three laboratories were found to be in compliance with standards.

- The American Association for Laboratory Accreditation assessed the Department's PT program in December 2016 and January 2019. These assessments take place every other year. The review found the program meets requirements subject to corrective action for any deficiencies cited. In total, eight deficiencies were cited in 2016 and two deficiencies were cited in 2019. For each deficiency, a root cause was identified and an adequate corrective action plan was indicated, with a completion/implementation date and supporting documentation.

Wadsworth Laboratories' On-Site Assessments

While the Florida accreditation body completes on-site assessments of the Wadsworth environmental testing laboratories every two years, selected programs are NYS-specific accreditations (not accredited by NELAP) and, therefore, are not reviewed by Florida. These include critical agents (added August 2004), medical marijuana (added October 2015), and legionella (added June 2016). ELAP officials explained that another state cannot review these programs in NYS because all labs are required to use assessment methods NYS has approved. Other states that do have medical marijuana, legionella, and/or critical agents have different requirements and approved methods, and don't offer the same accreditation, so they are unable to review NYS' program. In addition, marijuana is a controlled substance and cannot legally be transported across state lines.

For these programs, ELAP officials conduct the on-site assessments of the Wadsworth laboratories as part of the accreditation body function. Officials explained that they have no involvement in validation of the method or other communication with the

laboratories. Their role is to review only those specific technical areas that are not audited by another state. We reviewed all of the on-site assessment reports for our scope period as well as any related corrective action plans. Where required, we found corrective action plans were adequately completed and included a determination of a root cause, expected implementation dates, and supporting documentation.

As part of our review of the assessment process, we evaluated five of these ELAP reviews (all the general reviews with deficiencies cited). We found evidence of management review through the assessment review form. In addition, changes were made to the deficiencies on one of the five reviews, and these changes were adequately documented. Further, we found that Wadsworth is required to perform its own internal audits of all of its programs and these audits are reviewed when the Florida accreditation body or ELAP audits Wadsworth (as applicable).

Until April 2019, the three Wadsworth laboratories were the only NYS laboratories accredited to perform testing of medical marijuana, and, as of July 1, 2019, they had tested 9,310 medical marijuana samples. Officials explained that, since November 29, 2016, they have solicited environmental laboratories to apply to perform medical marijuana testing. However, only one private laboratory has successfully completed the application process. Officials stated the required Bureau of Narcotic Enforcement controlled substance license has been an issue. In addition, marijuana legally cannot be transported across state lines, so no out-of-state laboratories are eligible.

Disposal of Medical Marijuana Samples by Wadsworth Laboratories

Each laboratory is required to have procedures for the transportation, receipt, handling, protection, storage, retention, and/or disposal of samples. We reviewed the Standard Operating Procedures maintained by the Wadsworth laboratories for the disposal of medical marijuana samples and met with Wadsworth officials to discuss these procedures. The Wadsworth procedures require documentation from receipt to destruction of all medical marijuana samples received, as they are a controlled substance. All samples are required to be maintained in a secure location, and two people are required to be present any time a medical marijuana sample is out of storage. There is no central log book to document every sample received. Instead, Wadsworth maintains records for each individual sample. Documents maintained include:

- Microbiology Inventory Log - Kept by the Microbiology Lab, the log is an inventory of each sample received and information about whether it was transferred for destruction or completely used in initial testing.
- Form DEA-41 - Required by the DEA for registrants destroying controlled substances, the form documents each sample, date, and method of destruction and is signed by two witnesses.
- Chain of Custody Record - Documents the movement of a sample from storage to the laboratory for testing. The chain of custody must remain unbroken.
- Controlled Substance Inventory Record - Details the weights of the sample from

receipt to lockbox storage, each time the sample is taken out of the lockbox for testing, and at destruction.

We reviewed a judgmental sample of 10 of the 2,664 medical marijuana samples received between December 6, 2018 and June 7, 2019 to determine whether documentation of disposal was maintained, as required. We reviewed the four forms listed above (including a separate Form DEA-41 completed by the Microbiology Lab). We found all forms had been completed, as required.

Audit Scope, Objective, and Methodology

We audited certain aspects of the Department's oversight of the Wadsworth ELAP for the period from April 1, 2015 through July 16, 2019. The objective of our audit was to determine whether Wadsworth is adequately certifying, monitoring, and enforcing selected regulations over environmental laboratories.

To accomplish our objective and assess internal controls related to our objective, we interviewed ELAP officials and reviewed relevant laws, regulations, policies, and procedures. We also became familiar with and assessed the Department's internal controls as they relate to the fulfillment of its responsibilities for ELAP. From a list of 53 newly accredited laboratories, we selected a judgmental sample of 10 for review to determine whether they completed all requirements before receiving their accreditation. We selected this sample from those laboratories that had completed the application process and identified NYS as a primary accreditor, and we factored in the length of time it took to complete the review. We obtained PT data covering tests from February 15, 2016 through April 23, 2019 and reviewed this data to identify any laboratories that did not meet PT requirements to maintain accreditation. We also obtained a list of the 560 on-site assessments completed by ELAP officials for our scope period and reviewed all the inspections on the list to examine the timeliness of the deficiency reporting process. In addition, we reviewed the non-supplemental inspections from the list to identify any missing or late inspections. We selected a judgmental sample of 50 general assessments as well as the 3 remaining unreviewed Wadsworth general assessments (with deficiencies cited) from ELAP's list of on-site assessments for a detailed review. We selected this sample to include assessments from each year of our audit scope, based on the grades received and the length of time the assessments took to close out. Finally, we obtained a listing of the 2,664 medical marijuana samples received by Wadsworth from December 6, 2018 to June 7, 2019. Since Wadsworth retains samples for three months after initial testing for product stability reasons, we determined our sample of ten would be selected from December 2018 (three), January 2019 (four), and February 2019 (three). From this list, we selected a judgmental sample of ten medical marijuana samples for review to determine whether documentation of disposal was maintained, as required. For all of the judgmental samples we reviewed, the results cannot be projected to the population as a whole.

We conducted our performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our

findings and conclusions based on our audit objective. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

In addition to being the State Auditor, the Comptroller performs certain other constitutionally and statutorily mandated duties as the chief fiscal officer of New York State. These include operating the State's accounting system; preparing the State's financial statements; and approving State contracts, refunds, and other payments. In addition, the Comptroller appoints members to certain boards, commissions, and public authorities, some of whom have minority voting rights. These duties may be considered management functions for the purposes of evaluating organizational independence under generally accepted government auditing standards. In our opinion, these functions do not affect our ability to conduct independent audits of program performance.

Reporting Requirements

We provided a draft copy of this report to Department of Health officials for their review and comment. We considered their comments in preparing this final report, and they are attached to the end of it. Department officials were pleased that we found significant compliance with procedures and protocols for areas that we reviewed.

Major contributors to this report were Ed Durocher, CIA; Brandon Ogden; Vicki Wilkins, CIA; Matthew Conway; Jeffrey Dormond; and Chelsey Fiorini.

We wish to thank the management and staff of the Department for the courtesy and cooperation extended to our auditors during this audit.

Sincerely,

Brian Reilly, CFE, CGFM
Audit Director

cc: Lori Conway, Department of Health

Agency Comments

NEW YORK STATE OF OPPORTUNITY. Department of Health

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
Commissioner

SALLY DRESLIN, M.S., R.N.
Executive Deputy Commissioner

November 6, 2019

Mr. Brian Reilly, Audit Director
Office of the State Comptroller
Division of State Government Accountability
110 State Street – 11th Floor
Albany, New York 12236-0001

Dear Mr. Reilly:

The Department of Health acknowledges receipt of the OSC's draft report 2018-S-1, Environmental Laboratory Approval Program (ELAP), and is pleased to note OSC found significant compliance with ELAP procedures and protocols in the areas reviewed (Wadsworth's processes for certifying, monitoring and enforcing regulations over environmental laboratories).

Thank you for the opportunity to comment.

Sincerely,

Sally Dreslin, M.S., R.N.
Executive Deputy Commissioner

cc: Marybeth Hefner
Diane Christensen
Brad Hutton
Adrienne Mazeau
Jill Taylor
Michael Ryan
Victoria Derbyshire
Jeffrey Hammond
Jill Montag
Michael Spitz
Jessica Lynch
Lori Conway