ALAN G. HEVESI
COMPTROLLER

110 STATE STREET
ALBANY, NEW YORK 12236

STATE OF NEW YORK
OFFICE OF THE STATE COMPTROLLER

November 13, 2003

Antonia C. Novello, M.D., M.P.H., Dr. P.H.
Commissioner
Department of Health
Corning Tower
Empire State Plaza
Albany, NY 12237

Re: Controls Over Environmental Laboratories
Report 2002-S-56

Dear Dr. Novello:

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 have audited the Department of Health's controls over environmental laboratories. Our audit covered the period April 1, 2000 through May 1, 2003.

A. Background

The Environmental Laboratory Approval Program (ELAP), administered by the Department of Health (Department), certifies laboratories that perform analyses on environmental samples originating from New York State (State). These environmental samples include potable and non-potable water, air and emissions, and solid and hazardous waste. ELAP's mission is to protect the public health by ensuring that the laboratories generate accurate and reliable data for assessing the quality of the environment. To achieve its mission, ELAP issues standards for laboratories and monitors compliance with those standards. ELAP operates under the State Public Health Law, Section 502 and Title 10, Part 55-2 of the New York Codes, Rules and Regulations (regulations). Every two years, ELAP undergoes an independent review from the National Environmental Laboratory Approval Program (NELAP), a national accrediting authority. ELAP is a self-sustaining program that recovers its annual appropriation from certification fees charged to the laboratories.

To become certified in this State, a laboratory must: complete an ELAP application; be directed by a qualified individual; pass periodic proficiency tests; and pass an on-site inspection. Certification is normally for one year, but can extend beyond a year unless ELAP terminates or suspends certification. To remain certified, a laboratory must comply with all conditions listed on its

application, correct all deficiencies noted during on-site inspections, perform satisfactorily in at least two out of three ongoing proficiency tests, and pay its certification fee.

ELAP certifies 725 laboratories that are located in New York State, 30 other states and 7 foreign countries. New York State is the primary accrediting authority for 664 of these laboratories, while other states or countries are the primary accrediting authority for the remaining 61 laboratories. The 664 laboratories must meet the certification requirements and also comply with ELAP's internal procedures, which require proficiency tests every six months and a full inspection every two years. ELAP conducts the certification of the 61 laboratories and the proficiency tests, but routine inspections are the responsibility of the primary accrediting authority.

Seven inspectors from ELAP's central office perform proficiency tests and conduct certifications and inspections of laboratories. Each inspector is assigned a different geographical region of the State, plus a share of the laboratories located in other states and countries. Each inspector is responsible for about 95 of the 664 laboratories and, on average, inspects three to four laboratories per month.

ELAP has written policies and procedures for the inspection and certification process, and annually conducts internal reviews of the inspection and certification processes. ELAP produces a monthly list of laboratories that are due for their two-year inspections and distributes these monthly reports to each of the inspectors for tracking and scheduling. ELAP also produces and reviews monthly productivity and activity reports that show the total number of inspections performed during the month and the number of laboratories each inspector reviewed. ELAP officials also use these monthly reports to conduct reviews of the completeness of inspection files.

If an inspector notes deficiencies during an inspection, the laboratory must resolve the deficiencies and obtain the inspector's approval to resume testing. In the case of minor deficiencies, such as an addition needed to complete a procedure manual, the inspector reviews additional information from the laboratory documenting that the deficiency has been corrected. In the case of more serious deficiencies, the inspector performs an on-site visit to verify the correction has been made. Most laboratories are certified to test multiple substances. If a laboratory fails a proficiency test and is disqualified from testing for a particular substance (e.g., substance A), this disqualification does not affect its overall ELAP certification or its certification to test for other substances. Once a laboratory demonstrates that it has corrected the problem, its certification to test for substance A is reinstated. Enforcement actions are referred to an investigation unit.

B. Audit Scope, Objectives and Methodology

We audited the Department's oversight of environmental laboratories for the period April 1, 2000 through May 1, 2003. The objectives of our performance audit were to determine if environmental laboratories are certified and inspected in compliance with State regulations and procedures, and if inspection or certification deficiencies are corrected and appropriate enforcement actions taken.

To accomplish our objectives, we reviewed applicable laws, rules and regulations; interviewed ELAP staff to determine what tools they use to monitor laboratories, technical directors and inspection results; obtained and reviewed policies and/or procedures issued relative to

certifications, inspections, deficiencies and enforcement activities; and interviewed laboratory inspectors to determine how laboratories under their jurisdiction are monitored by ELAP. We reviewed the files for a judgmental sample of 25 of 664 laboratories operating during our audit period to ensure the files contained the appropriate documentation showing laboratory accreditation applications, laboratory director qualifications, requests for accreditation in specific fields, proficiency test results, on-site assessment checklists and any deficiency reports with laboratory responses. We made our judgmental selection of 25 laboratories to obtain a sample of inspections performed by each of ELAP's seven inspectors (six files from one inspector; four files from one inspector; and three files from each of five inspectors). To test the timeliness of deficiency reporting, we selected a judgmental sample of eight laboratories from ELAP's log of 139 deficiencies. Our testing was limited to these 139 deficiencies that occurred after ELAP instituted new procedures in January of 2003.

We conducted our audit in accordance with generally accepted government auditing standards. Such standards require that we plan and perform our audit to adequately assess the practices of the Department that are included in our audit scope. Further, these standards require that we understand the Department's internal control structure and its compliance with those laws, rules and regulations that are relevant to the operations included in our audit scope. An audit includes examining, on a test basis, evidence, supporting transactions recorded in the accounting and operating records and applying such other auditing procedures as we consider necessary in the circumstances. An audit also includes assessing the estimates, judgments and decisions made by management. We believe our audit provides a reasonable basis for our findings, conclusions and recommendations.

We use a risk-based approach when selecting activities for audit. This approach focuses our audit efforts on those operations that we identified through a preliminary survey as having the greatest probability for needing improvement. Consequently, finite audit resources are used to identify where and how improvements can be made. Thus, little effort is devoted to reviewing operations that may be relatively efficient and effective. As a result, our audit reports are prepared on an "exception basis." This report, therefore, highlights those areas needing improvement, and does not address activities that may be functioning properly.

C. Results of Audit

We determined that the Department generally has sufficient controls in place to provide reasonable assurance that ELAP operates according to regulations and procedures for certifying and inspecting environmental laboratories and resolving inspection or certification deficiencies. However, the Department could further improve ELAP's operating efficiency and gain better assurance that laboratories promptly correct identified deficiencies by: reducing or eliminating inspection backlogs; including all required inspection documents in laboratory files; and presenting inspection results to laboratories within ELAP's required timeframes. ELAP should also retain documentation to explain the conclusions reached as a result of internal control assessments.

1. Overdue Inspections

According to ELAP's policies, existing laboratories are to be inspected every two years. New laboratories are to be inspected once during the first year of operation, and every two years thereafter. We reviewed ELAP's monthly report of laboratories due for inspection during our audit period, as of April 9, 2003. The inspection due-date we used was two years from the last inspection plus a three-month extension that ELAP typically uses when monitoring due-dates. We determined that, of the 664 laboratories, 641 (97 percent) were inspected according to ELAP's timeframe standards. We identified 23 laboratories (three percent) that were overdue for inspections. Of these, 20 existing laboratories were overdue for a two-year inspection and three new laboratories were overdue for a first-year inspection. The number of days overdue for an inspection ranged from 22 to 282 days, as follows: 13 laboratories were between 22 and 88 days overdue; 7 laboratories were between 104 and 180 days overdue; and 3 laboratories were between 239 and 282 days overdue.

ELAP officials attribute the inspection backlog to various factors, including the following: new assignments (3 laboratories were new, and 8 laboratories were newly reassigned to a different inspector); laboratory caused delays (7 laboratories); and lapses in inspector oversight (5 laboratories). Inspections are a critical component of ELAP's process for ensuring that laboratories are operating according to State regulations. Laboratories that are not currently inspected could have deficiencies that may lead to problems in the testing of environmental substances. Laboratories with deficiencies could potentially report incorrect results on samples tested. The Department should take the steps necessary to address the inspection backlog, especially for laboratories that are overdue for their two-year inspections, and ensure that inspections are conducted according to ELAP's policies.

2. Retaining Documentation

According to ELAP's policies, ELAP must retain all inspection and certification documentation. This documentation includes laboratory accreditation applications; laboratory director qualifications; requests for accreditation in specific fields; proficiency test results; on-site inspection checklists; deficiency reports; and laboratory responses to deficiency reports. We reviewed the inspection files for our sample of 25 of 664 laboratories and determined that ELAP adhered to its documentation policy for all but 3 of our sampled laboratories. For two of these three laboratories, the files did not contain the inspection deficiency reports or the laboratories' responses to the deficiency reports; the file for the third laboratory did not contain the most recent on-site inspection checklist.

ELAP officials could not determine why documentation was missing from the files. Inspection documentation plays an important role in the inspection process. Before performing an on-site inspection, the inspector reviews any previous inspection checklists, deficiency reports and responses to these deficiency reports to ensure that previous deficiencies were corrected. If this documentation is not located in the laboratories' inspection files, the inspector would be unable to focus the inspection on the cited areas, and the laboratory could continue to operate without having corrected noted deficiencies. Moreover, the on-site inspection checklist is the sole document that depicts the detailed results of the inspection. Without the checklist, ELAP officials cannot adequately demonstrate that an inspection took place because there is no paper trail to document that it occurred. The Department should ensure that all required inspection documentation is included in

the laboratories' inspection files, particularly the on-site inspection checklists, the deficiency reports and the laboratories' responses to deficiency reports.

3. Timeliness of Deficiency Reports

According to ELAP's policies, deficiency reports resulting from an inspection must be submitted to the laboratory within 30 days of the inspection. In addition, the inspector must review the laboratory's response to the deficiency report within 30 days of receiving the response. In December 2002, ELAP conducted its own internal review and determined inspectors did not always comply with these time requirements. In its review of deficiency reports for 274 laboratories, ELAP noted that reports for 121 laboratories (44 percent) were not issued within the required 30 days. ELAP also examined the responses received from 223 laboratories, and determined that the responses from 42 of these laboratories (19 percent) were not reviewed by the inspectors within the required 30 days.

ELAP's corrective action plan recommended developing the steps necessary to timely issue deficiency reports, and including the status of deficiency reports in ELAP's monthly productivity and activity reporting process. ELAP officials implemented these recommendations in January 2003 and reported that timeliness of deficiency report issuance had improved. For example, ELAP reported that the percentage of deficiency reports issued late had dropped to 9.7 percent (12 of 124), and that the percentage of laboratory responses reviewed late had decreased to 11 percent (5 of 45).

To determine whether the deficiency reporting process did improve, we selected a judgmental sample of 8 laboratories from ELAP's log of 139 deficiencies. These deficiencies occurred between January 1, 2003 and April 17, 2003, after ELAP implemented its new procedures in January 2003. We found that, for one of these eight laboratories, ELAP had not issued the deficiency report within 30 days of inspection, and had not reviewed the laboratory's response within 30 days of receipt. Thus, although ELAP reports to have taken the steps necessary to correct problems related to timeliness, our audit results show that problems with timeliness still exist. Even though we identified one exception, this exception represented 12.5 percent of our sample, comparable to the results of ELAP's internal testing that identified similar results. Laboratories need to be informed of deficiencies in a timely manner so they can take the action necessary to generate accurate and reliable data for assessing the quality of the environment. The Department should ensure that deficiency reports are sent to laboratories within 30 days of inspection and that inspectors review laboratories' responses within the 30 days of receipt.

4. Documenting Annual Risk Reduction Evaluation Reviews

Every year, ELAP conducts an Internal Controls Risk Reduction Evaluation Review to verify compliance with ELAP's policies and procedures. This annual review addresses three areas: certification and regulation of environmental laboratories; research and development relating to proficiency test samples; and collection of certification fees.

According to the most recent review conducted in 2002, ELAP rated controls in each of these areas as adequate to provide reasonable assurance that the function was being accomplished without vulnerability or risk of failure. However, we could not verify ELAP's observations and conclusions of reasonable assurance and low risk. ELAP officials did not retain documentation supporting these

conclusions. The Department should ensure ELAP officials retain the supporting documentation for observations and conclusions made during this annual review.

Recommendations

1. *Address the backlog in laboratory inspections, especially for those laboratories whose two-year inspections are overdue, and ensure that inspections are conducted according to ELAP's policies.*

2. *Make sure laboratories' inspection files contain all required documentation, including on-site inspection checklists, deficiency reports and laboratories' responses to deficiency reports.*

3. *Send deficiency reports to laboratories within 30 days of the inspection and review laboratories' responses within 30 days of their receipt.*

4. *Establish written procedures for recording and retaining supporting documentation for observations and conclusions made during the annual Internal Controls Risk Reduction Evaluation Review.*

We provided draft copies of this report to Department of Health officials for their review and comment. We considered their comments in preparing this report. Department officials generally agreed with the report's recommendations and identified actions taken or planned to implement them. A complete copy of the Department's response is included as Appendix A.

Within 90 days after the final release of this report, as required by Section 170 of the Executive Law, the Commissioner of the Department of Health shall report to the Governor, the State Comptroller and the leaders of the Legislature and fiscal committees, advising what steps were taken to implement the recommendations contained herein, and where recommendations were not implemented, the reasons therefor.

Major contributors to this report were Al Kee, Sheila Emminger, Todd Seeberger, Brian Krawiecki, David Bell, Sri Ramen, Wendy Matson and Nancy Varley.

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

Very truly yours,

Kevin M. McClune
Audit Director

cc: Deirdre A. Taylor

STATE OF NEW YORK
DEPARTMENT OF HEALTH
Corning Tower The Governor Nelson A. Rockefeller Empire State Plaza Albany, New York 12237

Antonia C. Novello, M.D., M.P.H., Dr.P.H.
Commissioner

Dennis P. Whalen
Executive Deputy Commissioner

October 22, 2003

Kevin M. McClune
Audit Director
Office of the State Comptroller
110 State Street
Albany, New York 12236

Dear Mr. McClune:

Enclosed are the Department of Health's comments on the Office of the State Comptroller's (OSC) draft audit report (2002-S-56) entitled "Controls Over Environmental Laboratories."

Thank you for the opportunity to comment.

Sincerely,

Dennis P. Whalen
Executive Deputy Commissioner

Enclosure

Appendix A

cc: Dr. Eadon
Ms. Goldin
Mr. Howe
Dr. Jackson
Dr. Martin
Mr. Reed
Ms. Ryan
Ms. Stack
Dr. Sturman
Mr. Van Slyke

Department of Health
Comments on the
Office of the State Comptroller's
Draft Audit Report
2002-S-56 Entitled
"Controls Over Environmental Laboratories"

The following are the Department of Health's (DOH) comments on the Office of the State Comptroller's (OSC) draft audit report (2002-S-56) entitled "Controls Over Environmental Laboratories."

Recommendation #1:

Address the backlog in laboratory inspections, especially for those laboratories whose two-year inspections are overdue, and ensure that inspections are conducted according to ELAP's policies.

Response #1:

The Environmental Laboratory Approval Program (ELAP) Quality Assurance Officer continues to monitor inspection backlogs and issues a monthly report to the ELAP Director. The backlog of three percent (23 of 664 laboratories) noted by the auditors has now been reduced to 1.7 percent (only 11 of 664 laboratories) as of October 1, 2003. It is projected that this remaining backlog will be eliminated by the end of December 2003.

Recommendation #2:

Make sure laboratories' inspection files contain all required documentation, including on-site inspection checklists, deficiency reports and laboratories' responses to deficiency reports.

Response #2:

Some inspection checklists were missing from ELAP administrative office laboratory files at the time of the audit because they had been retained by the field-based consultants. ELAP's standard operating procedures (SOP) manual has now been revised to ensure that consultants return checklists to the ELAP files once all inspection deficiencies are dealt with, and that copies of all inspection documentation in the consultants' possession also be retained in ELAP's files. As an additional control measure, the ELAP Quality Assurance Officer now reviews the contents of randomly selected laboratory files monthly to ensure that all required inspection documentation listed in the audit report is available in each laboratory's file. Monthly reviews conducted since the OSC audit have not detected any files with missing documentation. Deficiency reports are also stored electronically.

Recommendation #3:

Send deficiency reports to laboratories within 30 days of the inspection and review laboratories' responses within 30 days of their receipt.

Response #3:

The timeliness of issuing deficiency reports and reviewing laboratories' deficiency responses is being monitored monthly and reported to the ELAP Director. Consultants are fully aware of documented SOP requirements regarding timeliness in these areas, and know that adherence to such timeliness requisites is an integral part of consultants' annual performance reviews. Any instances of late report issuance and response review are isolated to a few consultants with the largest backlogs. As the backlog of overdue inspections is being consistently reduced (see Response #1 above), it is expected that timeliness will also be achieved.

Recommendation #4:

Establish written procedures for recording and retaining supporting documentation for observations and conclusions made during the annual Internal Controls Risk Reduction Evaluation Review.

Response #4:

The ELAP Quality Assurance Officer routinely conducts an internal annual audit of the program. The review includes selected laboratory accreditation cases, complaints, disputes and appeals, consultant training records, and the timeliness of inspection reports. The audit report is presented to the ELAP Director, who develops and files a corrective action plan. The SOP for this annual audit has now been amended to state that the audit is conducted to satisfy the documentation requirements of the Department's Internal Controls Risk Reduction Evaluation review (ICRRE) for the area of certification and regulation of environmental laboratories. Please note that the ICRRE does not verify compliance with the accrediting standards of the National Environmental Laboratory Program (NELAP), as stated in the audit report, but rather with the Department's standards. The second area, research and development relating to proficiency test samples, has been already removed from the most recent ICRRE, since ELAP's certification activities – the subject of the OSC audit – are not dependent on its research efforts. A new and more comprehensive internal control document is being prepared for the third area, collection of certification fees, which will require supporting documentation for annual risk reduction evaluations of fee collection procedures. This document is expected to be finalized within three months.

* ***Note***

State Comptroller's Note:
We modified our report accordingly.