Alan G. Hevesi
COMPTROLLER

OFFICE OF THE
NEW YORK STATE COMPTROLLER

DIVISION OF STATE SERVICES

NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE

OFFICE OF RADIOLOGICAL HEALTH

Report 2004-N-7

AUDIT OBJECTIVES

Our objectives were to determine whether the internal control system of the Office of Radiological Health (Office) provides reasonable assurance (1) facilities using radioactive materials are inspected in a timely manner, (2) such facilities have their licenses renewed in a timely manner, and (3) the facilities' correction of safety violations is effectively tracked by the Office.

AUDIT RESULTS - SUMMARY

The Office is responsible for regulating the possession and use of radioactive materials in New York City, when such materials are to be used for non-industrial purposes such as medical diagnosis and treatment. The Office licenses individual physicians, institutions such as hospitals and academic facilities, and sister City agencies so they can use radioactive materials for these purposes. It also inspects the facilities at certain prescribed intervals to determine whether they are complying with various health and safety requirements.

We found a number of improvements are needed in the Office's internal control system. In response to our draft report, the Department agreed that improvements in the Office's administrative internal control system would aid in maintaining effective oversight of health and safety issues related to the use of radioactive materials in the City.

We found a significant percentage of the Office's inspections are not done within the required timeframes. For example, Priority 1 facilities (i.e., those posing the greatest risks to public health) are to be inspected every 15 months. However, 7 of the 22 Priority 1 inspections (32 percent) in our random sample were not done on time. We also found the inspections are not always planned, done and documented according to Office requirements. (See pp. 4-7)

Radioactive materials licenses expire after five years. We found long delays in the license renewal process. We recommend the Office re-engineer the license renewal process to reduce the delays. (See pp. 7-9)

The Office's license and inspection tracking database contains information about violations discovered during inspections of facilities. However, we found that the database does not show the severity of the violation, does not indicate whether a re-inspection is needed, whether a re-inspection was done, or whether corrective actions have been taken. We conclude the Office could more efficiently and effectively monitor the correction of safety violations if additional information about the violations is recorded on the database. (See pp. 10-11)

This report, dated April 25, 2006, is available on our website at: http://www.osc.state.ny.us. Add or update your mailing list address by contacting us at: (518) 474-3271 or
Office of the State Comptroller
Division of State Services
State Audit Bureau
110 State Street, 11th Floor
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BACKGROUND

The New York City Department of Health and Mental Hygiene (Department) is responsible for regulating the possession and use of radioactive materials in New York City, when such materials are to be used for non-industrial purposes such as medical diagnosis and treatment. The Department is given this responsibility by the New York State Sanitary Code, the New York City Health Code, and an agreement between New York State and the United States Nuclear Regulatory Commission (NRC). The Department's Office of Radiological Health (Office) is one of four components that comprise the New York State Agreement with the NRC. The other three components are the New York State Department of Health, the New York State Department of Labor, and the New York State Department of Environmental Conservation.

To fulfill this responsibility, the Department issues licenses to the facilities in New York City that use radioactive materials for non-industrial purposes. It also inspects these facilities to determine whether they are complying with the requirements relating to their radioactive materials. The facilities must have a license from the Department to possess and use radioactive materials and must comply with the conditions that are specified in their licenses. The facilities also must comply with various laws, rules and regulations governing the possession and use of radioactive materials. The license conditions, laws, rules and regulations are intended to protect the health and safety of the facilities' employees, the facilities' patients and the public in general.

Radioactive materials licenses may be issued in the names of individuals (such licenses are generally issued to physicians' offices) or in the names of institutions (such licenses are generally issued to hospitals). As of January 2005, there was a total of 356 active radioactive materials licenses in New York City. There were 335 individual licenses and 21 institutional licenses.

Applications for radioactive materials licenses must be approved by the Department's Office of Radiological Health (Office). The applications are reviewed by staff scientists in the Office. The licenses expire after five years, at which time a facility must apply for a license renewal if it intends to keep using radioactive materials. Generally, a facility needs only one radioactive materials license for its purposes, but in some instances, a facility may need more than one license.

All licensed facilities must be inspected by the Office at certain intervals. If safety violations are detected during an inspection, the violations are to be described in a written inspection report, which is to be sent to the facility within 30 days of the inspection. If the violations are serious, the facility will be ordered to take corrective actions and be re-inspected to determine whether such actions were in fact taken. Facilities that commit serious safety violations or repeatedly fail to comply with safety requirements may be fined and may have their licenses modified or revoked.

In the fiscal year ended June 30, 2005, the Office was budgeted 25 full-time equivalent employees, at a cost of $1.1 million, including five inspectors in the Materials Inspections Unit and two scientists in the Licensing Unit. A Director and the Chief of Radiological Materials are responsible for the overall management of these two units.

In addition to overseeing the use of radioactive materials, the Office also responds to emergencies involving these materials (such as transportation accidents and the inadvertent contamination of individuals), provides public education about radioactive

materials, and oversees the use of radiological equipment such as x-ray units. Our audit report 2001-N-9, issued in November 2002, addressed the process used by the Office in inspecting such equipment.

AUDIT FINDINGS AND RECOMMENDATIONS

Inspections and License Renewals

We found, in many instances, facilities using radioactive materials are not inspected by the Office as timely as required. In addition, in some instances, the inspections were not properly documented. We also found long delays in the license renewal process. We conclude a number of improvements are needed in the Office's operating practices and internal controls.

Office officials acknowledged the inspection and license renewal processes were not always timely in the past. However, they believed they had made progress in reducing delays and that the processes were more timely during the 2004-05 fiscal year. They also acknowledged that "paperwork for the inspections may not have been thoroughly completed."

Timeliness of the Inspection Process

We found a significant percentage of the Office's inspections are not done within the required timeframes. In its response to our preliminary findings, the Office admitted to "glitches" in its license and inspection tracking database. We recommend the Office expand the uses for its database and correct its weaknesses to ensure all required inspections are done in a timely manner.

According to regulations issued by the Nuclear Regulatory Commission and adopted by the Office in its Policy and Procedures Manual, the Office must inspect facilities using radioactive materials at least once during their first six months of licensed operation and at certain intervals thereafter. To determine whether the Office did these inspections within the required timeframes, we reviewed the timeliness of the inspections that were done for 38 selected licenses during the 35-month period July 1, 2002 through May 31, 2005. We randomly selected the 38 licenses from the 356 that were active as of January 4, 2005.

Initial Inspections

During this 35-month period, an initial six-month inspection should have been done for 5 of the 38 licenses, as these five licenses were newly issued. However, we found the initial inspection was significantly late for all five of these licenses. For four of the licenses, the initial inspection was done between 443 and 660 days late. The initial inspection for the fifth license was done 319 days late. Thus, the five newly licensed facilities could have used radioactive materials for at least 10 months, and as long as 22 months, beyond the six-month interval, before they received their first inspection.

When newly licensed facilities are inspected promptly, hazardous operating conditions can be identified and corrected before employees or patients are exposed to unsafe levels of radiation. However, when the initial inspection is delayed, unsafe conditions may persist and increase the risk of unhealthy radiation exposure.

The inspections after the initial inspection (called cyclical inspections) are scheduled automatically on the basis of information in the Office's license and inspection tracking database. Included in this information is each facility's license issuance date, license expiration date, and most recent date of inspection. The database uses the most recent

date of inspection to calculate the date by which the next required inspection should be completed.

Initial inspections, however, are not scheduled automatically by the database. Rather, they are scheduled manually by the inspectors. We note the database could use the license issuance date to calculate the date by which the initial inspection should be completed, and thus increase the likelihood the inspection would be done on time. We recommend the Office automate the scheduling process for initial inspections.

Cyclical Inspections

Cyclical inspections are to be done at certain intervals, depending on the priority assigned by the Office to the licenses. Facilities with Priority 1 licenses (i.e., those posing the greatest risks to public health) are to be inspected every 15 months (one year plus a three-month grace period) after the initial inspection, facilities with Priority 2 licenses are to be inspected every 30 months (two years plus a six-month grace period), and facilities with Priority 3 licenses are to be inspected every 45 months (three years plus a nine-month grace period).

Our random sample of 38 licenses included 9 Priority 1 licenses, 22 Priority 2 licenses, and 7 Priority 3 licenses. According to the license and inspection records maintained by the Office, during our 35-month audit period, a total of 51 cyclical inspections should have been done at the facilities holding these 38 licenses. We compared the dates these inspections should have been done to the dates the inspections were actually done (as indicated by the inspection documentation maintained in the Office's files for each license).

We found the Priority 3 inspections were generally done within the required timeframe. However, about one-third of the Priority 1 and Priority 2 inspections were not done within the required timeframe and were sometimes done significantly late. The results of our review are summarized as follows:

- A total of 22 inspections were required for the Priority 1 licenses in our sample. We found 15 of the inspections were done on time (i.e., within 15 months of the prior inspection) and seven of the inspections (32 percent) were not. Six of these seven inspections were done 43 to 237 days late. The remaining inspection had yet to be done and was already 100 days late at the time of our review.

- A total of 24 inspections were required for the Priority 2 licenses in our sample. We found 17 of the inspections were done on time (i.e., within 30 months of the prior inspection) and seven of the inspections (29 percent) were not. Six of these seven inspections were done 23 to 326 days late. The remaining inspection had yet to be done and was 79 days late at the time of our review.

- A total of five inspections were required for the Priority 3 licenses in our sample. We found four of these inspections were done on time (i.e., within 45 months of the prior inspection) and one inspection was not. This inspection was done 83 days late.

As a result of these delays in doing cyclical inspections, there is an increased risk that unsafe conditions at the facilities may not be detected and corrected in a timely manner.

Analysis of the Database

Our review of the 38 randomly selected licenses indicates, in many instances, both initial and cyclical inspections are not done

within their required timeframes. To further determine whether initial and cyclical inspections were done on time, we analyzed certain information in the Office's license and inspection tracking database for all 359 active licenses therein as of April 1, 2005. Specifically, we were able to identify 60 initial inspections that had been done since July 1, 2002. For these 60 initial inspections, we compared the inspection date recorded in the database to the license issuance date recorded in the database to determine whether the inspection was done within six months of the issuance date, as required. We did not verify the recorded dates against supporting documentation, so it is possible some of the dates were erroneously recorded in the database.

As is summarized in the following table, according to the information in the database, 42 of the 60 initial inspections (70 percent) were not done within the required timeframe:

Initial Inspections Done Late	
Days Late	**Late Inspections**
1 to 150	13
151 to 300	11
301 to 450	12
Over 450	6
Total	42

We also analyzed certain information in the database relating to cyclical inspections. Specifically, for each of the 255 licenses that were active as of April 1, 2005 and required a cyclical inspection during our audit period, we compared the date of the most recent cyclical inspection, as recorded in the database, to the date of the prior inspection. We did not verify the recorded inspection dates against supporting documentation, so it is possible some of the dates were erroneously recorded in the database.

According to the information in the database, 121 of the 339 cyclical inspections (36 percent) were not done within the required timeframes; 65 of these 121 inspections were done late, while the remaining 56 inspections had yet to be done. The following two tables indicate the extent to which the 121 inspections were delayed:

Cyclical Inspections Done Late	
Days Late	**Late Inspections**
1 to 100	34
101 to 200	9
201 to 400	11
401 to 700	10
Over 700	1
Total	65

Cyclical Inspections Not Yet Done But Overdue	
Days Overdue	**Overdue Inspections**
1 to 100	2
101 to 200	8
201 to 400	8
Over 400	38
Total	56

Thus, the results of our database analysis are consistent with the results of our review of our random sample of licenses. Office officials provided no explanation for the late inspections. However, we noted, in a number of instances, important license and inspection information in the database was incomplete or inaccurate. We believe these data errors and omissions were partly responsible for the late inspections, as the database was unable to calculate the next inspection date accurately.

For example, for 38 licenses, the next inspection due date recorded in the database was obviously incorrect, because it preceded the date of the last inspection. In some instances, the next inspection due date (e.g., September 27, 2002) preceded the date of the last inspection (e.g., October 1, 2003) by more than one year. In such instances, the

database cannot possibly calculate the next inspection date accurately. We also noted the license issuance date and license expiration date were missing for 13 licenses. We recommend the Office develop a process for ensuring the information in the database is complete and accurate.

The Office Director acknowledged the next inspection due date recorded in the database, due to programming errors, is not always correct, but stated Office staff can manually schedule the inspections when the calculated dates are obviously wrong. We agree the inspections can be scheduled manually, but believe it would be better to rely on the automated scheduling process.

Completeness of the Inspection Report

We found Office inspections of facilities using radioactive materials were not always documented according to Office requirements.

The Office's Policy and Procedures Manual (Manual) contains detailed guidelines for inspectors to follow when planning, doing and documenting inspections of facilities using radioactive materials. To determine whether the Office's inspectors complied with these guidelines, we examined the inspection reports, and the inspectors' field notes supporting these reports, for the 49 cyclical inspections that were done for the 38 sampled licenses during our audit period. (As was previously noted, 2 of the 51 inspections that should have been done during this period had yet to be done at the time of our review.)

We found most of the inspections were planned, done and documented in accordance with the Manual. However, 8 of the 49 inspections were not properly documented in complete accordance with the Manual, as certain required inspection procedures were not documented in the field notes. Specifically, the inspectors are expected to complete a standard questionnaire as part of every cyclical inspection and certain questions in the questionnaire were not answered in these eight inspections.

For example, in one of the inspections, the inspector failed to answer the questions under the category *Emergency Actions*. These questions relate to the facility's compliance with the requirement that it post appropriate emergency procedures in all restricted areas. The inspector marked "NA" in the *Emergency Actions* section of the field notes, but provided no explanation of why the questions were not applicable. In another inspection, the inspector provided no answer to the question asking whether the facility's radiation levels were "as low as reasonably achievable," a matter the Office considers critical to the health and safety of the facility's patients and employees. The inspectors did not explain why the questions were not answered. The eight inspections related to five Priority 1 licenses and three Priority 2 licenses.

When critical inspection questions are not answered, there is less assurance that all safety hazards have been identified and corrected.

Timeliness of the License Renewal Process

We found facilities generally did not apply for license renewals in a timely manner, and the Office often did not process their renewal applications in a timely manner.

A radioactive materials license expires after five years. Facilities seeking to renew their license must make a formal application for renewal. The application is reviewed by a staff scientist in the Office, who must determine whether any changes should be

made in the conditions of the license and whether there are any reasons the license should not be renewed.

According to the New York City Health Code, if a facility applies for a license renewal 30 or more days before its license is due to expire, the license will be considered valid until the Office completes its review of the application. However, if the facility does not file its application by then, the license will expire as scheduled.

If a license expires because a facility is late in submitting its renewal application, the facility is allowed by the Office to continue using radioactive materials as it did under the license. The Office sends the facility a letter acknowledging its receipt of the renewal application, and the facility can use this letter to obtain new supplies of radioactive materials. If a facility does not apply for a license renewal, it cannot lawfully continue to possess and use radioactive materials after its license expires.

To determine whether license renewal applications are submitted in a timely manner (i.e., 30 or more days before the license is due to expire), we reviewed the renewal applications that were submitted for the licenses in our sample between July 1, 2002 and April 14, 2005. During this period, renewal applications were submitted for 11 of the 38 sampled licenses, and we found nine of these applications were not submitted in a timely manner, as follows:

- Five of the applications were submitted before the license was due to expire, but they were not submitted 30 days before the license was due to expire. Rather, they were submitted between 1 and 28 days before the scheduled expiration date.
- Four of the applications were submitted after the licenses had already expired. The four applications were submitted between 32 and 125 days after the scheduled expiration date.

We note the Office does not notify facilities when their licenses are about to expire to remind them of the need to submit a renewal application. We recommend the Office send such notifications.

Once a renewal application has been submitted to the Office, it must be reviewed and evaluated by the Office's staff scientists. There are no limits, either in law or in the Office's regulations, on the length of the review and evaluation process. We examined the length of the process for the renewal applications in our sample. We found it often took the Office several months to complete its review and evaluation of renewal applications.

For example, it took the Office an average of about 285 days (more than nine months), and as long as 970 days (2.7 years), to complete its review and evaluation of the following nine renewal applications:

License	Date Renewal Application Received	Date License Renewed	Days Taken to Complete Renewal Process
A	4/29/04	7/26/04	88
B	11/01/02	2/05/03	96
C	3/24/04	7/08/04	106
D	5/25/04	10/07/04	135
E	8/14/04	2/01/05	171
F	5/14/03	11/17/03	187
G	7/30/04	4/15/05	259
H	4/12/03	10/08/04	555
I	12/03/01	7/30/04	970

We believe these processing times are excessive. Office officials disagreed. They stated renewal applications may be complex and numerous communications may be required between the Office and the facility before the evaluation process can be completed. We recommend the Office re-engineer the license renewal process to minimize the delays in the review and evaluation of renewal applications.

We also note, as of April 14, 2005, renewal applications had not been submitted for four of the licenses in our sample. The four licenses expired between August 31, 2000 and June 30, 2002. Thus, the four facilities holding these licenses may have been using radioactive materials for between 2.8 and 4.6 years without valid licenses.

We further note, when we analyzed the information in the Office's license and inspection tracking database, we found indications many facilities were operating with expired licenses. According to the information in the database, as of April 1, 2005, a total of 71 of the 359 active licenses were expired. Moreover, 25 of these 71 licenses had been expired for more than 24 months, as follows:

Number of Months Expired	Number of Licenses
1 to 24	46
25 to 48	13
49 to 72	7
Over 72	5
Total	**71**

It thus appears, in April 2005, a significant percentage of the facilities using radioactive materials in New York City were either waiting for their license renewal applications to be approved or had yet to submit an application for their expired licenses. In either case, we question whether the Office's regulation of these facilities was as vigilant as the law intended it to be.

In their response to our preliminary audit findings, Office officials stated "the expirations were predominantly among low-risk Priority 3 facilities." The officials further stated the Office "plans to contact any expired or about to be expired licensees to remind them to submit their applications in a timely manner or risk violations." The officials also noted one of the four facilities in our sample with an expired license (its license had been expired for 4.6 years) was no longer active and another of the four facilities (its license had been expired for 3.9 years) planned to stop using radioactive materials.

We note, while Priority 3 facilities pose a lower risk to public health and safety than Priority 1 and Priority 2 facilities, they pose such a risk nonetheless and should be appropriately regulated. We also note, if licenses are no longer active, their inactive status should be reflected in the Office's records.

Recommendations

The Director of the Office of Radiological Health should:

1. Develop a process for ensuring the information in the license and inspection tracking database is complete and accurate.

(The Department agreed with our recommendation, stating that it currently has a continuous quality assurance program that is performed on the database. In addition, it looks forward to the implementation of a new and comprehensive data tracking and management database system (REMtrack), scheduled for mid-2007.)

2. Use information in the license and inspection tracking database to automate the scheduling process for initial inspections.

(The Department agreed with our recommendation, stating its REMtrack system will automatically assign newly issued licenses to field personnel for inspection.)

3. Use information in the license and inspection tracking database to strengthen the scheduling process for cyclical inspections to ensure they are done in a timely manner.

(The Department agreed with our recommendation, indicating it is designing REMtrack to automatically present due dates and other pertinent information, allowing for more efficient, accurate, automated, as well as interactive, staff scheduling.)

4. Strengthen management controls to ensure inspections are planned, done and documented in accordance with the guidelines in the Manual.

(The Department agreed with our recommendation, describing ways it has initiated increased oversight in the inspection program.)

5. Develop a process for routinely notifying facilities when their licenses are about to expire.

(The Department agreed with our recommendation, stating a reminder letter is being developed to inform licensees that their licenses are due to expire.)

6. Re-engineer the license renewal process to minimize the delays in the review and evaluation of renewal applications.

(The Department agreed with our recommendation, indicating REMtrack will automate much of the physical production aspects of the license renewal process which should reduce some of the time involved.)

Safety Violations

The Office does inspections to determine whether facilities with radioactive materials licenses are complying with various public health and safety requirements. If an inspector determines a facility is not complying with one or more requirements, the inspector is to analyze the violations and classify them, in accordance with guidelines contained in the Manual, as either Severity I, Severity II or Severity III violations. The three types of violations are defined in the Manual as follows:

- Severity I violations are the most serious type of violation. Such violations either have caused a public health hazard or will cause a public health hazard if they are not corrected. Typical examples include radiation exposures in excess of allowed amounts, unauthorized releases of radioactive materials, unsafe transportation of such materials, inadequate security over stored materials, unreported loss or theft of radioactive materials, falsification of records, the recurrence of prior violations, and a combination of violations indicating the radiation safety program is not being implemented.

- Severity II violations may lead or contribute to Severity I violations if they are not promptly corrected. Typical examples include improper waste disposal practices, inadequate instruction of facility personnel, and possession of unauthorized amounts or forms of radioactive materials.

- Severity III violations are the least serious type of violation and have no

direct impact on health and safety. A typical example is noncompliance with recordkeeping/documentation requirements.

If any Severity I violations are detected during an inspection, the facility will be ordered to take corrective actions. The facility should then be re-inspected by the Office to determine whether appropriate corrective actions were taken.

To determine whether the Office's internal control system provides reasonable assurance prompt corrective actions are taken when Severity I violations are detected, we reviewed the information on the Office's license and inspection tracking database. We found violations detected during inspections are recorded in the database (a total of 20 violations were recorded for the period July 1, 2002 through April 1, 2005). However, the database does not show the seriousness of the violations (i.e., whether they were classified as Severity I, Severity II or Severity III), does not indicate whether a re-inspection was needed, does not indicate whether a re-inspection was done, and does not indicate whether corrective actions have been taken. Rather, the only information recorded about violations are abbreviations that generally describe the nature of the violations (e.g., "VRR," which could be either a Severity I or Severity II violation). As a result, the database cannot be used to ensure facilities take prompt corrective actions when Severity I violations are detected.

Office officials stated the database is not used to monitor corrective actions. Rather, separate paper files are used for this purpose. We recommend the Office record all relevant violation information on the database and use the database to monitor re-inspections and facility corrective actions. Using a single automated system for all such monitoring purposes would be more efficient and more effective than using an automated system for some monitoring purposes and a separate paper system for other monitoring purposes.

Recommendation

7. Record all relevant violation information (e.g., the severity of the violation, whether a re-inspection was needed, whether a re-inspection was done, and whether corrective action was taken) on the license and inspection tracking database, and use the database to monitor re-inspections and facility corrective actions.

   (The Department agreed with our recommendation, stating its new REMtrack database is being designed to capture the recommended improvements.)

AUDIT SCOPE AND METHODOLOGY

We did our performance audit according to generally accepted government auditing standards. We audited certain actions taken by the Office in licensing and inspecting facilities using radioactive materials. Our audit covered the period July 1, 2002 through May 31, 2005. We focused on the Office's internal controls and the recordkeeping systems associated with these licensing and inspection activities. We randomly selected 38 of the 356 radioactive materials licenses that were active as of January 4, 2005, and reviewed inspection and license renewal documentation relating to these licenses.

Our random sample consisted of 27 individual licenses and 11 institutional licenses. The documentation we reviewed included license applications, issued licenses, field notes prepared by Office inspectors, inspection reports, Office memoranda, and correspondence between the Office and the facilities. We also reviewed data that was downloaded from the Office's license and inspection tracking database. In addition, we

interviewed Office officials, sent a questionnaire about the inspection process to 324 licensed facilities, and visited ten of the facilities holding licenses in our random sample to follow up on our questionnaire and learn more about the inspection process.

As is our practice, at the outset of the audit we requested a representation letter from Department management. The representation letter is intended to confirm oral representations made to the auditors, and to reduce the likelihood of misunderstandings. Agency officials normally use the representation letter to assert that, to the best of their knowledge, all relevant financial and programmatic records and related data have been provided to the auditors. They affirm either that the agency has complied with all laws, rules and regulations applicable to their agency's operations that would have a significant effect on the operating practices being audited, or that any exceptions have been disclosed to the auditors. However, officials of the Mayor's Office of Operations have informed us that, as a matter of policy, Mayoral agency officials do not provide representation letters in connection with our audits. As a result, we lack assurance from Department officials that all relevant information was provided to us during this audit.

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, several of which are performed by the Division of State Services. 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 purposes of evaluating organizational independence under generally accepted government auditing standards. In our opinion, these management functions do not affect our ability to conduct independent audits of program performance.

AUTHORITY

The audit was done according to the State Comptroller's authority as set forth in Article V, Section 1 of the State Constitution and Article III of the General Municipal Law.

REPORTING REQUIREMENTS

We provided a draft copy of this report to Department officials for their review and comment. The Department's response pointed out that certain issues raised in the draft needed to be either put into proper perspective or clarified. Accordingly, certain matters presented in the draft report were revised or deleted in this final report based on the response. Department officials generally agreed with our recommendations and indicated actions planned or taken to implement them. A complete copy of the Department's response is included as Appendix A. Appendix B contains State Comptroller comments which address certain points in the Department's response.

Within 90 days of the final release of this report, we request the Commissioner of the New York City Department of Health and Mental Hygiene report to the State Comptroller, advising what steps were taken to implement the recommendations contained herein, and where recommendations were not implemented, the reasons therefor.

CONTRIBUTORS TO THE REPORT

Major contributors to this report include William Challice, David R. Hancox, Albert Kee, Stuart Dolgon, Todd Seeberger, Robert Tabi, John Ames, Zenaida Bhuiyan, Joseph Giaimo and Dana Newhouse.

APPENDIX A - AUDITEE RESPONSE

THE CITY OF NEW YORK
DEPARTMENT OF HEALTH AND MENTAL HYGIENE
OFFICE OF THE COMMISSIONER

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February 10, 2006

William P. Challice
Audit Director
Office of the State Comptroller
123 William Street, 21st Floor
New York, NY 10038

Re: Draft Audit Report on the New York City Department of Health and Mental Hygiene's Office of Radiological Health's Radioactive Materials Program; Report No. 2004-N-7

Dear Mr. Challice:

We have reviewed the draft audit report and appreciate your consideration of our comments on the findings and recommendations.

We are pleased that this audit identified no adverse health and safety conditions in our regulated facilities and agree that improvements in the Office's administrative internal control system would aid in maintaining our effective oversight of health and safety issues related to the use of radioactive materials in this City. That being said, the Department feels that the auditors' expectations of the Office's current radiological database capabilities are not realistic. As was explained at the outset of this audit, the current database was designed in 1996 as a simple tool to store license data such as license expiration dates, initial license inspection due dates and license inspection due dates based on license priorities. It was never intended or designed to store specific license inspection information nor was it designed to be used as suggested in the report. In any event, the Department of Health and Mental Hygiene strongly supports the use of technology to enhance operational efficiency as recommended by your office.

It should be noted that the Department was fully aware of the capabilities of the current database prior to the audit and actively sought funding for the development of a new management and database system that would encompass all of the recommendations subsequently made by the auditors. This new system, REMtrack, has been funded and is now in development.

Attached to this letter are detailed comments on this draft audit report. We appreciate the courtesy and consideration of your audit staff in the performance of this audit as well as the consideration and recommendations your office has made on behalf of the affected public. If you have any questions or need further information, please contact Charles Troob, Assistant Commissioner, Business Systems Improvement at (212) 219-5044.

Sincerely,

Thomas R. Frieden, M.D., M.P.H.
Commissioner

TRF/jp

NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE
BUREAU OF ENVIRONMENTAL SCIENCES AND ENGINEERING
OFFICE OF RADIOLOGICAL HEALTH

Statement in Response to the New York State Comptroller's Audit

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The following statements address the Office of the State Comptroller's (OSC) Draft Report: "New York City Department of Health and Mental Hygiene (the Department) Office of Radiological Health (the Office) Report 2004-N-7" issued on January 4, 2006.

AUDIT RESULTS - SUMMARY

The summary of audit results fails to provide the proper perspective to the audit findings. The Department does not disagree with the literal findings and does agree with "the Office's controls need to be strengthened." However, improving protocols would result only in a more efficient administration of the program. We strongly disagree with OSC stating that internal controls need to be strengthened to "reduce the risk of [health or safety] conditions [at the regulated facilities] in the future." * Comment 1

The Department also finds that OSC failed to provide the proper perspective to the findings for the reason that the entire audit period was treated as a whole, although the data indicate that controls did improve within that time period (between 2002 and the end of the audit period in 2005). OSC cites that one scheduled inspection had occurred "nearly eight months late," but does not note that the scheduled inspection was from 2002. * Comments 1 & 2

Again, OSC can be interpreted as alarmist when stating that "facilities may operate for years with expired licenses" without pointing out that: 1) facilities cannot receive radiological materials without a current license; 2) the licensing process is complex and may require a great deal of back and forth between ORH and the licensee; and 3) facilities continue to be inspected to ensure safety. * Comment 1

With respect to the finding "the Office could more …effectively monitor facilities and facility corrective actions if it made better use of its automated information system" the Office acknowledges the current database system does not track the severity of the violations. However, nowhere in the report does OSC find any situation where the Office is not currently effectively conducting compliance inspections and ensuring that corrective actions were taken. With respect to the Office's radioactive materials database, the agency has secured funding for and has begun work on the creation of a new and comprehensive data tracking and management system, referred to as "REMtrack" (Radiation Equipment and Materials Tracking System). We look forward to the successful completion and implementation of this new system in order to maximally enhance program efficiency. We anticipate REMtrack to be operational by mid 2007. * Comment 1

* See State Comptroller Comments, page 24

BACKGROUND

- The Department would like you to add that the Office of Radiological Health (Office) is one of four components that comprise the New York State Agreement with the U.S. Nuclear Regulatory Commission. The other three components are the New York State Department of Health, the New York State Department of Labor, and the New York State Department of Environmental Conservation.

- The report requires clarification as to whom the Office issues licenses. Radioactive materials licenses are issued to individual physicians, to institutions such as hospitals and academic facilities, and to sister agencies in New York City.

* Comment 1

- The Director and the Chief of Radiological Materials (referred to in the report as the "Head Scientist") are responsible for the overall management of the Inspections and Licensing Sections.

- The budget for ORH was not correctly portrayed. At the end of June 30, 2005, CTL and grant headcount was budgeted at 25 (not 26) at a cost of $1.1 million (not $1.3 million).

AUDIT FINDINGS AND RECOMMENDATIONS

Inspections and Licensing Renewal

The statement that "materials are not inspected as frequently as required" should be modified to "inspection of materials may not have been done as timely as required." The Office acknowledges that there were instances when inspections were done past the recommended time period; however, all routine inspections were conducted.

* Comment 1

Based upon the audit scope and findings, the report is unfounded in its statement that "the inspections may not be as thorough as intended." The auditors did not accompany inspectors and cannot comment on the thoroughness of the inspection. OSC needs to change the sentence to read "paperwork for the inspections may not have been thoroughly completed."

* Comment 1

The Department feels that OSC was provided the information necessary to "… confirm that the (inspection and renewal) processes were in fact more timely during the 2004-2005 fiscal year" even though the auditors stated that "our analysis did not compare earlier periods to more recent periods." The Department found that 5 of the 7 findings were for scheduled inspections from early 2003 or before, 2 from 2004 and none from 2005. Certainly this could and should have been reported for a fair presentation.

* Comment 1 & 2

* See State Comptroller Comments, page 24

Timeliness of the Inspection Process

The statement "the database is not used to schedule initial inspections" is incorrect. The database is used to schedule initial inspections in the following manner: once the date of license issuance is input into the system, the database automatically sets an inspection date for 6 months past this date. The Chief of Radiological Materials Section and the Program Director utilize this database information to schedule inspections with staff during weekly meetings. The database information is one of a set of factors and information sources involved in establishing an inspection schedule.

* Comment 1

Initial Inspections

OSC has no basis for declaring that "facilities had been using material for at least 20 months and as long as 27 months before their first inspection. The auditors appear to be confusing the date of licensing with the date of receipt of materials and the onset of operations. Specific to this audit's findings, the Department provided mitigating documentation showing that one licensee did not have materials on site. Another was a mobile van with delayed entry into New York City.

* Comment 1

Another case references the situation where an inspection date was listed in the database but no inspection report was found in the files, suggesting the possibility that the inspection had not been performed (further suggesting the inspection was three years overdue). The referenced inspection documentation was in fact located and is available for the auditor's review.

* Comment 1

Although OSC did acknowledge that the auditors "saw no indication these five newly licensed facilities were unsafe in the months preceding their initial inspection", the Department feels that OSC fails to provide the proper perspective to the audit findings when making the statement "the Office needs to improve scheduling process for initial inspections so that newly licensed facilities are not subject to an increased risk of unhealthy radiation exposure." Of the 5 facilities that were late, 4 licenses were issued to individuals and the fifth was issued to a mobile PET (Positron Emission Tomography) company that was licensed for check sources used to calibrate the equipment. The facilities hiring the services of this company are the ones that are licensed and responsible for the radioactive materials used for these scans.. The amount of radioactive material in private physicians' offices is considerably less than can be found in institutional licensees, but is nonetheless thoroughly reviewed, as are the credentials and training of the proposed users. Second, all of the late initial inspections cited in this report stem from license requests from 2002. The Department has made significant progress in scheduling initial inspections.

* Comment 1

Cyclical Inspections

* See State Comptroller Comments, page 24

Similarly, for the Cyclical Inspections, the auditors do not place the findings in proper perspective when stating that because of the "…delays in doing cyclical inspections, there is an increased risk unsafe conditions at the facilities may not be detected and corrected in a timely manner." The dates used in the report to indicate the date of the inspection are based on the date that the inspection is completed, not the date inspectors are first on site. The auditors were advised that the inspection process can be lengthy depending on the number of sites involved with the particular facility.

* Comment 3

It should also be noted that the day-to-day oversight of a facility's radiation safety program is the responsibility of the Radiation Safety Officer (RSO), named on each radioactive materials license. The training and qualifications of each RSO is thoroughly checked prior to license issuance and whenever there is a change of RSO. Events at facilities that jeopardize or may jeopardize public and worker health and safety are required to be reported to the Office and are promptly investigated by our inspectors.

Finally, the Department would like to point out that of the 15 cyclical inspections conducted late, more than half (8) were from 2002, with 2 of them having scheduled inspection dates that preceded the audit scope.

Analysis of Database

The Department believes that the following statement is based on a misunderstanding, and should be removed from the report: "There was a default date of January 1, 1990 entered. Therefore, we believe no initial inspection was reported for these 15 licenses as of April 1, 2005."

* Comment 1

The Department uses a default date (January 1, 1990) on the database to indicate that the licenses have not been issued yet and are not ready for an inspection. Once the issuance date is input, the system records an inspection due date 6 months past this date. No inspection was required for any facility with a date of January 1, 1990.

* Comment 1

As for the related recommendation," the Office develop a process for ensuring the information in the database is complete and accurate.", we again point out that licenses with default dates are not missing information-they simply indicate that license applications have been received and are under review and have not been issued yet. These entries are not missing information, nor are they inaccurate. Going forward, we anticipate REMtrack to more effectively and clearly identify those facilities that have applied for a license but do not yet have a license issue date.

Thoroughness of the Inspection Process

Based upon the audit findings, OSC is unfounded in its statement that "inspections of facilities …are not always planned, done and documented according to Office requirements. As a result the inspections may not be a thorough as intended." Since the scope of the audit was a review of records and database, OSC cannot comment on the

* Comment 1

* See State Comptroller Comments, page 24

conduct of an inspection and cannot make any statements about the thoroughness of the inspection.

The findings were not put in proper perspective regarding planning. OSC correctly states "inspections are to be guided by the results of the facility's previous inspections." However the example given - "subsequent inspection did not follow up on [a recommended amendment during a previous inspection.] is not an inspectional health and safety finding but an observation made by the inspector to the licensee. Any action to amend the license must be made by the licensee. In this case, the Office will follow up with the licensee in order to verify whether the two doctors listed on the license are no longer, and permanently, associated with the facility – if this is the case, the Office will request the licensee to submit the appropriate license amendment request.

* Comment 1

The Department does agree that documentation was at times not performed according to protocol. With the anticipated completion and implementation of REMtrack, the inspections will be performed using a computer, enhancing the inspection documentation process.

Timeliness of the License Renewal Process

The following statement by OSC is erroneous: "We found facilities generally did not apply for license renewals in a timely manner, and the Office often did not process their renewal applications in a timely manner. As a result of these delays, some facilities operate for years with expired licenses." OSC fails to take into account that The U.S. Nuclear Regulatory Commission (NRC) and the Agreement States consider that licenses with "timely filed" renewal applications are not expired, and may operate under conditions of those licenses until they are issued renewals. Suppliers of radioactive materials are required to make sure that facilities are currently authorized to possess this material before shipping.

* Comment 1

The Department strongly disagrees with the statements "the Office's oversight is compromised when facilities are allowed to operate with invalid licenses. There is also an increased risk to public health and safety since renewal applications may not be approved as submitted and may not be approved at all." The Office's oversight of licensed activities is not compromised when facilities are in the application review process. Materials and activities that are employed during this process had been reviewed and approved during the previous application process and licensees are inspected under these license conditions until their new application has been approved. Neither the NRC nor the New York Agreement States consider these to be "invalid licenses."

* Comment 1

OSC made inappropriate use of examples. OSC states: "We note the long delays in the existing license renewal process can adversely affect some facilities. For example, in response to our audit survey questionnaire, a physician stated, when his license expired, he was unable to obtain certain radioactive materials until his renewal application was approved." This statement is correct (the statement was made by the RSO, not a physician, according to information the Office received from the OSC), but is out of

* Comment 1

* See State Comptroller Comments, page 24

context given the following additional information. This facility had submitted a renewal application in January 21, 2004, and, instead of submitting all necessary information at the beginning of the renewal process, subsequently sent in 7 separate requests to add additional radiological materials to the license during the period February 24, 2004 through July 1, 2004. These piecemeal submissions did significantly delay the license renewal process as each individual request required additional time to evaluate and approve. The facility was granted a renewal on July 29, 2004.

The OSC statement "We believe these processing times are excessive" fails to take into account the complexity of the license renewal process. While all processes can be reengineered, this has to be balanced with assuring that health and safety issues are not compromised. We intend to automate much of this process with our REMtrack system, but reviewer oversight and thoroughness will remain the guiding principle.

OSC cites four licenses that had expiration dates between August 31, 2000 and June 30, 2002 and states "Thus the four facilities may have been using radioactive material unlawfully for between 2.8 and 4.6 years." We point out again that expired licenses that do not have timely filed letters cannot receive new radioactive materials.

* Comment 4

RECOMMENDATIONS

The Director of the Office of Radiological Health should:

1. Develop a process for ensuring the information in the license and inspection tracking database is complete and accurate.

Response:
Currently, the Office has a continuous QA program that is performed on the database on a bi-annual basis. License folders are pulled from files and license and inspection data is compared to database printouts. Information in the database is corrected and updated where indicated. The Office began to actively plan and seek funding for REMtrack well in advance of this audit and looks forward to REMtrack's successful implementation in mid-year 2007.

2. Use information in the license and inspection tracking database to automate the scheduling process for initial inspections.

Response:
The Office is now requiring the Licensing Review Section to bring newly issued licenses into the weekly Radiation Materials meeting and these are immediately assigned for initial inspection. When REMtrack is in place, the system will automatically assign newly issued licenses to field personnel for inspection.

* See State Comptroller Comments, page 24

3. Use information in the license and inspection tracking database to strengthen the scheduling process for cyclical inspections to ensure they are done in a timely manner.

Response:
As described, inspection due date and license type information data are drawn from the database and used to assist scheduling in a weekly staff meeting presided by both the Director and the Chief of Radiological Materials Section. The Office and Department note and agree with the stated and implied import of efficient and timely scheduling. It may not have been made thoroughly apparent to the auditors that the Office has been using the current database for a number of years and knows how to best utilize the present system and in a manner which does not compromise the mission of the program. The Bureau of Informatics and Information Technology, with the full support and assistance of the Office, is designing REMtrack to automatically present due dates and other pertinent information and will allow for more efficient, accurate, automated, as well as interactive, staff scheduling.

4. Strengthen management controls to ensure inspections are planned, done and documented in accordance with the guidelines in the Manual.

Response:
There are several layers of oversight in place. In the last year, the Office has initiated increased oversight of the inspection program. The weekly scheduling meetings previously described cover, among other aspects, inspections performed, inspections due (including initial, cyclical, and compliance), inspection results, and timeliness of letters to licensees concerning inspection findings. In addition, Bureau and Division representatives participate in monthly "Tracking Meetings" to assist the program in its effective operation. Finally, the Division and the Department review and analyze statistics relating to the program on a monthly basis and provide guidance, feedback, and assistance in order to ensure maximum operational and fiscal efficiency as well as maximum public health impact.

5. Develop a process for routinely notifying facilities when their licenses are about to expire.

Response:
A reminder letter is being developed to inform licensees that they are due to expire and will be implemented within two months from this date. The timeframe for advance notification will be determined and established after thorough consideration of the complexities involved in the process. The Office also plans on adding a series of reminder letters (as part of the licensing module) to the REMTrack system as an accompaniment to the performance of timely compliance inspections.

6. Re-engineer the license renewal process to minimize the delays in the review and evaluation of renewal applications.

Response:
REMTrack will automate much of physical production aspects of the license review process, which should reduce some of the time involved. The Office does require that licensees respond to deficiencies of the application within prescribed time frames and will be less forgiving of very late responses.

Safety Violations

Based upon the audit findings, OCS is unfounded in its statement that "the Office could more …effectively monitor facilities and facility corrective actions if it made better use of its automated information system." Nowhere in the report does OCS find any situation where the Office is not currently effectively conducting compliance inspections and ensuring that corrective actions are taken.

* Comment 1

RECOMMENDATION

7. Record all relevant violation information (e.g., the severity of the violations, whether a re-inspection was needed, whether a re-inspection was done, and whether corrective action was taken) on the license and inspection tracking database, and use the database to monitor re-inspections and facility corrective actions.

Response:
At no time during the audit did the Office indicate the current database had these capabilities. This database was originally designed to list licenses, license expiration dates, inspection dates and inspection due dates. It is capable of recording assignments for licensing actions and inspections assignments. Regardless, the Office concurs with the recommended improvements to the database and supports the use of technology to improve functionality and efficiency as well as maximize resources. As such, REMtrack, which was in the planning and funding stages prior to the audit, is being designed to have the capabilities recommended by OSC.

* See State Comptroller Comments, page 24

APPENDIX B - STATE COMPTROLLER COMMENTS ON AUDITEE RESPONSE

1. Certain matters addressed in the draft report were revised or deleted in the final report. Therefore, some Department comments included in Appendix A may relate to matters no longer contained in this report.

2. Based on our sample results, we acknowledge that the inspection process was timelier in the more recent periods. However, we still found that in the more recent periods, inspections were either done late or had not been completed.

3. We believe the grace periods for the completion of cyclical inspections sufficiently compensate for the extra time needed to complete inspections at those facilities where there are several radioactive material sites.

4. While we understand that the four facilities with expired licenses cannot receive new [emphasis added] radioactive materials, there is still the risk that they can use existing radioactive materials.