New York State Office of the State Comptroller
Thomas P. DiNapoli

Division of State Government Accountability

Selected Aspects of Inspecting and Licensing Radioactive Materials and Radiation Equipment

New York City Department of Health and Mental Hygiene

Report 2016-N-4 August 2018

Executive Summary

Purpose

To determine whether the New York City Department of Health and Mental Hygiene (DoHMH) ensured that facilities using or possessing radioactive materials were appropriately licensed and inspected; facilities with radiation equipment were registered and inspected; facilities complied with selected licensing and registration regulations; and identified violations were followed up on in a timely manner. The audit covered the period July 1, 2014 to June 27, 2017.

Background

Radioactive materials are commonly used for a variety of purposes in medicine and other industries. Under an agreement between New York State and the U.S. Nuclear Regulatory Commission, DoHMH has regulatory authority pertaining to the use and possession of radioactive materials and equipment in New York City, and is responsible for the scientific review and approval of applications for new, renewed, and amended radioactive material licenses and the registration of facilities with radiation equipment.

To ensure compliance with applicable rules, regulations, and license conditions, DoHMH is required to inspect all licensed and registered facilities. Licensing, registration, and inspection helps to protect and safeguard the public health from the misuse or abuse of such materials and equipment.

Key Findings

DoHMH did not always ensure that facilities which use radioactive material or radiation equipment were licensed or registered, inspect such facilities in a timely manner, or follow up on violations.

Of the 67 randomly sampled facilities with radioactive materials, 5 were not licensed and 4 were not inspected, as required. Similarly, of the 53 sampled hospitals with radiation equipment, 5 did not have registration certificates for the current and the prior registration period, 4 had gaps in their registration periods, and 2 had no registration records. Moreover, 6 were not inspected. Similar results were found when we reviewed a random sample of 80 other facilities, including dental facilities (the most prevalent type of facility requiring registration), urgent care facilities, research centers, diagnostic centers, and small medical, podiatry, and veterinary facilities using radiation equipment. Additionally, even when non-compliance was identified in the sample of hospitals, DoHMH did not always follow up on violations to ensure that a facility took action to correct the identified condition.

Not licensing, registering, inspecting, or following up on violations in facilities with radioactive materials or radiation equipment increases the risk that radioactive material may be improperly handled or stored at such facilities, and may expose employees, patients, and others to increased levels of radiation.

Key Recommendations

- Take steps to comply with the regulations to license and register all facilities with radioactive materials and radiation equipment.
- Inspect dental facilities before they commence operations.
- Re-inspect facilities with violations within 60 days, as required.

State of New York
Office of the State Comptroller

Division of State Government Accountability

August 21, 2018

Ms. Mary T. Bassett
Commissioner
New York City Department of Health and Mental Hygiene
42-09 28th Street
Long Island City, NY 11101

Dear Commissioner Bassett:

The Office of the State Comptroller is committed to helping State agencies, public authorities, and local government agencies manage their resources efficiently and effectively. By so doing, it provides accountability for tax dollars spent to support government operations. The Comptroller oversees the fiscal affairs of State agencies, public authorities, and local government agencies, as well as their compliance with relevant statutes and their observance of good business practices. This fiscal oversight is accomplished, in part, through our audits, which identify opportunities for improving operations. Audits can also identify strategies for reducing costs and strengthening controls that are intended to safeguard assets.

Following is a report of our audit entitled *Selected Aspects of Inspecting and Licensing Radioactive Materials and Radiation Equipment*. The audit was performed pursuant 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.

This audit's results and recommendations are resources for you to use in effectively managing your operations and in meeting the expectations of taxpayers. If you have any questions about this draft report, please feel free to contact us.

Respectfully submitted,

Office of the State Comptroller
Division of State Government Accountability

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Background

To protect public health, it is imperative that all facilities using radioactive materials and radiation equipment comply with licensing, registration, and inspection requirements. The New York City Department of Health and Mental Hygiene (DoHMH) has regulatory authority pertaining to the use and possession of radioactive materials and radiation-producing equipment in New York City. It is responsible for the scientific review and approval of applications for new, renewed, and amended radioactive material licenses; the registration of facilities with radiation equipment; and the inspection of all licensed and registered facilities, including dental facilities (the most prevalent type of facility requiring registration), urgent care facilities, research centers, diagnostic centers, and small medical, podiatry, and veterinary facilities using radiation equipment. DoHMH's Office of Radiological Health (ORH) performs the licensing and inspections-related activities.

The licensing and registration rules and regulations regarding radiation control are set forth in Article 175 of the New York City Health Code (Article 175), as contained in the Rules of the City of New York. Article 175 specifies requirements for licensing radioactive material and registering radiation equipment, and regulates license/registration application, inspection, disposition, and transportation. As of July 13, 2016, DoHMH reported that there were 358 facilities licensed for radioactive materials. In addition, there are 97 hospitals and 7,030 non-hospitals (5,660 dentists, 744 podiatrists, 386 other facilities [such as stand-alone facilities and urgent care centers], and 240 veterinary facilities) with registered radiation equipment.

Audit Findings and Recommendations

We found that DoHMH did not always license and inspect facilities that had radioactive materials, register and inspect radiation-producing equipment in a timely manner, or follow up on violations, as required. For example, we examined a random sample of 67 facilities and found that 5 were not licensed, including 2 for more than two years. This increases the risk that radioactive materials are not being used for authorized purposes. Moreover, for those facilities that were licensed, DoHMH has not complied with selected Article 175 licensing and inspection procedures, increasing the risk that violations would not be detected and corrected timely. Additionally, multiple hospitals and other facilities that were required to be registered did not have registration certificates for the current and/or prior registration periods or had gaps in their registration periods. Furthermore, even for facilities that were registered, there was a lack of compliance with the registration requirements, thus increasing the risk of radiation exposure to employees, patients, and others at these facilities. We recommend that DoHMH license and inspect all radioactive materials, register and inspect radiation equipment, and follow up on violations, as required.

Radioactive Materials

DoHMH has incorporated some of the Nuclear Regulatory Commission's (NRC) regulations into Article 175, such as increased controls for materials of concern. The NRC's increased controls cover materials in quantities it considers susceptible to misuse for unauthorized purposes.

Our examination showed that during our scope period, DoHMH did not license 5 of the 67 randomly selected facilities with radioactive materials, including 2 that were unlicensed for more than two years. If such facilities operate without licenses, there is a risk of radioactive material being used for unauthorized purposes. Further, DoHMH failed to conduct inspections at four of the facilities within our sample, increasing the risk that violations would not be detected and corrected timely.

According to DoHMH officials, of the five unlicensed facilities, one was no longer using radioactive materials (although it had not yet disposed of them). In regards to the four uninspected facilities, DoHMH officials stated that they inspected the facilities in accordance with NRC regulations, which allow a six-month grace period after two years. However, this is not documented in their policies and procedures.

We also found 27 instances where DoHMH did not verify that the licensee complied with Article 175 licensing procedures, and 52 instances where it did not verify compliance with inspection procedures. In addition, three licensees were allowed to operate without a decommissioning funding plan, which is required for facilities that possess certain amounts of radioactive materials. A decommissioning funding plan ensures that financing is available to safely dispose of such materials in the event of a closure. Without such a plan, DoHMH may be responsible for decommissioning costs. Two of these three facilities also operated without implementing the NRC's controls over certain types and quantities of radiological materials, as required. These controls allow only authorized employees full access to dangerous radioactive materials. By not

verifying compliance, DoHMH is increasing the possibility of unauthorized employees accessing radioactive materials and endangering the public health.

We also determined for these three facilities that DoHMH did not verify the quantities of radioactive materials when the application was processed and during inspections. DoHMH claimed that it did, and that this information was documented in the material folders. However, we reviewed these files, which were provided by DoHMH, and could not find such documentation. Consequently, we maintain that there is limited evidence that DoHMH verified the quantities of radioactive materials at application.

Recommendations

1. License all radioactive materials and retain documentation of licensure.

2. Conduct the required inspections.

3. Require a decommissioning funding plan from each of the licensees cited in this report.

Radiation Equipment

Hospitals

We selected a random sample of 53 hospitals from a total population of 97 to test for compliance with registration requirements. For 51, we examined compliance with eight registration regulations and six inspection regulations from Article 175. (DoHMH did not have records for the other two hospitals).

Our review determined that five hospitals did not have registration certificates for the current and the prior registration periods and another four had gaps in their registration periods. DoHMH officials explained that, during part of the audit scope period, they were not in complete control of the registration process, and that the New York City Department of Consumer Affairs (DCA) was responsible for maintaining equipment registration certificates. When we contacted DCA, we were told it processed applications and collected the fees for the registration certificates, but did not issue the certificates, as that is DoHMH's responsibility under Article 175. DoHMH officials advised us that the unregistered facilities we identified are now registered, with the certificates maintained by DoHMH. For the four hospitals with gaps between registration periods, DoHMH officials stated that they considered the hospitals registered, even though their registrations had expired before new ones were issued.

Overall, we found various levels of non-compliance with selected registration procedures for 37 of the 51 hospitals sampled (see Table 1), as follows:

Table 1 - Selected Article 175 Registration Procedures for Hospitals

Hospital	1. Application was not made 30 days before the expected operation start date - 175.51(d)(1)(i)	2. No ALARA program and radiation protection program - 175.03(b)	3. Registrant did not have written procedures for auditing QA - 175.07(b)(2)	4. Registrant did not implement a quality assurance program - 175.07(b)(2)	5. Facility not registered - 175.51(b)	6. The period of registration certificates exceeded two years - 175.51(h)	7. Couldn't verify equipment - 175.64(b)(vi)(A&B)	8. No application - 175.51(d)(1)(i)(A)
1		X						
2	X	X			X			
3	X	X						
4	X	X	X					
5	X	X	X					
6	X	X						
7		X						
8		X						
9		X	X					
10	X		X		X	X		
11	X	X	X				X	
12	X	X	X				X	
13						X		
14						X		
15					X			
16					X			
17						X		
18					X	X		
19					X			
20						X		
21						X		
22					X			
23						X		
24					X			
25					X			
26						X		
27						X		
28						X		
29						X		
30						X		
31						X		
32						X		
33						X		
34						X		
35						X		
36						X		
37						X		
Total	**8**	**11**	**6**	**0**	**9**	**20**	**2**	**0**

For hospitals subject to renewal, our testing also found that DoHMH was not retaining registration information that would enable it to easily determine when the next registration was due. Without complete and accurate information about the registration period for each hospital, DoHMH's ability to effectively monitor registration renewals is lessened.

In addition, DoHMH is required to inspect facilities with radiation equipment at various intervals, such as every two years for hospitals. According to Article 175, an "inspection" is an official examination or observation, including tests, surveys, and monitoring, to determine compliance with rules, regulations, orders, requirements, and conditions. Our testing found that DoHMH did not inspect 6 of the 51 hospitals sampled. In response to our findings, DoHMH admitted that it has an inspection backlog and stated it is working to reduce it.

Moreover, even for facilities that were inspected, we found that DoHMH did not ensure that all requirements were met. For 40 of the 51 hospitals in our sample, we found various levels of non-compliance for the six inspection procedures selected. (See Table 2) There were 14 instances where DoHMH did not conduct a follow-up inspection on a timely basis, or at all. The failure to conduct follow-up inspections within 60 days of identifying a violation is of particular concern, as unsafe conditions may remain uncorrected.

Also of concern is that for six hospitals, ORH did not verify that it reviewed the registrants' compliance with all the requirements of a radiation protection program, which ensures that controls based on sound radiation protection principles are in place so that occupational doses are achieved at levels that are "as low as reasonably achievable" (ALARA). Components of a radiation protection program include providing a radiation safety officer to ensure the implementation of such a program and a radiation safety committee to administer the program in medical centers, hospitals, and institutions of higher education. Consequently, there may be an increased risk to both patients and employees because the facility may not be ensuring that doses are ALARA.

Table 2 - Selected Article 175 Inspection Procedures for Hospitals

Hospital	1. No ALARA program or radiation protection program - 175.03(b)	2. Registrant did not have written procedures for auditing QA - 175.07(b)(2)	3. ORH reviewed the annual audit reports of the registrant's quality assurance program - 175.07(b)(2)	4. Not inspected as required by Article 175 - 175.51(n)(1)	5. Not inspected at the frequency established by ORH - 175.51(n)2(A)	6. Not re-inspected or re-inspection not timely after the violation was issued
1	X					X
2						X
3	X	X	X			
4				X		
5	X					X
6	X					
7				X		
8					X	
9					X	
10	X	X	X		X	
11					X	
12					X	
13					X	
14				X		
15					X	
16					X	
17					X	
18					X	X
19					X	X
20					X	
21					X	
22				X		
23	X	X	X	X		
24					X	
25					X	X
26					X	
27					X	
28					X	X
29					X	X
30					X	X
31					X	
32					X	
33					X	X
34					X	
35					X	X
36						X
37					X	
38					X	X
39				X		
40					X	X
Total	**6**	**3**	**3**	**6**	**28**	**14**

Recommendations

4. Work with DCA to formally designate, in writing, each agency's role with respect to the issuing of certificates.

5. Retain evidence of registration for all registrants for at least two registration periods.

6. Conduct and document inspections of all facilities.

7. Review registrants' compliance with the radiation protection program.

Dentists, Podiatrists, Non-Hospitals, and Veterinarians

A similar lack of compliance was found when we reviewed a random sample of 80 dental, non-hospital (urgent care facilities, research centers, diagnostic centers, and small medical facilities), podiatry, and veterinary facilities using radiation equipment from the total population of 7,030 non-hospital facilities.

Our examination found 25 facilities without active registration certificates and nine certificates issued subsequent to the expiration date of the previous certificate. DoHMH officials, as with hospitals, explained that they were not in complete control of the registration process during our scope period. Additionally, to determine if all dental facilities that have radiation equipment are included on the DoHMH list of facilities, we selected a sample of 96 dental providers from a list maintained by a private dental insurance provider. We searched for these providers in the DoHMH database and found that two were not registered. DoHMH officials agreed with this finding and took action after we notified them about the facilities.

Similar to our findings at hospitals, we found that DoHMH has not ensured compliance with required registration and inspection procedures at non-hospital facilities. We examined compliance with six selected registration procedures at 72 facilities (see Table 3) and with four selected inspection procedures at 63 facilities (see Table 4). In addition to problems with registration, other issues of identified non-compliance included:

- Nine facilities that filed an application less than 30 days prior to "establishing the installation and/or installing the x-ray equipment;"
- Ten facilities that were not inspected; and
- Thirteen dental facilities that were inspected initially by a Certified Radiation Equipment Safety Officer (CRESO) instead of DoHMH, contrary to regulations.

Of concern was the finding that 18 of the 72 facilities tested did not have an ALARA program or a radiation protection program, and that 61 of 63 facilities tested did not have a radiation safety program. DoHMH officials explained that a radiation safety program review was not necessary at most of these facilities because they determined that the radiation exposure was similar to background radiation and confined to one room.

Additionally, DoHMH pointed out that the Dental Equipment Survey and Radiation Safety Survey forms are sufficient evidence to verify compliance with the ALARA program. Nonetheless, ALARA is required by the regulations and is not documented within the files, as would be expected. DoHMH officials did not explain why they allow registrations for more than two years or why CRESOs, instead of DoHMH, are conducting initial inspections of dental facilities.

Table 3 - Selected Article 175 Registration Procedures for Radiation Equipment

Dentist, Podiatrists, Non-hospitals, and Veterinarians	Application was not made 30 days before establishing the installation of x-ray equipment - 175.51(B)(2)	No ALARA program and radiation protection program - 175.03(b)(2)	Facility not registered - 175.51(b)	Registration certificates exceeded two years - 175.51(h)	Application incomplete - 175.51(d)(2)(i)	Dental facility not initially inspected by ORH inspector - 175.51(d)(2)(ii)
1			X	X		
2				X		
3		X				X
4				X		
5			X	X		
6				X		
7				X		
8				X		
9			X			
10				X		
11				X		
12			X	X		
13			X			
14			X	X		
15				X		
16				X		
17				X		
18		X				X
19		X				X
20			X			
21			X			
22				X		
23				X		
24				X		
25			X	X		
26				X		
27				X		
28			X			
29		X				X
30				X		
31				X		
32			X			
33				X		
34			X			
35				X		
36				X		

Dentist, Podiatrists, Non-hospitals, and Veterinarians	Application was not made 30 days before establishing the installation of x-ray equipment - 175.51(B)(2)	No ALARA program and radiation protection program - 175.03(b)(2)	Facility not registered - 175.51(b)	Registration certificates exceeded two years - 175.51(h)	Application incomplete - 175.51(d)(2)(i)	Dental facility not initially inspected by ORH inspector - 175.51(d)(2)(ii)
37				X		
38			X			
39		X				
40				X		
41		X				
42			X			
43			X			
44			X	X		
45				X		
46				X		
47			X			
48		X	X			X
49			X	X		
50			X			
51	X			X		X
52				X		
53	X	X	X	X		X
54		X	X			
55				X		
56		X	X			X
57				X		
58				X		X
59				X		
60		X	X			X
61				X		
62	X			X		
63	X			X		
64	X	X				
65	X	X		X		X
66				X		
67		X		X	X	
68					X	
69		X				X
70	X	X				
71	X	X				X
72	X	X	X			
Total	**9**	**18**	**25**	**44**	**2**	**13**

Table 4 - Selected Article 175 Inspection Procedures for Dentists

Dentists	No ALARA program - 175.03(b)	Not inspected - 175.51(n)(1)	Not inspected at the frequency established by ORH - 175.51(n)(2)(B)	Not re-inspected after the violation was issued - 175.51(n)(2)(D)
1	X			
2	X			
3	X			
4	X			
5	X			
6	X			
7	X			
8	X			
9	X			
10	X			
11	X			
12	X			
13	X			
14	X			
15	X			
16	X			
17	X			
18	X			
19	X			
20	X			
21	X			
22	X			
23	X			
24	X			
25	X			
26	X			
27	X			
28	X			
29	X			
30	X			
31	X			
32	X			
33	X			X
34	X			
35	X			
36	X	X		

Dentists	No ALARA program - 175.03(b)	Not inspected - 175.51(n)(1)	Not inspected at the frequency established by ORH - 175.51(n)(2)(B)	Not re-inspected after the violation was issued - 175.51(n)(2)(D)
37	X	X		
38	X	X		
39	X			
40	X			
41	X		X	
42	X			
43	X	X		
44	X			
45	X			
46	X			
47	X			
48	X			
49	X			
50	X			
51	X	X		
52	X	X		
53	X			
54	X			
55	X	X		
56	X			
57	X			
58	X	X		
59	X			
60		X		
61		X		
62	X			
63	X			
Total	**61**	**10**	**1**	**1**

Recommendations

8. Register all radiation facilities/equipment and retain registration certificates for all registrants for at least two registration periods.

9. Conduct and document inspections for all facilities.

10. Review registrants for compliance with the radiation protection program or, if not applicable, document the rationale.

11. Have DoHMH inspectors conduct initial inspections of dental facilities rather than CRESOs.

Radiation Equipment Disposal

Section 175.56(b) of Article 175 states that "Radiation equipment which is not intended to be used must be made inoperable to the satisfaction of [DoHMH] by dismantling or sealing with an official [DoHMH] seal or other suitable method, and shall not be unsealed or restored to operable condition without prior authorization by [DoHMH]."

During our examination of the equipment sample, we found seven facilities with radiation equipment whose registrations had expired. We found that the registration for one of these facilities was not renewed, and DoHMH did not document that the facility had complied with Section 175.56(b). A DoHMH official stated that they are not responsible for radiation equipment at closed facilities. However, if compliance with this regulation is not verified, these equipment items may be reused, unbeknownst to ORH.

Recommendation

12. Verify that the registrant makes the radiation equipment inoperable.

Qualifications

The New York City Department of Civil Service specifies position qualification requirements. Hiring individuals who do not meet the minimum qualifications presents a risk that they will not be able to properly perform all of the required tasks, and is of particular concern when these individuals will be dealing with hazardous material and radiation equipment, which impact public safety.

We examined the qualifications for 18 ORH employees, including two supervisors, in the division responsible for inspections during the audit period and found that DoHMH did not have documentation regarding the qualifications of four employees. For example:

- For one of two inspectors hired as Assistant Scientists, there was no record of any prior work experience. For the other Assistant Scientist, there was no support that the minimum academic qualifications or the prior work experience requirements were met. Although DoHMH indicated that this employee took courses in the required field, there is no indication that the employee majored in the required field.
- One of two inspectors hired as Level II Scientists attested to one year of prior work experience, even though the position requires two. The other attested to his prior work experience, and DoHMH accepted it without verification.

In response to our preliminary findings, DoHMH indicated it implemented a process in late 2015

whereby candidates for employment are required to provide written verification of required and claimed experience. All four employees above were hired prior to the new process.

Recommendation

13. Ensure that the experience and qualifications of employees are validated and documented.

Audit Scope, Objectives, and Methodology

To determine whether DoHMH ensured that: new and existing facilities using or possessing radioactive materials were appropriately licensed and inspected; facilities with radiation equipment were registered and inspected; facilities complied with selected licensing and registration regulations; and identified violations were followed up on in a timely manner.
The audit covered July 1, 2014 to June 27, 2017.

To accomplish our objectives and evaluate the related internal controls, we interviewed DoHMH officials regarding their licensing, registration, and inspection procedures for radioactive materials and radiation equipment. We reviewed statistical samples of radioactive materials and radiation equipment to determine whether the facilities were licensed, registered, periodically inspected, and had violations followed up on. We selected the statistical samples from DoHMH's databases of radioactive materials, hospitals, and the combined totals of dentists, podiatrists, non-hospitals, and veterinary facilities, as follows:

- Radioactive materials sample of 67 from a population of 358;
- Hospitals sample of 53 from a population of 97; and
- Dentists, podiatrists, non-hospitals, and veterinary sample of 80 from a population of 7,030.

We also visited ten facilities with radiation equipment and radioactive materials to confirm the information in DoHMH's records. We examined the qualifications of the 18 ORH employees, including two supervisors, in the division responsible for inspections during the audit period.

Additionally, for 96 facilities selected from a private dental insurance provider's listing, we traced each facility's name and address to DoHMH's "RAD database."

We conducted our performance audit in accordance with generally accepted government auditing standards. These 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 objectives. We believe that the evidence obtained during our audit provides a reasonable basis for our findings and conclusions based on our audit objectives.

As is our practice, we notify agency officials at the outset of each audit that we will be requesting a representation letter in which agency management provides assurances, to the best of their knowledge, concerning the relevance, accuracy, and competence of the evidence provided to

the auditors during the course of the audit. 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 affirm that, to the best of their knowledge, all relevant financial and programmatic records and related data have been provided to the auditors. They further affirm either that the agency has complied with all laws, rules, and regulations applicable to its 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 at the New York City Mayor's Office of Operations have informed us that, as a matter of policy, mayoral agency officials will not provide representation letters in connection with our audits. As a result, we lack assurance from DoHMH officials that all relevant information was provided to us during the 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. 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 performed pursuant 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

A draft copy of this report was provided to DoHMH officials for their review and formal comment. Their comments were considered in preparing this final report and attached in their entirety to the end of it.

DoHMH disagreed with the audit findings and recommendations because it concluded that the auditors did not understand the licensing and inspections processes it followed. The response also indicated that the auditors did not provide DoHMH with information about the sampled facilities during the audit and in some cases, even after the draft report was issued. Nonetheless, we maintain that the report's findings, conclusions, and recommendations are correct. Our rejoinders to specific comments are included in the report's State Comptroller's Comments, which are embedded in DoHMH's response.

Within 90 days of the release of our final report, we request that 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 in this report, and if the recommendations were not implemented, the reasons why.

Contributors to This Report

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Vision

A team of accountability experts respected for providing information that decision makers value.

Mission

To improve government operations by conducting independent audits, reviews, and evaluations of New York State and New York City taxpayer-financed programs.

Agency Comments and State Comptroller's Comments

NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE
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July 13, 2018

Tina Kim
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Albany, NY 12236

Dear Ms. Kim:

The Department of Health and Mental Hygiene (DOHMH or Department) has reviewed the draft audit report entitled Selected Aspects of Inspecting and Licensing Radioactive Materials and Radiation Equipment. The stated objective of the audit was to determine whether DOHMH ensured that (i) facilities using or processing radioactive materials were appropriately licensed and inspected, (ii) facilities with radiation equipment were registered and inspected; and (iii) identified violations were followed up in a timely manner. The audit covered the period July 1, 2014 to June 27, 2017.

The attached response details DOHMH's position in regard to the auditors' findings and recommendations. We appreciate the efforts and professionalism of your staff during the audits. If you have any question, please contact Sara Packman, Assistant Commissioner for Audit Services at (347) 396-6679.

Sincerely,

Oxiris Barbot, M.D.

cc:

Mary T. Bassett, MD, MPH, Commissioner, DOHMH
Corinne Schiff, Deputy Commissioner, Environmental Health, DOHMH
Sara Packman, Assistant Commissioner, Audit Services, DOHMH
George Davis, Director, Mayor's Office of Operations

Attachments:

RESPONSE TO THE OFFICE OF STATE COMPTROLLER'S AUDIT ON

SELECTED ASPECTS OF INSPECTING AND LICENSING RADIOACTIVE MATERIALS AND RADIATION EQUIPMENT

AUDIT NUMBER 2016-N-4

The Department of Health and Mental Hygiene (DOHMH or Department) has reviewed the draft audit report entitled Selected Aspects of Inspecting and Licensing Radioactive Materials and Radiation Equipment. The stated objective of the audit was to determine whether DOHMH ensured that (i) facilities using or processing radioactive materials were appropriately licensed and inspected, (ii) facilities with radiation equipment were registered and inspected; and (iii) identified violations were followed up in a timely manner. The audit covered the period July 1, 2014 to June 27, 2017.

The auditors conclude that DOHMH did not always ensure that facilities which use radioactive material or radiation equipment were licensed or registered, inspect such facilities in a timely manner, or follow up on violations to ensure that a facility took action to correct the identified condition.

While we appreciate the opportunity to respond to the draft report, we strongly disagree with the auditors' conclusion. DOHMH's Office of Radiological Health (ORH) has controlled processes for issuing licenses and permits to facilities that use radioactive material or radiological equipment; timely conducts inspections; and conducts follow-up inspections to monitor compliance.

The New York City Health Code Article 175 sets out the requirements for facilities with radiation-producing materials and radiological equipment. ORH is part of the New York State Agreement with the United States Nuclear Regulatory Commission (NRC), and accordingly, the Health Code provisions addressing radiation producing materials align with NRC regulations and ORH follows NRC guidelines.

DOHMH is greatly disappointed that the auditors, who are not trained or experienced in the field of radiation safety and regulation, did not integrate in their assessments DOHMH's (i) explanation about Health Code requirements and how those are enforced and (ii) the responses to the auditors' preliminary issues. Had the auditors understood the radiation control provisions ofthe Health Code and their enforcement, they would not have reached the conclusions presented in this draft report.

State Comptroller's Comment - DOHMH's comments that the auditors did not incorporate its explanations or responses to the preliminary findings when arriving at the conclusions and

recommendations is without merit. The audit criteria were Article 175 of the New York City Health Code, United States Nuclear Regulatory Commission policies, as well as DOHMH's policies. We also evaluated DOHMH's explanations of its practices, which were not in writing, during inspections and licensing. Thus, the audit report is an accurate representation of the work done by DOHMH based on its inspection and licensing records.

This response will address the audit's detailed issues and recommendations (in italics) in the order they appear beginning on page 6 of the subject report.

A. Radioactive Material

Issue 1: *DOHMH did not license 5 of the 67 randomly selected facilities with radioactive materials, including 2 that were unlicensed for more than two years.*

Response: DOHMH strongly disagrees with this audit finding. The auditors randomly selected 67 facilities required to have a radioactive materials license and determined that 5 were not licensed and had fallen outside DOHMH oversight. This is incorrect. The Health Code provides that a license remains fully in effect beyond the expiration date if the facility has timely filed a renewal application, and, even where a renewal application has not been filed, the license remains in effect until DOHMH terminates it. *See* NYC Health Code §175.101(h)(1) and §175.101(h)(4)(viii). These provisions are designed to ensure that patient care and scientific research can continue uninterrupted even when paperwork is pending, and that facilities that are planning to relinquish the license will dispose of radioactive material pursuant to Health Code requirements and subject to DOHMH oversight. When facilities are in this "pending renewal status" their license expiration is tolled and ORH continues to inspect them.

State Comptroller's Comment - These licensees did not file an application for renewal prior to the expiration of their previous licenses. The regulations provide that if the licensee does not submit an application for renewal prior to expiration of the license, the licensee shall terminate the use of radioactive materials and dispose of its radioactive materials.

Three of the 5 facilities in the auditor report fall into this "pending renewal" status and remained subject to DOHMH inspections. They were not "unlicensed" and without oversight. The remaining 2 facilities are linear accelerator facilities that do not have radiological materials and therefore do not need a radiological materials license.

State Comptroller's Comment - These two facilities had LINAC machines, which may produce radioactive materials when operated. In addition, both have a type 77 license, which is defined as a separate category in the DOHMH database for radioactive materials.

Issue 2: *DOHMH failed to conduct inspections at four facilities within our sample [of 67], increasing the risk that violations would not be detected and corrected timely*

Response: DOHMH strongly disagrees that any meaningful public health risk arose because DOHMH missed internal frequency targets for inspection at four facilities. These four facilities were timely inspected in accordance with the performance indicators required by NRC regulations. DOHMH internal targets aim to inspect even more frequently than NRC requires.

Issue 3: *27 instances where DOHMH did not verify that the licensee complied with Article 175 licensing procedures, and in 52 instances where it* [DOHMH] (sic) *did not verify compliance with inspection procedures. In addition, three licensees were allowed to operate without a decommissioning funding plan.*

Response: DOHMH strongly disagrees with the auditors' assessments that DOHMH did not verify licensee's compliance with (i) licensing procedures, (ii) inspection procedures and (iii) existence of decommissioning funding plan. Subsequent to receipt of the draft report, at DOHMH's request, the auditors provided the instances (license numbers) and the relevant sections of the Health Code with which the auditors alleged DOHMH did not comply. However, the auditors did not explain the basis for their conclusions. DOHMH reviewed the instances provided and explains the Health Code requirements, DOMHM's licensing and inspection processes and why we believe the auditors' conclusions are wrong.

State Comptroller's Comment - DOHMH's reply states that the auditors did not explain the basis for their conclusions. Contrary to DOHMH statements, DOHMH received preliminary findings with the reason why we concluded it was not in compliance and the identifying information throughout the audit. Moreover, DOHMH officials had every opportunity to request any information they required but, as shown in the subsequent notes, were not responsive to the audit team during the audit.

(i) *27 instances where DOHMH did not verify that the licensee complied with Article 175 licensing procedures*

The 27 instances are in 4 categories of licensing procedures:

a. *Increased Controls—Health Code Section §175.101(k)(3) (6 instances)*

Response: DOHMH strongly disagrees with the auditors' assessment for the following reasons. For 4 of the 6 licenses allegedly affected by this requirement, the facility was not required to meet the increased controls (IC) requirement per Health Code §175.101(k)(3). The applicable Health Code provisions require facilities to implement its security requirements only if they have above certain quantities of certain materials, and the criteria are specified in the NRC IC Order of 2005. Previous versions of these licenses mistakenly listed a possession limit that would have required compliance with IC provision. However, subsequent amendments to these licenses reduced the possession limit.

State Comptroller's Comment - The documentation in the files indicated the quantities required increased controls (IC). DOHMH's reply to the draft report claims that previous versions of these licenses mistakenly listed possession limits that would have required compliance with the IC provision, and that subsequent amendments to these licenses reduced the possession limit. However, if correct, this explanation begs other questions, such as why such critical information was not in the files and why this information was not provided to the audit team during field work so that it could be verified.

For the other 2 licenses, which were required to comply with the IC provision, DOHMH strongly disagrees with the auditors' assessment that ORH was deficient in verifying or enforcing it. ORH had previously provided a copy of an IC inspection report for one of the facilities (license number 75-2885-01). The remaining facility has more than one license; and the license cited (75-2960-04) receives IC inspections under a separate license (74-2960-12) of the same facility. There was no lack of oversight. Going forward, to increase clarity and reduce possible confusion (as occurred in this assessment), ORH will reference the IC inspection requirement with license 75-2960-04.

State Comptroller's Comment - The report did not state that six facilities were not in compliance with the IC requirement. For license 75-2885-01, DOHMH subsequently provided an undated IC inspection report, which was not in the file at the time of our review. We therefore have no assurance that this inspection was done during the audit period. For license 75-2960-04, DOHMH claims there was a separate license for the facility, but there was no IC inspection report in the file at the time of our review. We question why this information was not in the files and why this information was not provided to the audit team during field work so that it could be verified.

b. *Decommissioning Plan—Health Code Section §175.101(n)(1)(a) (3 instances)*

Response: DOHMH strongly disagrees with the auditors and believes that the auditors' findings are based on a misunderstanding of the requirements of this section of the Health Code. The 3 licenses cited do not require decommissioning plans. Two of the three licenses cited do not even authorize the possession of materials of the type described in §175.101(n)(1)(a) (unsealed material with half-life greater than 120 days). The third license (sample no. 30; license 75-2885-01) allows possession of some material of the type described in §175.101(n)(1)(a), however, the quantities possessed are below the criteria in the Health Code for requiring a decommissioning funding plan. On September 14, 2017, in DOHMH response to the auditors' preliminary draft issues, DOHMH provided the calculation for the quantities this licensee possesses. Thus, the Health Code section §175.101(n)(1)(a) cited in the report does not apply to these facilities.

State Comptroller's Comment - The materials listed on the license required a decommissioning plan if they were unsealed. The license issued to this establishment listed materials without indicating "sealed." We were advised that if the materials are not noted as sealed, they are unsealed. The quantity licensed for this material would require a decommissioning plan.

c. *Radiation Protection Program—Health Code §175.03(b) (18 instances)*

Response: DOHMH strongly disagrees with the auditors' assessment that DOHMH did not verify licensee's compliance with Radiation Protection Program. The basis for the auditors' finding is not set out in the draft report, making it difficult to reply. We, thus, offer this relevant information. On September 14, 2017, DOHMH responded to the auditors' preliminary draft issues that stated "ORH did not review or retain records that they have reviewed the radiation protection program". ORH stated that that the auditors were incorrect and explained that "ORH reviews the Radiation Safety Program by checking the application if the licensee includes the commitment statement such as: "we have developed and will implement and maintain procedures for ….". This commitment statement is used in the suggested response by NRC for the Radiation Safety Program." ORH also attached sampled submissions with the application as evidence (91-3364-01). It appears that the auditors completely ignored this response.

State Comptroller's Comment - We examined the sampled submission provided and there was no indication that ALARA was checked. We therefore determined no change was warranted. Moreover, DOHMH officials were kept apprised throughout the audit at meetings and with preliminary findings with details and analyses of DOHMH's responses. DOHMH should be well aware of this as often this resulted in written requests for additional documents. We reviewed all files DOHMH provided as well as the response to the preliminary for each sampled item. Auditors did not ignore the response, they simply deemed the information provided insufficient to change the finding.

During the audit, ORH explained to the auditors that during the licensing process, ORH's physicists thoroughly reviews the application's engineering protocols to check that they are based upon sound radiation protection principles to achieve dose of radiation emission "As Low As Reasonably Achievable" (ALARA) and that it is below the dose specified in the Health Code. ORH also reviews the qualification of the applicant's radiation safety officer (RSO) who is responsible for ensuring the implementation of the radiation protection program the objective of which is to achieve ALARA. As part of the new and renewal license-application, ORH verifies the applicant has a radiation safety committee where required.

During inspections, the ORH inspector reviews licensee's documentation of radiation safety committee's activities, qualification and training of staff involved in the Radiation Protection Program, radiation surveys to insure source accountability and compliance with dose limits, and licensee's monitoring of occupational exposures which the licensee documents using form RAD-4 "Cumulative Occupational Radiation Exposure History" or other equivalent form. The form shows each period in which the individual staff received occupational exposure to radiation or radioactive material and is signed by the individual who received the exposure. Measuring exposure at a required frequency is an important activity to assure that doses are achieving the ALARA goal.

ORH documents its review of Radiation Protection Program by making notations on the application and following up with the applicant for a new or renewal of a license, as well a by approving the issuance of a license when requirements are met. During inspections, ORH documents its review of Radiation Protection Program elements using the inspection form. Considering together, the licensee's governance structure (i.e, radiation safety committee), staff qualification and roles, and control activities and structured measurements of exposure, ORH determines the effectiveness of the licensee's Radiation Protection Program and whether ALARA is met.

(ii) *52 instances where it* [DOHMH] (sic) *did not verify compliance with inspection procedures*

a. *No RAD-4* "Cumulative Occupational Radiation Exposure History"(sic)—*Health Code §175.03(c)(5)(iv) (31 instances*)

Response: DOHMH strongly disagrees with the auditors' assessment. The auditors do not explain the basis for this critique. As we explained to the auditors in the September 12, 2017 response to preliminary draft issues, Article 175 requires facilities with radiological materials to document occupational exposure to radiation with the use of RAD-4 form or equivalent form. For example, many facilities use an equivalent form provided by the Landauer Company in place of the RAD-4 form. During a radioactive materials inspection, the ORH inspector is required to verify that the facility is conforming to appropriate cumulative occupational exposure monitoring and the inspector's determination is reflected on relevant inspection forms. For a short period of time, ORH's protocol was for the inspectors to bring back to the office dosimetry reports—which are many pages long—and place them in the hard copy file for the licensee. The protocol was revised to be more efficient and less burdensome: the inspector now reviews the dosimetry reports during the onsite inspection and notes verification on the inspection report, and does not bring hard copy dosimetry reports back to the office. This improvement in the documentation protocol did not change the inspection in substance, but may be the source of confusion here.

State Comptroller's Comment - DOHMH officials advised us of the process for determining occupational exposure during the audit field work, including the use of different forms. The files were provided to support that DOHMH followed its inspection and license processes. Although DOHMH describes a change in its documentation protocol, they did not provide any information as to when this change was made.

b. *Did not verify compliance with the radiation protection program and/or ALARA—Health Code §175.03(b) (4 instances*)

Response: DOHMH strongly disagrees with the auditors' assessment that DOHMH did not verify compliance with this Health Code provision during inspections in the four cited instances. As already stated, the concept of radiation safety is embedded in every Radiation

Protection Program with ALARA as a key objective. During inspections of facilities with radioactive materials, ORH inspectors check that every procedure is described in sufficient details to enable monitoring of the safety of the patient, doctor and all people who are associated with the procedure.

State Comptroller's Comment - This response is not relevant to our exception because our finding is that ORH did not verify compliance with the ALARA program during the application process and not at inspection.

As already stated above, during inspections, the ORH inspector reviews licensee's documentation of radiation safety committee's activities, qualification and training of staff involved in the Radiation Protection Program and licensee's monitoring of occupational exposures which the licensee documents using form RAD-4 "Cumulative Occupational Radiation Exposure History" or other equivalent form. The form shows each period in which the individual staff received occupational exposure to radiation or radioactive material and is signed by the individual who received the exposure. Measuring exposure at a required frequency is an important activity to assure that doses are achieving the ALARA goal.

ORH inspector documents that he/she has reviewed licensee's elements of the Radiation Protection Program using the inspection form. Taken into account licensee's governance structure (i.e, radiation safety committee), staff qualification and roles, and control activities and structured measurements of exposure, ORH determines the effectiveness of the licensee's Radiation Protection Program and whether ALARA is met.

During the auditors' walkthrough and in response to the preliminary draft issues, DOHMH officials demonstrated to the auditors that ORH retains evidence of compliance with ALARA and licensee radiation protection program activities.

c. *No evidence of verifying record of receipt —Health Code §175.03(k)(3) (2 instances*)

Response: DOHMH strongly disagrees with the auditors' finding regarding the 2 instances cited. One facility (52-2770-01) did not receive any radioactive material under its license as noted in a 3/14/12 inspection report (a date outside the audit scope). There was also an inspection on 3/25/15 and the inspection form notes that the facility was in compliance with shipping requirements. The second facility (52-3135-01) did not receive any shipment of radioactive material during the period in question, thus, it did not have any records of receipt. The licensee only had sealed sources of radiological material which were already on hand. This was documented on the inspection form dated 5/26/17.

State Comptroller's Comment - For the first instance, there was no documentation of a receipt concurrent with actual receipt of materials. For the second incident, the inspection was done on May 26, 2017, two days after we issued the preliminary findings. If DOHMH took corrective action

based on our preliminary findings, it should be noted as such and not be used to attempt to refute a finding that DOHMH's own response shows was correct.

d. *No evidence of conducting independent and confirmatory tests—NRC Inspection Manual 2800-05 (3 instances)*

Response: DOHMH strongly disagrees with the auditors' assessment that independent and confirmatory testing was not performed. Under NRC 2800-05, the inspector must independently measure radiation dosage during the course of their inspection. For all 3 facilities cited, the inspectors conducted an independent and confirmatory test. For license # 91-3434-01, see inspection report dated 12/31/15 on page 13 and 14. For license #52-2770-01, see inspection report dated 3/25/15. For license #52-3214-01, an inspection was performed on 7/15/15 and the inspection documents that the inspector performed an independent and confirmatory dose rate survey.

State Comptroller's Comment - We requested the documentation for testing from DOHMH during the audit. It was not provided. We therefore cannot verify if the information now provided is accurate.

e. *Did not conduct unannounced inspection—NRC Inspection Manual 2800-05.01(b)(6)(b) (4 instances)*

Response: DOHMH strongly disagrees with this finding. ORH's regular inspections are all unannounced, and the inspections at the 4 cited facilities were all unannounced. It is unclear why the auditors believe DOHMH's regular inspections are scheduled with the facilities. If the auditors would provide information about the basis for this finding, we would be happy to respond.

State Comptroller's Comment - DOHMH's response to the draft report contradicts its earlier responses to our preliminary findings. In those responses, it stated that two were not announced, but the inspector checked the wrong box on the form. In one case, the response did not provide a reason why the inspection was not unannounced.

f. *ORH did not determine whether the licensee followed up on cited violations—NRC Inspection Manual (b)(6)(b) (3 instances)*

Response: DOHMH strongly disagrees with this finding. DOHMH records show that ORH had followed up with the 3 facilities cited to check correction of violations. For license # 52-3135-01, the inspection was performed on 5/26/17 and a follow-up inspection occurred on 9/6/2017. For license #91-3262-01, an inspection was performed on 2/23/17, and a follow-up inspection occurred on 6/29/17. For 77-0000065 (a.k.a., 7765), an inspection was performed on 6/29/16, and a follow-up inspection occurred on 12/7/2016. DOHMH provided

the auditors with a copy of ORH's 2/7/17 letter to the licensee stating the results of its follow-up inspection.

State Comptroller's Comment - DOHMH did not provide any documents to show it followed up on the violations.

g. *ORH Inspection Schedule/Inspection Frequency—Health Code- §175.03(c)(5)(iv) (5 instances)*

Response: For 3 of the 5 instances, ORH agrees that inspections were not performed within DOHMH's internal frequency target. However, these inspections were performed in accordance with NRC guidelines for inspection frequency and do not present a meaningful public health risk. For the 4th instance (77-0000048), the facility was inspected in accordance with DOHMH internal policy. For the 5th instance (91-3470-01), the facility did not begin operation until December 2013 and the cycle inspection was performed in December 2015, within ORH's internal inspection target and within the NRC inspection requirements for this type of facility.

State Comptroller's Comment - While these inspections may have been performed in accordance with NRC guidelines, they were not done in compliance with DOHMH requirements. If DOHMH wishes to follow the NRC requirements, then it should formally reflect this change in its regulations. ORH's record for license 77-0000048 shows the facility was inspected on July 30, 2015, with the prior inspection done on June 10, 2013. For license 91-3470, the license was issued October 30, 2013 and should have been inspected again within two years. However, the files received on January 18, 2017 had no record of another inspection.

h. *Facilities allowed to operate without a decommissioning funding plan—Health Code §175.101(n)(1)(a) (3 instances)*

Response: DOHMH strongly disagrees with this finding. The basis for the disagreement is included in the response to (i) b above. As previously stated, the license for each of these facilities does not allow the facility to possess any of the type of material described in Health Code §175.101(n)(1)(a), and these 3 facilities are not required to have financial assurance for decommissioning.

State Comptroller's Comment - The materials listed on the license required a decommissioning plan if they were unsealed. The license issued to this establishment listed materials without indicating "sealed." We were advised that if the materials are not noted as sealed, they are unsealed. The quantity licensed for this material would require a decommissioning plan.

i. *Facilities operated without implementing NRC's controls over certain types and quantities of radiological materials, as required (2 instances)*

Response: Following the receipt of the draft report and in response to DOHMH's request for details to support assessments, the auditors noted that DOHMH was not in compliance with Health Code §175.101(c) in 2 instances (relating to License #75-2885 and #91-2901 (auditors' June 14, 2018 email). The auditors' concerns remain unclear. DOHMH notes that Health Code §175.101(c) mainly pertains to the exemption of radiological materials from the provisions of the Health Code under specific quantities. Thus, we cannot address this assessment except to state that the cited licenses were included in DOHMH's response to (i)(a) above.

State Comptroller's Comment - The requirement for increased NRC controls cites Health Code section 175.101(k)(3). It was provided to DOHMH during the field work.

j. *Did not verify the quantities of radioactive materials when the application was processed and during inspection- Health Code §175.101(n)(1)(a) (3 instances)*

Response: DOHMH strongly disagrees with this finding. The basis for DOHMH's disagreement is presented in section (i) b. Also, the requirement in §175.101(n)(1)(a) is addressed only during licensing, not during inspection.

State Comptroller's Comment - The Health Code requires that a decommissioning plan be submitted when quantities of certain materials exceed specified amounts. By only verifying quantities during licensing, it does not have assurance that licensees have not exceeded the threshold amounts with additional acquisitions, thereby necessitating a decommissioning plan.

Recommendations

Recommendation 1: *License all radioactive materials and retain documentation of licensure.*

Response: This recommendation is not needed. ORH licenses facilities according to guidelines established by the United State Nuclear Regulatory Commission (NRC). An application package for radioactive materials license is thoroughly reviewed by ORH's scientists to check that the facility and its personnel are appropriately qualified for handling and utilizing the radioactive materials that they have sought to use. Prior to approving a license, ORH performs a pre-licensing visit to make sure the facility meets all regulatory requirements set by NRC. Prior to approving a new license, an internal peer review is performed by other ORH staff to ensure the application contains accurate and relevant information.

State Comptroller's Comment - As described in the report, we identified deficiencies in the licensing, inspection, and documentation processes.

Each license has a unique number and issued on a certificate paper. The license information is manually entered in ORH's RAD database.

Recommendation 2: *Conduct the required inspections.*

Response: This recommendation is not needed. ORH inspectors perform inspections in accordance with NRC guidelines. Inspectors use inspection forms that incorporate the required regulations. The inspection forms are manually completed by the inspectors. The Material Unit supervisor reviews staff inspection reports and once the reports are reviewed and approved the information is entered in the RAD database.

State Comptroller's Comment - As described in the report, we identified deficiencies in the licensing, inspection, and documentation processes.

In 2016, ORH implemented an annual quality assurance review of inspection reports and RAD data. RAD data of sampled licenses is compared to information in the hard copy file. If errors are found the Unit supervisor makes corrections to the database.

ORH inspectors are qualified scientists trained in accordance with NRC requirements.

Recommendation 3: *Require a decommissioning funding plan from each of the licensees cited in this report.*

Response: This recommendation is inappropriate and may reflect the auditors misunderstanding of the Health Code's radiation control provisions. As explained in the response to the findings above, only licensees authorized to possess unsealed radioactive material of a half-life greater than 120 days and in quantities exceeding 10^5 times certain applicable quantities are required to submit a decommissioning funding plan. The auditors cited no instance of a missing or incorrect decommissioning funding plan. The 3 facilities cited in the draft audit report do not require decommissioning funding plans.

State Comptroller's Comment - DOHMH officials advised us that if the materials are not noted as sealed, they are unsealed. The quantities licensed for these materials would require a decommissioning plan.

B. Radiation Equipment - Hospitals

Issue 1: *Seven hospitals did not have registration certificates for the current and the prior registration periods.* Also, *DOHMH did not have records for two hospitals.*

State Comptroller's Comment - The report was revised to reflect information provided in the response to the draft report.

Response: DOHMH strongly disagrees with the auditors' assessment. First, as to the 7 registration certificates, the basis for the auditor's finding appears to be that DOHMH did not print copies of

the registration certificates. As explained to the auditors, however, each of the 7 cited facilities were properly registered, and details about the facilities' current registration status is available in ACCELA, the City's online licensing and permitting system. DOHMH was unable to print some of the registration certificates due to a system issue, but on October 4, 2017, the auditors were given the opportunity to view registration records in the ACCELA system and they printed copies of 5 of the 7 cited registration certificates (40506174; 40506145; 40506158; 40506230 and 40506229).

Next, regarding the records for two hospitals (samples #72 and 82), these are not available because their registrations were cancelled over 15 years ago. Specifically, sample #72 (40506146) is [hospital name to be provided upon request], the registration of which was cancelled on 3/6/1997 as the hospital was acquired by [hospital name to be provided upon request]. Sample #82 (40506170) belonged to [hospital name to be upon request], the license of which was cancelled on 9/18/1996 and its X-Ray equipment was removed. DOHMH document retention requirements dictate that registration records are maintain only for 4 years and inspection records for 7 years. The registration documents for these facilities are more than 20 years old and, according to record retention rules, no longer maintained by DOHMH. DOHMH provided the auditors with proof of the cancelled registrations.

State Comptroller's Comment - The records for these two hospitals were requested but not provided.

Issue 2**:** *Four [hospitals] (sic) had gaps in their registration periods.*

Response: DOHMH strongly disagrees with the auditors' assessments. The four registrations were renewed after the certificate had expired, nevertheless, a registration always remains current in the Citywide system (ACCELA) unless DOHMH takes action and cancels it. DOHMH allows registrations to be renewed after the certificate expiration date because it would create a health risk to deny the medical application of x-rays simply because the renewal paperwork was not timely filed by the registrant. Once renewed, the registration start date is retroactive to the previous certificate expiration date, so there is no gap in the registration period.

State Comptroller's Comment - Although DOHMH indicates that a registration remains in effect even if it has expired, the requirement for periodic renewal exists for a purpose, which is to protect the public. The focus should be that these registrations were not renewed timely in accordance with the Health Code.

Issue 3*: Various levels of non-compliance with selected registration procedures for 39 of the 51 hospitals sampled.*

Response: DOHMH strongly disagrees with the auditors' assessments. For the 39 sampled hospitals, the auditors list instances of non-compliance in 6 of 8 categories of registration procedures (Table 1). The listed instances include those referenced in issue #1 and # 2 above,

and the others are explained below for each category of registration procedures.

Table 1 – Selected Article 175 Registration Procedures for Hospitals.

1. *Application was not made 30 days before the expected operation start date - Health Code §175.51(d)(1)(i)* (Table 1, category 1, 8 instances)

Response: DOHMH strongly disagrees with the auditors' assessment. The Heath Code provides that a facility cannot operate radiation equipment without a registration approved by the Department. In order to provide DOHMH with time to process the application, applicants are directed to submit the application at least 30 days before the intended start date. If the application is not submitted within that time frame, the facility is on notice that DOHMH may not be able to approve it, and accordingly, the facility may not meet its intended time to open operations. Because the application must be approved before the equipment can be used, no matter when it is submitted, there is no risk to public health. If 8 facilities did not submit their application 30 days before their intended operation start date, as the auditors state, those facilities were simply on notice that DOHMH may not meet their preferred timeline.

State Comptroller's Comment - DOHMH indicates that late submission of an application poses no health risk, however, the audit did not say that it posed a health risk. The audit stated that applications were not submitted in accordance with the NYC Health Code, which requires that an application be made 30 days before the expected operation start date.

2. *No ALARA program and radiation protection program- Health Code §175.03(b)* (Table 1, category 2, 11 instances)

Response: We disagree with the auditors' assessment and believe that their assessment stems from not being trained or experienced in the field of radiation safety and regulation. ORH registers x-ray units according to the requirements of NYC Health Code §175.51(d)(1) & (2), not §175.03(b) noted in Table 1 of the draft report. Health Code §175.51(d)(1) (ii) indicates the documents that need to be submitted: "a completed application form…, a medical physicist report detailing the results of initial quality control tests conducted on all radiation-producing equipment in the facility… and a radiation protection survey…." ORH thoroughly reviews a facility's application for registration, including verifying that a facility is in compliance with ALARA and radiation protection program requirements. ALARA is not a defined program, but rather a set of engineering controls and processes (e.g., structural shielding of the site, lead aprons, moveable shields) that exist at a facility to minimize the x-ray exposure to the public and the x-ray operator. The Radiation Protection Survey (RPS) shows radiation levels around the x-ray site and to the x-ray operator, thus verifying the efficacy of the engineering controls in place at the site. An ORH physicist reviews the RPS for compliance prior to approving the registration, thus verifying that ALARA is in place.

State Comptroller's Comment - DOHMH replied that Section 175.51 (d) (1) (ii) is the correct requirement for radiation equipment. The response also states "ORH thoroughly reviews a facility's application, including verifying that a facility is in compliance with ALARA and radiation

protection program requirements." Similarly, Article 175.03 (b) requires the operator of a radiation installation to develop, document, and implement a radiation protection program commensurate with the scope and extent of the program. Although DOHMH indicates that it ensures the facility is in compliance with Section 175.51(d) (1)(ii), our review identified facilities where the implementation of such processes was not documented. Therefore, DOHMH cannot corroborate that it checks each facility for compliance with the Health Code.

3. *Registrant did not have written procedures for Auditing QA- Health Code §175.07(b)(2)* (Table 1, category 3, 6 instances)

Response: DOHMH strongly disagrees with the auditors' assessment, which refers to the incorrect provisions of the Health Code. The relevant registration requirements are provided in Health Code §175.51(d) (1) & (2), rather the one cited by the auditors. Health Code §175.51(d) (1) & (2), indicate the quality control reports that need to be submitted during an application for an x-ray registration. The submission of procedures for auditing QA programs is not required for new applicants.

State Comptroller's Comment - Health Code section 175.07(a) specifies that the section applies to all applicants, licensees, and registrants. There is no indication that submission of procedures for auditing QA programs is not required for new applicants.

4. *Registrant did not implement a quality assurance program – §175.07(b)(2) (Table 1, category 4 – No exceptions)*

Response: Not needed as the draft report includes zero exceptions.

5. *Facility not registered-Health Code §175.51(b)* (Table 1, category 5, 11 instances)-

Response: DOHMH strongly disagrees. The cited exceptions are duplicates of those discussed in Issue #1 and #2 above.

State Comptroller's Comment - These 11 exceptions were discussed in the narrative and categorized in the table.

6. *The period of registration certificates exceeded two years- Health Code §175.51(h)* (Table 1, category 6, 20 instances)

Response: DOHMH strongly disagrees with the auditors' assessment. As stated above, the registration date and renewal period are established based on the date the facility received permission to operate. The renewal effective date for all of the facilities identified by the auditor conforms to the Health Code.

When an application for renewal of registration is processed, the start date of the renewal is automatically set to the expiration date of the previous registration, and the registration period remains exactly two years.

State Comptroller's Comment - The Health Code provides that the registration period extends

from the date of issuance to the date of expiration, not to exceed two years.

7. Couldn't verify equipment- Health Code- §175.64(b)(vi)(A&B) (Table 1, category 7, 2 instances)

Response: DOHMH strongly disagrees with the auditors' assessment. An ORH physicist reviews the technical reports submitted with the application against the equipment list provided. ORH provided the auditors copies of the equipment lists that were submitted during the registration application process, substantiating ORH's verification of the equipment type. The renewal application does require submission of an equipment list. ORH verifies and updates the equipment list during the inspection.

State Comptroller's Comment - The files did not contain any equipment listings for these two facilities. Moreover, DOHMH did not provide any lists in response to the preliminary findings.

Table 2 - Selected Article 175 Inspection Procedures for Hospitals

1. *No ALARA program or radiation protection program- Health Code §175.03(b)* (Table 2, category 1, 6 instances)

Response: DOHMH strongly disagrees with the auditors' assessment. As already stated in the response to the registration procedures (Table 1), ORH does not simply check the box in documenting that a facility's ALARA and radiation protection program exists. ALARA is a set of engineering controls and processes (e.g. the structural shielding of the site, the lead aprons and movable shields, personnel radiation monitoring badges) that exist on site. ALARA principles (not "program") are verified by inspecting the registrants' x-ray site for the following: the registrant's radiation protection survey reports, inspecting lead aprons for quantity and integrity, detailed review of the registrant's personnel radiation monitors for the past several years. The inspection results of the latter are recorded in DOHMH ORH RC 37 Form which requires each inspector to record the results of his/her investigation into successful compliance of the ALARA concepts at the registrant's site.

State Comptroller's Comment - There was no documentation in the files to support compliance with ALARA or Radiation Protection Programs, written procedures for Quality Assurance, or review of registrants' annual audit reports.

ORH inspectors conduct a thorough review of a facility's radiation protection as documented in the registrant's Radiation Safety Policy and Procedures Manual. The review consists of verifying code compliance of the stated radiation safety policies for patient holding, pregnant workers and patients, employee personnel monitoring for radiation exposure levels, repeat reject analysis, etc. If policies are in compliance, then no specific documentation is brought to the office, however if existing written policies are not code-compliant, copies of such policies are brought to the office for follow-up.

2. *Registrant did not have written procedures for auditing QA- Health Code §175.07(b)(2)* (Table 2, category 2, 3 instances)

Response: DOHMH strongly disagrees with the auditors' assessment. Written procedures for auditing Quality Assurance (QA) Programs for a registrant consists of the QA Manual and the associated Quality Control (QC) tests mandated in the QA Manual and associated equipment repairs.

State Comptroller's Comment - There was no documentation in the files to support compliance with ALARA or Radiation Protection Programs, written procedures for Quality Assurance, or review of registrants' annual audit reports.

Each inspector reviews the Registrant's QA Manual for policies that are insufficient and/or incorrect, and reviews all the mandated QC tests conducted during the inspection cycle and reviews the equipment repair logbook.

For a large facility, these actions are documented in the Large Facility QA Review Inspection Checklist Form RC 37 lines 5, 6, 7, 8, 9,11,13,15, 16, 17, 18, CT Checklist Pg. 6, and 29. For small x-ray facilities these actions are documented on Inspection Report- Notice of Violation-Small Facility Form RC 42 lines 305, 306, 308, 309, 311, 312, 313, 315, and 324. Our internal review found that the inspection reports for 40506191 (9/2/14 and 3/10/17 inspection) and 40506247 (11/18/14 and 6/13/17 inspection) included the RC-42 form. The small non-hospital facility 50047955 (11/3/16 inspection) also included the RC-42 form.

If existing policies and/or QC reports are not code compliant, the registrant is cited the violation and is required to correct it. Where evidence of non-compliant is available in paper format, the Inspector will collect the documentation to substantiate their violations.

3. ORH reviewed the annual audit reports of the registrant's quality assurance program – §175.07(b)(2) (Table 2, category 3, 3 instances)

The auditors list 3 instances where DOHMH did not review the registrant's annual audit report.

Response: DOHMH strongly disagrees with the auditors' findings. Line 7 of ORH Form RC 37 Quality Assurance Audit requires inspectors to conduct an inspection of a registrant's Program Review. If the facility is code-compliant, no further action is taken. Failure to conduct an annual audit will cause a violation to be issued to the facility. ORH supervisors review inspection reports as part of ORH quality assurance activities and if a form is missing or a citation was not issued, it would be detected during the review and accordingly addressed. The auditors do not indicate that these steps were not taken.

State Comptroller's Comment - There was no documentation in the files to support compliance with ALARA or Radiation Protection Programs, written procedures for Quality Assurance, or review of registrants' annual audit reports.

4. *Not inspected* as required by Article §175.51(n)(1) (Table 2, category 4, 6 instances)

Response: DOHMH strongly disagrees with the auditors. After carefully reviewing the below findings that were not previously presented to DOHMH, DOHMH concludes that the auditors are mistaken. Please see below summary, which shows that the inspections were completed or not subject to inspection during the time period. The auditors have not made clear why they cite this finding.

40506171	The auditors' finding is incorrect. The facility was not in operation during the audit period.
50045527	The auditors' finding is incorrect. This non-hospital was inspected on 7/8/16 and is due for inspection on 7/7/19.
40506175	The auditors' finding is incorrect. The facility was inspected on 3/8/16 and 5/21/18.
50005697	The auditors' finding is incorrect. The facility was inspected most recently on 6/25/15 and is due for inspection on 6/24/18.
40506247	The auditors' finding is incorrect. The facility was most recently inspected on 7/13/17.
40506174	The auditors' finding is incorrect. The facility was inspected most recently on 6/1/16.

State Comptroller's Comment - The licenses in DOHMH's table are not the license numbers that were cited in the draft report as not meeting the inspection requirements. The correct license numbers were previously provided to DOHMH.

5. *Not inspected at the frequency established by ORH - §175.51(n)2(A)* (Table 2, category 5, 28 instances)

Response: DOHMH strongly disagrees with the auditors' assessment for 9 of the 28 facilities. Details showing that the inspection was timely conducted are below:

(i) Four (4) facilities were new Non-hospitals with a 2 yr. or 3 yr. inspection frequency (50043464, 50047955, 50043363, 50032651, 50007278, 50043363) that were inspected timely.

(ii) One (1) hospital not in operation during the audit (4506170)

(iii) One (1) new dental facility with a 5 year inspection frequency (50016446). The facility was inspected by a Certified Radiation Equipment Safety Officer (CRESO) on 8/11/14 as authorized by Health Code §175.51(n)(2)(E). The facility is due for another inspection on 8/10/2019.

(iv) One (1) facility does not exist based on registration number provided by the auditors (50005930).

(v) Two (2) other findings that were not correct. For registration #40506150, the facility was inspected timely on 12/16/2013 and 1/25/2016. For registration # 40506240, the facility was inspected timely on 9/22/2015 and 10/27/2017.

Of the remaining 19 hospitals, DOHMH agrees with the auditors and is working to reduce the inspection backlog and perform inspections within established timeframes. ORH now has one

additional inspector, and this additional staff will help in reducing inspection backlog.

State Comptroller's Comment - The licenses in DOHMH's response are not the licenses cited in the report. The correct license numbers were previously provided to DOHMH.

6. *Not re-inspected or re-inspection not timely after violation was issued Health Code 175.51(n)(2)(D)* (Table 2, category 6, 14 instances)

Response: DOHMH strongly disagrees with the auditors' assessment with respect to 11 facilities, which were timely re-inspected or did not require re-inspection—see details below. DOHMH agrees that 3 facilities that were re-inspected late, with one hospital (50010717) being only a few days late. DOHMH is working to address any backlog and has already hired additional staff to address this.

(i) Two (2) Non-Hospital dental facilities received an inspection by CRESO (50016446-8/11/14, 50032651-7/24/15) and no follow-up inspection was required.

(ii) Nine (9) hospital facilities (50005936, 40506149, 40506132, 40506150, 40506258, 40506153, 41323376, 40506241, and 40506219) were re-inspected timely.

State Comptroller's Comment - Ten of the 11 license numbers in DOHMH's response were not among the 14 instances cited. For one facility (50005936), there was no evidence of re-inspection after a violation was found. The correct license numbers were previously provided to DOHMH.

Recommendations

Recommendation 4: *Work with DCA to formally designate, in writing, each agency's role with respect to the issuing of certificates.*

Response: This recommendation is not needed. DOHMH has an intra-city Memorandum of Agreement (MOU) with the NYC Department of Consumer Affairs (DCA). The MOU formally documents the role of each Agency relevant to licensing and permits.

State Comptroller's Comment - DOHMH did not provide the auditors with an MOU with DCA during our audit.

Recommendation 5: *Retain evidence for all registrants for at least two registration periods.*

Response: This recommendation is not needed. The registration certificates and history of each registration is retained in the ACCELA online permit and licensing system. In light of this, it is unclear the basis for this recommendation. DOHMH notes that it is not aware of any federal, NY State or Health code that requires maintaining hard copies of registrations. The auditors do not cite any such a requirement.

State Comptroller's Comment - The audit found instances where the registration certificates

could not be located. Moreover, auditors did not specify the format in which registration certificates should be kept. Instead, the recommendation focuses on maintaining documentation.

Recommendation 6: *Conduct and document inspections of all facilities.*

Response: This recommendation is not needed. ORH has comprehensive inspection process controls. ORH inspectors follow the Health Code provisions for inspections and document inspections using a checklist Form RC – 37 for large facilities, and Form RC-42 for small facilities. Inspectors document non-compliance, where found, and collect documents to substantiate violations. ORH's review inspection documents and approve the final inspection reports.

Recommendation 7: *Review registrants' compliance with the radiation protection program.*

Response: This recommendation is not needed. Please refer to DOHMH's position relevant to instances of non-compliance listed in Table 2 category 2.

C. Radiation Equipment - Dentists, Podiatrists Non-Hospital, and Veterinarians

Issue 1: 25 facilities without active registration certificates and nine certificates issued subsequent to the expiration date of the previous certificate

Response: DOHMH strongly disagrees with the auditors' assessments. Each of the cited facilities were properly registered and there is a history of each registration in the NYC Department of Consumer Affairs (DCA) registration database (ACCELA). As stated above for hospitals – equipment, a registration always remains active in the City-wide system (ACCELA) unless DOHMH takes action and cancels it. DOHMH allows registration to be renewed after the certificate expiration date because it would create a health risk to deny the medical application of x-rays simply because the renewal paperwork was not timely filed by the registrant.

Regarding the "nine certificates issued subsequent to the expiration date of the previous certificate," DOHMH strongly disagrees with the auditors' assessment that the issue date on a registration certificate can be used to determine a gap in the facility's registration. When an initial application is approved, the expiration date of the initial certificate is set 2 years from the last day of the month in which the application is approved. When a registration renewal application is processed, the start date of the renewed registration is automatically set to the expiration date of the previous registration, and the registration period remains exactly two years. The renewal effective date for all of the facilities identified by the auditors conforms with the Health Code.

State Comptroller's Comment - The use of radiation-producing equipment after certificate expiration and before renewal could create a public health risk because the facility has not been reviewed by DOHMH timely. The timeline exists in the Health Code to ensure public safety.

Two [dental facilities] *(sic) not registered*

The auditors state that they selected a sample of 96 dental facilities from a list maintained by a private dental insurance provider and identified 2 that were not registered.

Response: DOHMH actively identifies facilities that are operating without having obtained an initial registration by cross referencing notifications of new x-ray installations received from FDA with new registration applications. DOHMH also inspects the premises of facilities that request cancellation of their registration to determine whether a new occupant is using x-rays. ORH works with the regulated community to ensure timely renewal of the registrations when they expire through written notification and enforcement. Registration renewal notices are mailed by NYC Department of Consumer Affairs (DCA) 90 days in advance of expiration and a follow-up reminder is mailed by DOHMH. All registered facilities are inspected on their routine cycle until ORH verifies the facility is no longer operating.

State Comptroller's Comment - We are encouraged that DOHMH actively identifies facilities operating without obtaining an initial registration. However, as evidenced by our finding of two unregistered facilities, DOHMH needs to enhance its efforts in this area.

Issue 2: *DOHMH has not ensured compliance* with required registration and inspection procedures at non-hospital facilities.

The auditors assess that DOHMH did not comply with 6 selected registration procedures in 72 facilities. The auditors base their assessment on instances of non-compliance in 6 registration procedures categories (table 3). The 6 categories include the 25 instances that are already presented in issue #1 above, *25 facilities without active registration certificates.*

DOHMH strongly disagrees with the auditors' assessments as explained below.

Table 3 – Selected Article 175 Registration Procedures for Radiation Equipment

1. *Application was not made 30 days before establishing the installation of x-ray equipment – §175.51 (B)(2)* (Table 3, column 2, 9 instances)

Response: Since the auditors did not provide the registration numbers for the 9 cited facilities, DOHMH cannot verify the validity of the exception. Nevertheless, as already stated, the Heath Code provides that a facility cannot operate x-ray equipment without a registration approved by the Department. In order to provide DOHMH with time to process the application, applicants are directed to submit the application at least 30 days before the intended start date. If the application is not submitted within that time frame, the facility is on notice that DOHMH may not be able to approve it, and accordingly, the facility may not meet its intended time to open

operations. Because the application must be approved before the equipment can be used, there is no risk to public health.

State Comptroller's Comment - We provided the details, including the registration numbers, at the preliminary findings phase of the audit.

2. *No ALARA program and radiation protection program- §175.03(b)(2)* (Table 3, column 3, 18 instances)

The auditors state that "*18 of the 72 facilities did not have an ALARA program or a radiation protection program…*". The auditors also state that ALARA was not "*documented within the files, as would be expected*".

Response: DOHMH strongly disagrees with the auditors. Fourteen of the 18 facilities cited here are dental or podiatric facilities. Dental and podiatric equipment emit low levels of radiation (very small beam size and low output radiation levels) that is close to background radiation levels. An ALARA and radiation protection programs are thus not required. An Operator Protection Survey is sufficient to verify that operator's radiation exposure is as low as reasonably achievable for x-ray operation at a dental or podiatric office and that the ALARA concept is being implemented. The Operator Protection Survey is part of the Certified Radiation Equipment Safety Officer (CRESO) report, which is a required part of each dental facility application. Each CRESO report is reviewed and approved by ORH and a copy is kept in ACCELA.

State Comptroller's Comment - Although DOHMH officials stated that radiation exposure at dental and podiatric facilities was similar to background radiation, ALARA is required by the regulations. If DOHMH determines that it is not necessary, it should amend the regulations.

As for the non-dental and podiatric facilities, ORH registers x-ray units according to the requirements of NYC Health Code §175.51(d) (1) & (2). The Health Code §175.51(d)(1)(ii) indicates the documents that need to be submitted: "a completed application form…, a medical physicist report detailing the results of initial quality control tests conducted on all radiation-producing equipment in the facility… and a radiation protection survey…." ORH thoroughly reviews a facility's application for registration, including verifying that a facility is in compliance with ALARA and radiation protection program requirements. ALARA is not a defined program, but rather a set of engineering controls and processes (e.g., structural shielding of the site, lead aprons, moveable shields) that exist at a facility to minimize the x-ray exposure to the public and the x-ray operator. The Radiation Protection Survey (RPS) shows radiation levels around the x-ray site and to the x-ray operator, thus verifying the efficacy of the engineering controls in place at the site. An ORH physicist reviews the RPS for compliance prior to approving the registration, thus verifying that ALARA is in place. The RPS for applicants are filed in ACCELA.

State Comptroller's Comment - Our review of the files for the sampled facilities to determine compliance with ALARA included examining inspection reports, determining whether there was documentation of a radiation protection program, whether there was a radiation protection officer, and whether the facility had a quality assurance program.

3. *Facility not registered –§175.51(b) (Table 3, column 4, 25 instances*)

   Response: DOHMH strongly disagrees with the auditors' assessment. This finding and the DOHMH response is presented in Issue 1, above.

State Comptroller's Comment - The use of radiation-producing equipment after certificate expiration and before renewal could create a public health risk because the facility has not been reviewed by DOHMH timely. The timeline exists in the Health Code to ensure public safety.

4. *Registration certificates exceeded two years-§175.51(h)* (Table 3, column 5, 44 instances)

   Response: DOHMH strongly disagrees with the auditors' assessment. As explained in DOHMH's response to Issue 1 above, the registration date and renewal time period are established based on the date the facility received permission to operate. The renewal effective date for all of the facilities identified by the auditors conforms with the Health Code.

   When an initial application is approved, the expiration date of the initial certificate is set 2 years from the last day of the month in which the application is approved. When an application to renew registration renewal application is processed, the start date of the renewed registration is automatically set to the expiration date of the previous registration, and the registration period remains exactly two years.

State Comptroller's Comment - Our review found instances where the registration period exceeded two years.

5. *Application incomplete – [Health Code] 175.51(d)(2)(i)* (Table 3, column 6, 3 instances)

   Response: DOHMH strongly disagrees with this audit finding. The Agency provided the auditors with the equipment list for 2 of the 3 samples (50033783, 50039501). The other was a dental facility with a complete application.

State Comptroller's Comment - The report was revised to reflect information provided in the response to the draft report.

6. *Dental facility not initially inspected by ORH Inspector – [Health Code] 175.51(d)(2)(ii)* (Table 3, column 7, 13 instances)

   Response: DOHMH strongly disagrees with the auditors' assessment. The auditors misunderstand the Health Code requirements when they claim that these facilities were not properly inspected. Inspections of new dental and podiatric facilities are conducted by

DOHMH inspectors or by Certified Radiation Equipment Safety Officers (CRESO) inspectors when directed by the Department. The auditors should review Health Code sections §175.51(b), §175.51(d) and §175.51(n), which together set forth the requirements for inspections of new facilities and for inspections to be conducted by CRESOs. The application instructions for new dental and podiatric registrants requires such applicants to "contact a DOHMH-certified CRESO (Certified Radiation Equipment Safety Officer) to secure an inspection." Since securing an initial CRESO-inspection is a permit application requirement for new dental and podiatric facilities, it constitutes a directive by the Department as required by section §175.51(n)(2)(E). Therefore, ORH is in compliance with the section §175.51 inspection requirements in requiring CRESOs to conduct initial Department inspections.

State Comptroller's Comment - The Health Code section cited in the report states that "Prior to any clinical usage of radiation-producing equipment, all such new facilities shall be inspected by the Department."

Table 4 – Selected Article 175 Inspection Procedures for Dentists

The auditors assess that DOHMH did not comply with four categories of inspection procedures. DOHMH's response to the instances cited are as follows:

1. *No ALARA program – [Health Code] 175.03(b)* (Table 4, column 2, 61 instances)

The auditors stated that 61 of the 63 facilities sampled "did not have a radiation safety program." The auditors cite DOHMH's response to the preliminary issue that "Dental Equipment Survey and Radiation Safety Survey forms are sufficient evidence to verify compliance with the ALARA program. The auditors are on the opinion, however, that ALARA was "not documented within the [ORH] files".

State Comptroller's Comment - Although DOHMH officials stated that radiation exposure at dental and podiatric facilities was similar to background radiation, ALARA is required by the regulations. If DOHMH determines that it is not necessary, it should amend the regulations.

Response: DOHMH strongly disagrees with the auditors' assessment for the reason already stated above (issue 2. (b)). Dental facilities emit low levels of radiation (very small beam size and low output radiation levels) that is close to background radiation levels. Thus, ALARA and radiation protection programs are not required. An operator protection survey is sufficient to verify that dental operator's radiation exposure is as low as reasonably achievable for x-ray operation at a dental office and that the ALARA concept is being implemented. The operator survey is part of the CRESO report and the ORH dental facility inspection report.

2. *Not inspected - Health Code 175.51(n)(1) (Table 4, column 3, 10 instances*)

Response: DOHMH acknowledges that during the audit period 10 of the dental facilities reviewed by the auditors were not inspected as required. To improve compliance, ORH implemented new procedures in June 2017 that require dentists and podiatrists to include a

copy of a current inspection report with their registration renewals. DOHMH will not approve a renewal application that does not include proof of inspection. To further promote compliance, ORH quarterly provides all approved CRESOs with a list of facilities needing an inspection, encouraging CRESOs to contact the facilities directly. In addition, DOHMH issues violations to facilities that fail to have their inspection performed timely. Starting July 1, 2018 ORH will issue Commissioners Orders to facilities ordering them to obtain a CRESO inspection when they become due.

3. *Not inspected at the frequency established by ORH – [Health Code] 175.51(n)(2)B)* (Table 4, column 4, 1 instance)

Response: The facility was ordered to obtain a CRESO inspection within ORH's internal inspection frequency guidelines but did not comply with the timeline established by the order. As a result the facility was issued a summons and the inspection was performed late.

4. *Not re-inspected timely after the violation was issued - Health Code 175.51(n)(2)(D)* (Table 4, column 5, 1 instance)

Response: We acknowledge this exception. However, during inspection on 10/3/16, we determined that the facility was out of business.

Recommendations

Recommendation 8**.** *Register all radiation facilities/equipment and retain registration certificates for all registrants for at least two registration period.*

Response: This recommendation is not needed. These documents are maintained electronically in ACCELA. To the extent the recommendation is to maintain hard copies, DOHMH is not required to maintain hardcopies of current and prior registration certificates, and maintaining hardcopies is not necessary as they are maintained electronically in ACCELA and would be burdensome and wasteful.

State Comptroller's Comment - As described in the report, we identified deficiencies in the licensing, inspection, and documentation processes.

Recommendation 9. *Conduct and document inspections for all facilities.*

Response: This recommendation is not needed. Inspections are currently scheduled and tracked in a secure database and each complete inspection report is uploaded to the system.

Recommendation 10. *Review registration for compliance with the radiation protection program or, if not applicable, document the rationale.*

Response: This recommendation is not needed.

Recommendation *11. Have DOHMH inspectors conduct initial inspections of dental facilities rather than CRESOs.*

Response: This recommendation is not needed. The Health Code §175.51 must be considered as a whole concerning Department inspections. Section §175.51(d)(2)(ii) does require a Department inspection of new dental and podiatric facilities. However, section §175.51(n)(2)(E) allows Department inspections of dental and podiatric facilities to be conducted by CRESOs "as the Department shall direct". The application instructions for new dental and podiatric registrants requires such applicants to "contact a DOHMH-certified CRESO (Certified Radiation Equipment Safety Officer) to secure an inspection." Since securing an initial CRESO-inspection is a permit application requirement for new dental and podiatric facilities, it constitutes a directive by the Department as required by section §175.51(n)(2)(E). Therefore, ORH is in compliance with the section §175.51 inspection requirements in requiring CRESOs to conduct initial inspections.

State Comptroller's Comment - The Health Code section cited in the report states that "Prior to any clinical usage of radiation-producing equipment, all such new facilities shall be inspected by the Department."

D. Radiation Equipment Disposal

The registration for one of [seven facilities that had an expired registration*](sic) was not renewed, and DOHMH did not document that the facility had complied with Section 175.56(b)*

Response: DOHMH strongly disagrees with this finding. For one of the facilities, the auditors misunderstand the requirements and the circumstances: the registration was not renewed for one facility because the facility did not pay the civil penalties owed for violations that had been sustained at a hearing held by the Office of Administrative Trials and Hearings. The Health Code requires that any civil penalties be paid before a registration or permit can be renewed. Pending this payment, the registration remains in renewal status so that patient care can continue and DOHMH monitoring will continue, both of which are in the best interest of public health.

State Comptroller's Comment - The audit is not disputing the circumstances under which the facilities stopped using the radiation equipment. Health Code Section 175.56(b) requires that "Radiation equipment which is not intended to be used must be made inoperable to the satisfaction of the Department by dismantling or sealing with an official Department seal or other suitable method, and shall not be unsealed or restored to operable condition without prior authorization by the Department." We did not find evidence that DOHMH ensured compliance with this requirement.

Of the remaining six facilities, four are out of business, one has been renewed and one has not been renewed.

To maintain radiological equipment on site that is not intended to be used, facilities must (i) make their request to DOHMH ORH in writing, (ii) identify the specific equipment and reason for request, (iii) make equipment inoperable, (iv) seal equipment with an "Out of Service" tag, and save DOHMH ORH acknowledgement of request. Facilities with sealed radiological equipment must maintain a current registration and they remain subject to regular inspection by DOHMH.

A registration always remains current in the system (ACCELA) unless DOHMH takes action and cancels it. DOHMH allows registrations to be renewed after the certificate expiration date because it would create a health risk to deny the medical application of x-rays simply because a registration certificate had expired. Once renewed, the registration start date is retroactive to the previous certificate expiration date, so there is no gap in the registration period.

Recommendation:

Recommendation *12. Verify that the registrant makes the radiation equipment inoperable*.

Response: This recommendation is not needed. A registration always remains current unless DOHMH cancels it and thus, DOHMH will continue to monitor it and perform regular inspections. As part of this oversight, during inspections, DOHMH will verify that the facility followed the provisions of the Health Code §175.56(b) listed in the response to the issue above.

E. Qualifications

DOHMH did not have documentation regarding the qualifications of four employees

The Comptroller's auditors examined the qualification of 18 inspectors active during the audit period, including the Director and Assistant Commissioner. The draft report indicates that DOHMH "did not have documentation regarding the qualifications of four employees", 2 inspectors hired as Level II Scientists and 2 inspectors hired as Assistant Scientists.

Response: DOHMH acknowledges that it did not have the requested documentation for the 4 employees for the following reason. Employment Law restricts employers to information that can be released for employment verification and allows employers to release limited information such as dates of employment, job title, full- or part- time status and, prior to 2017, verification of a salary amount, if given. Prior to 2015, DOHMH's practice was to assess the candidate's abilities through interview questions, skills assessment measures etc., and candidate's signed affirmation.

In late 2015, DOHMH implemented a process whereby the selected candidates are required to provide written verification of the required and claimed experience before granting clearance. Two of the 4 referenced employees were hired prior to 2009, and the other 2 were hired in 2015 prior to the new verification procedure implemented by DOHMH.

For all employees, including those audited, several structured processes were used to measure their abilities and knowledge in order to make a hiring decision. Interviews were conducted by subject matter experts (SME) to determine competency. The SMEs asked specific questions related to the tasks, experience, knowledge and abilities needed for the job. If the candidate was a top runner for the position, before the job was offered, the program conducted a telephone verification of the reference provided by the candidate.

In addition, per Civil Service law, new employees are subject to a probationary period during which they are evaluated on their ability to perform the actual tasks associated with the job and continue employment only if they meet all the job requirements.

Recommendation

Recommendation *13. Ensure that the experience and qualifications are validated and documented.*

Response: DOHMH agrees with recommendation. In 2015, DOHMH implemented a process to require candidates to provide written verification of the required and claimed experience to the extent allowed under Employment Law.