Department of Health

Oversight of Registration, Licensing, and Inspection of Radioactive Materials Facilities and Radiation Equipment Facilities

Report 2019-S-64 | September 2021

OFFICE OF THE NEW YORK STATE COMPTROLLER
Thomas P. DiNapoli, State Comptroller

Division of State Government Accountability

Audit Highlights

Objectives

The objectives of this audit were to determine if the Department of Health (Department) is ensuring that the registration, licensing, and inspection of radioactive materials facilities and radiation equipment facilities are completed as required. The audit covered licensing and inspection records for the period of January 1, 2017 through February 28, 2020 and other information through March 5, 2021.

About the Program

When handled correctly, radioactive materials have many beneficial medical, industrial, and academic uses. Radioactive materials can be used for diagnostic and therapeutic purposes, to test new drugs and to study cellular functions, and in various industrial applications to protect food and blood supplies, increase the safety of roads and buildings, and locate new energy sources. However, high amounts of radiation exposure can cause serious bodily harm.

The Department is responsible for the supervision and regulation of radiation and radioactive materials in New York State, outside of New York City. To fulfill these responsibilities, the Department has established the Bureau of Environmental Radiation Protection, whose duties include licensing and inspecting approximately 1,100 radioactive materials facilities (RAM facilities), as well as registering and inspecting approximately 9,900 radiation equipment facilities that use diagnostic, mammography, and stereotactic equipment. Failure to promptly register, license, inspect, or follow up on facilities that use radioactive materials or radiation equipment increases the risk that radioactive materials or equipment may be improperly handled or stored, and may expose employees, patients, and others to increased levels of radiation.

Key Findings

- The Department completed 94% of RAM facility and radiation equipment facility inspections on time; however, it completed 44% of those inspections beyond the established 1- to 5-year inspection time frames by relying on a buffer. The buffer is intended to allow for more flexibility and logical extensions to the inspection intervals, such as for staff time and travel. Additionally:
  - Of the 259 RAM facility inspections that needed the buffer to be considered inspected on time, 86 (33%) showed facilities were, at the time of inspection, not in compliance with established standards. Further, for 33 of those 86 inspections (38%), our analysis showed that, during the prior inspection, the Department had also found the facility was not in compliance.
  - Of the 2,720 radiation equipment facility inspections that needed the buffer to be considered inspected on time, 249 (9%) showed facilities were, at the time of inspection, not in compliance with established standards. Further, for 55 of those 249 inspections (22%), our analysis showed that, during the prior inspection, the facility was found not in compliance at that time as well.

  Recurring and timely inspections help to ensure sustained regulatory compliance and help address risky situations that could compromise health and safety standards. Instances of non-compliance and repeat non-compliance raise a greater concern about the Department's reliance on the buffer.

- The Department did not complete all license actions within the Department's 1-year benchmark. For example, as of July 20, 2020, the Department had not completed 55 licensing actions that were beyond the 1-year benchmark. This could potentially jeopardize the quality of the Department's licensing program, which can have a direct bearing on public health and safety, as well as security.

Key Recommendations

- Ensure that all required inspections are completed on time.
- Continue to work toward reducing the backlog of pending licensing actions and ensure that future licensing actions are completed within their established benchmark.

Office of the New York State Comptroller
Division of State Government Accountability

September 23, 2021

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

Dear Dr. Zucker:

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 the 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 *Oversight of Registration, Licensing, and Inspection of Radioactive Materials Facilities and Radiation Equipment Facilities*. This audit was performed pursuant to the State Comptroller's authority under Article V, Section 1 of the State Constitution and Article II, Section 8 of the State Finance 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 report, please feel free to contact us.

Respectfully submitted,

Division of State Government Accountability

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Glossary of Terms

Term	Description	Identifier
Department	Department of Health	*Auditee*
MQSA	Mammography Quality Standards Act	*Key Term*
NRC	U.S. Nuclear Regulatory Commission	*Key Term*
NYCRR	New York Codes, Rules and Regulations	*Regulations*
RAM facility	Radioactive materials facility	*Key Term*
X-ray	Diagnostic	*Key Term*

Background

When handled correctly, radioactive materials have many beneficial medical, industrial, and academic uses. In medicine, radioactive materials are used for diagnostic and therapeutic purposes. Similarly, in biological and biomedical research, they are used to test new drugs and to study cellular functions and bone formation in mammals. In addition, radioactive materials are used in various industrial applications to protect food and blood supplies, increase the safety of roads and buildings, locate new energy sources, light emergency exits, warn of fires, and more. However, based on amount of exposure, radiation can cause injury or death by damaging bodily systems. The regulatory system for radioactive materials is designed to allow the beneficial uses of radioactive materials while minimizing the risk to public health and the environment by preventing the possibility of exposure anywhere close to the levels that might inflict even short-term damage.

The Department of Health (Department) is responsible for the supervision and regulation of radiation and radioactive materials in the State, outside of New York City, excluding large quantities of certain nuclear materials and the storage of high-level radioactive waste. To fulfill these responsibilities, the Department has established the Bureau of Environmental Radiation Protection, whose duties include licensing and inspecting approximately 1,100 radioactive materials facilities (RAM facilities), as well as registering and inspecting approximately 9,900 radiation equipment facilities that use diagnostic (X-ray) equipment, mammography equipment, and stereotactic equipment (used to conduct stereotactic breast biopsies, which are non-surgical assessments performed by specially trained radiologists on an outpatient basis). The Department is also responsible for responding to incidents involving either radioactive materials or radiation equipment and is involved in overseeing county and private inspection programs.

The U.S. Nuclear Regulatory Commission (NRC) has a long-standing agreement with New York State to regulate the possession and use of radioactive materials for entities located within the State that are not within the federal government's exclusive jurisdiction, and performs a review of the Department's program operations every 4 years. The Department must follow NRC's Inspection Manual when performing RAM facility inspections. The Department issues 121 different radioactive materials license types. Licensees are generally associated with academic fields, medical fields, or fields associated with materials testing (e.g., lead analyzer) and/or environmental components (e.g., moisture density).

The Department's responsibilities pertaining to the oversight of radiation equipment do not fall within the scope of the agreement with the NRC and, as such, are not part of the NRC's program review of the Department's operations. Instead, the Department must follow the New York Codes, Rules and Regulations (NYCRR) for X-ray and stereotactic equipment inspections. Facilities with mammography equipment fall under the federal Mammography Quality Standards Act (MQSA). The Department must follow MQSA requirements for these inspections. Facilities under the MQSA generally include hospitals, clinics, physician offices, and women's health centers.

Audit Findings and Recommendations

For the period of January 1, 2017 through February 28, 2020, we found the Department completed 6,786 (94%) of RAM facility and radiation equipment facility inspections on time. However, 44% of those inspections were considered on time only by relying on a buffer period that extended the established 1- to 5-year inspection time frames. The buffer is intended to allow for more flexibility and logical extensions to the inspection intervals, such as for staff time and travel. We found that the Department relies on the buffer a high percentage of time for higher-risk facilities (more frequent inspections are required for facilities that pose a higher risk of harmful effects). In addition, 335 RAM facility and radiation equipment facility inspections that needed the buffer to be considered inspected on time showed the facilities were not in compliance with established standards, and 88 of those inspections showed the facilities were not in compliance during the prior inspection as well. Instances of non-compliance and repeat non-compliance raise a greater concern about the Department's reliance on the buffer.

We also found that the Department did not complete all license actions (new applications, renewals, and amendments) promptly. For example, as of July 20, 2020, the Department had not completed 55 licensing actions that were beyond the 1-year benchmark, which included six new licensing actions that the Department considers a higher-risk area and therefore need timely processing. We did not identify any issues with the registration of radioactive equipment.

Additionally, the Department has not yet formalized all of its policies and procedures for licensing and inspecting activities—a step that would help ensure consistency in carrying out the Department's responsibilities and its compliance with new laws, regulations, or other Department practices.

Inspection Activities

According to the NRC Inspection Manual, inspections assess licensee performance to determine whether radioactive materials are being used safely and whether an individual or organization is in compliance with established standards, such as orders, regulations, conditions, and commitments submitted in support of a license. The NRC Inspection Manual also states that inspections involve a visit to a licensee's facility and/or temporary job site by inspectors, observations of licensed activities, interactions with licensee personnel, independent radiological measurements, and transmission of the inspection findings.

If inspections are not performed within the required time frames and resulting inspection reports are also delayed, violations, equipment defects, or other instances of non-compliance with established standards could go undetected and unaddressed for a prolonged period. This could result in extended periods of risk for individuals reliant on potentially faulty equipment, such as employees providing examinations and treatments and the patients receiving services. Likewise, frequently using the inspection buffer delays equipment inspections, reports, and the timely remediation of issues identified. It can also increase the risk that individuals are exposed to higher levels of radiation.

RAM Facility Inspections

Facilities are categorized based on risk using a scale from 1 (most harmful effects on a human in a short period of time) to 5 (unlikely to cause harm). For each category, the NRC has established a corresponding inspection frequency—for example, a 1-year frequency for Category 1 facilities and a 5-year frequency for Category 5 facilities. However, the NRC allows additional time for RAM facility inspections, referred to as an inspection buffer, which is intended to provide flexibility and logical extensions to the inspection intervals. The buffer allows for 6 months of additional time for facilities with a 1-year inspection frequency requirement and 1 year of additional time for facilities with other inspection frequencies.

During the period from January 1, 2017 through February 28, 2020, the Department performed 725 RAM facility inspections (outside of New York City). Due to data limitations and sampling techniques, we examined the timeliness of 584 RAM facility inspections (see Table 1). Of the 584 RAM facility inspections we analyzed, the Department conducted 32 late. Of those late inspections, 56% occurred at Category 1 and 2 (higher risk) facilities with 1-year and 2-year inspection frequencies, respectively. While the Department conducted the other 552 inspections on time, 47% were considered on time only because of the inspection buffer. Further, a high percentage of the Category 1 and 2 facility inspections (89% and 63%, respectively) were completed in the buffer period.

Table 1 – Timeliness of RAM Facility Inspections

Facility Category/ Inspection Frequency	Total Inspections Analyzed	On-Time Inspections	On-Time Inspections Using Buffer*	Percent of On-Time Inspections Using Buffer	Late Inspections	Percent of Late Inspections
1 - 1 year	36	28	25	89%	8	22%
2 - 2 year	140	130	82	63	10	7
3 - 3 year	16	13	11	85	3	19
4 - 4 year	2	2	1	50	0	0
5 - 5 year	390	379	140	37	11	3
Totals	**584**	**552**	**259**	**47%**	**32**	**5%**

* Buffer is an additional 6 months for facilities with a 1-year inspection requirement and an additional 1 year for facilities with 2- to 5-year inspection requirements.

Of the 259 inspections that needed the buffer to be considered inspected on time, according to Department records, 86 inspections (33%) showed that the facilities were found not to be in compliance with established standards at the time the Department conducted the inspection. Further, for 33 of those 86 inspections (38%), our analysis showed that, during the prior inspection, the Department had found the facility was not in compliance at that time as well. These instances of non-compliance and repeat non-compliance raise a greater concern about the Department's reliance on the buffer.

Diagnostic Equipment Facility Inspections

Title 10 NYCRR Part 16 states that radiation installations shall be inspected periodically and reported on in writing, as prescribed by the Department. These reports shall include all recommendations necessary to accomplish compliance and to reduce radiation exposure as far below the limits as reasonably achievable, as described in regulations. Although X-ray and stereotactic inspections do not fall within the scope of the agreement with the NRC, the Department allows a 50% buffer based on the scheduled inspection frequency for these facilities. For example, for a facility with an inspection frequency of 4 years, the Department allows 2 additional years, for a total of 6 years to perform the inspection and consider it completed on time. Similar to the RAM facility inspections, a shorter inspection frequency is indicative of the greater risks the facility poses and, as such, a need for the Department to more closely monitor the equipment.

During the period January 1, 2017 through February 28, 2020, we identified 162 instances where the Department should have conducted diagnostic X-ray facility inspections but had not done so. During that same period, the Department performed 8,874 X-ray equipment facility inspections. Due to data limitations and sampling techniques, we examined the timeliness of 5,409 of those inspections (see Table 2).

Table 2 – Timeliness of Diagnostic X-ray Facility Inspections

Inspection Frequency	Total Inspections Analyzed	On-Time Inspections	On-Time Inspections Using Buffer*	Percent of On-Time Inspections Using Buffer	Late Inspections	Percent of Late Inspections
1 year	36	16	11	69%	20	56%
2 year	1,152	942	504	54	210	18
3 year	968	935	401	43	33	3
4 year	136	133	65	49	3	2
5 year	3,117	3,106	1,361	44	11	<1
Totals	**5,409**	**5,132**	**2,342**	**46%**	**277**	**5%**

*Buffer is an additional 50% of the frequency (e.g., a 1-year frequency allows 1.5 years, a 2-year frequency allows 3 years).

We found that the Department conducted 277 of 5,409 inspections late. Of those 277 late inspections, 83% were associated with facilities with 1-year and 2-year inspection requirements. Further, 56% of the inspections for facilities with a 1-year requirement were completed late. While the Department completed the other 5,132 of 5,409 inspections on time, 46% were considered on time only due to the buffer allowance. Moreover, a higher percentage of the 1-year and 2-year facility inspections (69% and 54%, respectively) were completed in the buffer period.

In addition, of the 2,342 inspections that needed the buffer to be considered inspected on time, according to Department records, 205 (9%) showed that the facilities were not in compliance with established standards at the time of inspection. Further, for 46 of those 205 inspections (22%), our analysis showed that, during the prior inspection, the facility was found not in compliance at that time as well.

MQSA Facility Inspections

The MQSA requires mammography facilities across the nation to meet uniform quality standards to ensure high-quality mammography for early breast cancer detection, which can lead to early treatment, a range of treatment options, and increased chances of survival. The MQSA requires an annual facility inspection and permits a 2-month buffer, for a 14-month total allowance before an inspection is considered late. The shorter inspection frequency is indicative of the importance of completing these types of inspections timely.

During the period from January 1, 2017 through February 28, 2020, the Department performed 1,074 MQSA facility inspections. Due to data limitations and sampling techniques, we examined the timeliness of 924 MQSA facility inspections. We found that the Department completed 85 of the 924 inspections late (outside the 14-month total allowance). While the Department completed the other 839 of 924 inspections on time, 44% (367 of 839) were considered on time only due to the inspection buffer. According to Department records, 44 of those 367 inspections (12%) showed that the facilities were found to be not in compliance with established standards at the time of inspection. Further, for nine of those 44 inspections (20%), our analysis found that, during the prior inspection, the facility was found not in compliance at that time as well.

Stereotactic Equipment Facility Inspections

Stereotactic equipment is used to conduct stereotactic breast biopsies, which are non-surgical assessments performed by specially trained radiologists on an outpatient basis. The Department prescribed a 2-year inspection frequency (3 years with buffer) for all stereotactic equipment.

During the period from January 1, 2017 through February 28, 2020, we identified 16 instances where the Department should have conducted a stereotactic facility inspection but had not done so. During that same period, the Department performed 342 inspections. Due to data limitations and sampling techniques, we examined the timeliness of 287 of those inspections. We found the Department conducted 24 of 287 (8%) inspections late. The Department completed the other 263 of 287 inspections on time, with only 11 of those 263 relying on the buffer period.

Licensing Activities

According to the NRC, the quality, thoroughness, and timeliness of licensing actions can have a direct bearing on public health and safety, as well as security. The Department established 1 year as its benchmark for approving license actions, which include processing new license applications, license renewals, and amendments to previously issued licenses (amendments include items such as requests to change the radiation safety officer for a facility or the location for storing and using radioactive materials).

Between January 1, 2017 and February 28, 2020, the Department completed 2,604 licensing actions (178 new license applications, 419 renewals, and 2,007 amendments), of which we randomly sampled 21 new license applications. We found that the Department approved 20 of those 21 new license applications within the 365-day benchmark. The one new license we sampled that the Department processed outside the 1-year benchmark (477 days) was late due to a staffing issue. Despite that, the Department, on average, processed the 21 new license applications in 88 days.

An NRC report dated July 19, 2018 indicated that, as of March 2018, the Department had a backlog of licensing actions that included 83 renewals and 41 amendments that were pending for over 1 year. Although, during our audit, the Department had dedicated resources and was making progress in reducing its backlog of licensing actions pending processing for more than 365 days, we found the Department still had 55 licensing actions pending processing outside the 365-day benchmark (see Table 3), which included six new licensing actions the Department considers a higher-risk area and therefore need timely processing. Of those 55 licensing actions, 49% (27 of 55) were pending processing for more than 3 years, including one renewal awaiting processing for over 12 years. In its report, the NRC indicated that issues with completing licensing actions within the required time frame are the result of the Department lacking adequate staff.

Table 3 – Pending Licensing Actions Over 365 Days

Years Pending	New Applications	Renewals	Amendments	Totals
1-2 Years	1	5	15	21
2-3 Years	1	3	3	7
3-5 Years	2	3	4	9
5-10 Years	2	6	9	17
10+ Years	0	1	0	1
Totals	**6**	**18**	**31**	**55**

However, for the 18 renewals and 31 amendments, we found that the Department conducted the required inspections for 47 of the 49 licenses, thus mitigating potential risks associated with not processing the license actions within 365 days. For the other two (of 49) licenses, according to the Department, it has been logistically difficult to access the source of one license (an out-of-state dredging ship), but it is currently working with the license holder to arrange a remote inspection, and the other license holder has been unresponsive to the Department's inspection requests. Although the Department believes that this licensee's radioactive materials have since decayed and are no longer usable, the license is still valid, which would allow the license holder to obtain, possess, and use radioactive materials.

The ability to conduct effective licensing and inspections programs depends largely on having a sufficient number of experienced, knowledgeable, well-trained technical personnel. Failure to promptly license, register, inspect, or follow up on violations

in facilities with radioactive materials or radiation equipment increases the risk that radioactive materials may be improperly handled or stored, and may expose employees, patients, and others to increased levels of radiation. The NRC's report identified performance issues related to a backlog of licensing actions that indicate the Department did not have adequate staffing, and also found that the Department had not implemented a well-conceived and balanced staffing strategy. This staffing issue is also likely contributing to the Department's reliance on the buffer for its inspections. According to the Department, it attempts to be cost efficient by having inspectors perform multiple inspections in a geographic region, a strategy that can conflict with performing inspections on time. Further, Department staff have other responsibilities such as training for nuclear power plant emergencies, investigating complaints, and responding to emergencies. Recurring and timely inspections and prompt attention to licensing actions help ensure sustained regulatory compliance and address risky situations that could compromise health and safety standards, and staffing issues can hinder the Department's efforts on these actions.

Inspection and Licensing Procedures

Uniform and written policies and procedures help ensure consistency in performing Department responsibilities such as registering, licensing, or inspecting facilities. Policies outline what tasks need to be performed. Procedures complement policies by explaining how and when those tasks should be completed, as well as who should be primarily responsible for completing them.

We found that, as of October 31, 2020, the Department had not yet formalized all of its policies and procedures for licensing and inspection activities, as it has been focused on conducting inspection and licensing activities. At the beginning of our audit, the Department did not have written procedures that covered all areas of operations, such as license application reviews and inspections for certain radioactive materials. Since then, the Department has developed, but not yet formalized, an X-ray inspection manual, licensing application review processes, and inspection procedures pertaining to certain radioactive materials licensees. Department officials stated that they will need to assess the long-term impacts of the COVID-19 pandemic on changes to regulations, and after the completion of our fieldwork, will finalize existing draft operating procedures. Officials also indicated they will review and update those procedures periodically to reflect changes in regulations or policy.

We also found that the Department had not documented policy changes, such as changes to mandated inspection schedules. According to the NYCRR, inspections are not to exceed the maximum frequency specified in NYCRR Part 16. However, Part 16 allows the Department to establish a revised inspection schedule that changes the specified frequency. For example, Part 16 specifies that the Department inspect dentists and podiatrists every 3 years and hospitals every year. However, the Department inspects dentists and podiatrists every 5 years and hospitals every 2 years. While the Department is allowed to establish a different frequency, individuals may be unaware of the departure from the schedule specified in Part 16 because the

Department has not established a written policy that memorializes these changes. Recording and sharing these policies and changes would help reduce the risk that Department staff may follow inconsistent practices or follow old policies that fail to comply with new laws, regulations, or other Department practices.

Recommendations

1. Ensure that all required inspections are completed on time.
2. Assess buffer use and the feasibility of reducing reliance on the buffer, especially for facilities that have had past inspections showing non-compliance with established standards.
3. Continue to work toward reducing the backlog of pending licensing actions and ensure that future licensing actions are completed within their established benchmark.
4. Formalize the written policies and procedures necessary to support the Department's operations and that address changes to regulations, and ensure policy changes, such as changes to inspection schedules, are documented.

Audit Scope, Objectives, and Methodology

The objectives of this audit were to determine if the Department is ensuring that the registration, licensing, and inspection of RAM facilities and radiation equipment facilities are completed as required. The audit covered licensing and inspection records for the period of January 1, 2017 through February 28, 2020 and other information through March 5, 2021.

To accomplish our objectives and assess related internal controls, we interviewed officials from the Department regarding the registration, licensing, and inspection processes for RAM facilities and radiation equipment facilities. We also reviewed the Department's written policies, procedures, databases, and inspection and licensing forms. We reviewed the NRC Inspection Manual and the NRC's 2018 Integrated Materials Performance Evaluation Program report of the Department's radioactive materials program. We also assessed the reliability and accuracy of the inspection and licensing data. Overall, we determined the data to be reliable for the purposes of our audit objectives, but the results of our audit tests cannot be projected to the population as a whole.

To assess whether the Department was ensuring facilities were registered as required, we identified three types of facilities (dentists, chiropractors, and podiatrists) listed on a publicly available Medicaid data file that we believed were most likely to have diagnostic equipment that required registering, and selected a random sample of 50 from each type. We compared those 150 entities to the Department's registered facilities inventory and found 56 (5 dentists, 27 chiropractors, and 24 podiatrists) that were not listed on the Department's inventory. We spoke with representatives for 25 entities and conducted Internet searches for an additional 20 entities (45 of 56 reviewed in total), and obtained satisfactory information to support that those entities either practiced under a different name or used a third party for diagnostic services, all of which the Department had listed on its inventory. As a result, we ended our testing and did not pursue reviewing the other 11 entities.

To assess whether the Department was ensuring licensing actions were completed as required, we focused on new licensing actions rather than renewals and amendments because we considered these actions to be higher risk if they were not processed timely. We selected a random sample of 21 (of 178) new licensing actions for review and compared the dates the applications were received to the dates the licenses were issued. We also compared two overdue licensing action reports to determine the extent of change in the Department's licensing backlog.

To assess whether the Department was ensuring inspections of RAM facilities and radiation equipment facilities were completed as required, we judgmentally selected samples from the Department's RAM and radiation equipment databases. We focused on records that had two or more inspection dates and analyzed the length of time between inspections. We then compared the length of time to the established inspection frequency (with and without a buffer) to determine whether it was conducted on time. In addition, for radiation equipment facilities, we focused on the periodic inspections (during the period January 1, 2017 through December 31, 2019) for certain facility descriptions that we considered to be higher risk such as hospitals, clinics, and dentists.

Statutory Requirements

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 II, Section 8 of the State Finance Law.

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

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. These duties could be considered management functions for purposes of evaluating organizational independence under generally accepted government auditing standards. In our professional judgment, these duties do not affect our ability to conduct this independent performance audit of the Department's oversight and administration of registration, licensing, and inspection of radioactive materials facilities and radiation equipment facilities.

Reporting Requirements

A draft copy of the report was provided to Department officials for their review and formal comment. Their comments were considered in preparing this final report and are attached in their entirety to the end of it. In general, Department officials agreed with our recommendations and indicated actions they would take to implement them. Our State Comptroller's Comment addressing certain Department remarks is embedded within the Department's response.

Within 180 days after final release of this report, as required by Section 170 of the Executive Law, the Commissioner of the Department of Health shall report to the Governor, the State Comptroller, and the leaders of the Legislature and fiscal committees, advising what steps were taken to implement the recommendations contained herein, and where recommendations were not implemented, the reasons why.

NEW YORK STATE OF OPPORTUNITY. Department of Health

ANDREW M. CUOMO
Governor

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

LISA J. PINO, M.A., J.D.
Executive Deputy Commissioner

August 23rd, 2021

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

Dear Mr. Reilly:

Enclosed are the Department of Health's comments on the Office of the State Comptroller's Draft Audit Report 2019-S-64 entitled, "Oversight of Registration, Licensing, and Inspection of Radioactive Materials Facilities and Radiation Equipment Facilities."

Thank you for the opportunity to comment.

Sincerely,

Theresa Egan
Deputy Commissioner for Administration

Enclosure

cc: Diane Christensen
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Department of Health Comments on the Office of the State Comptroller's Draft Audit Report 2019-S-64 entitled, Oversight of Registration, Licensing, and Inspection of Radioactive Materials Facilities and Radiation Equipment Facilities

The following are the Department of Health's (Department) comments in response to the Office of the State Comptroller's (OSC) Draft Audit Report 2019-S-64 entitled, "Oversight of Registration, Licensing, and Inspection of Radioactive Materials Facilities and Radiation Equipment Facilities."

Recommendation #1

Ensure that all required inspections are completed on time.

Response #1

The Department works to ensure that all required inspections are conducted in a timely manner. The inspection workload is continually assessed and prioritized based on the level of potential public/occupation risk of the facility and/or equipment. As noted, the Department completed 6,786 or 94% of the required radioactive materials (RAM) facility and radiation equipment facility inspections within an acceptable time frame. Similarly, it was documented that the inspection of mammography facilities and stereotactic equipment facilities were completed in a timely manner greater than 90% and 91%, respectively, of the time. It should be noted that the mammography and stereotactic inspections that fell outside of the acceptable time frame were completed. The inspection of these type of facilities is highly technical in nature. The Department works to balance and prioritize the replacement of staff due to turnover and retirement with the time it takes to adequately train new inspection staff. On average it requires 3 to 5 years to fully train a new inspector to perform these highly technical inspections. The Department will continue to work on improving its overall timeliness of these inspections.

Recommendation #2

Assess buffer use and the feasibility of reducing reliance on the buffer, especially for facilities that have had past inspections showing noncompliance with established standards.

Response #2

The use of a variable inspection frequency (buffer) is the U.S Nuclear Regulatory Commission's recommended approach for agreement states to use for managing their radioactive materials licensee inspection program. This +/- 50% buffer for the performance of inspections allows the completion of inspections within a flexible time period rather than an arbitrary fixed date. The specific time periods for inspections are a reference value and the buffer allows programmatic flexibility and risk-based inspection concerns to drive the actual performance. The use of this buffer considers inspection history, compliance history and the risks involved in the specific licensee. While some facilities with prior items of non-compliance were inspected at a later time,

those violations had either been resolved in a follow up inspection or they were minor items such as missing signage or outdated policy/procedure. This buffer allows the Department flexibility to adjust the scheduling of inspections to accommodate staff turnover and the time it takes to hire and train replacement inspectors. Further, the flexibility of the buffer allows inspectors to bundle inspections co-located in remote areas that increases efficiency and reduces travel expenses.

State Comptroller's Comment – As stated in our report, the buffer is intended to allow for more flexibility and logical extensions to the inspection intervals. However, frequently using the inspection buffer delays equipment inspections, reports, and the timely remediation of issues identified. It can also increase the risk that individuals are exposed to higher levels of radiation.

Recommendation #3

Continue to work toward reducing the backlog of pending licensing actions and ensure that future licensing actions are completed within their established benchmark.

Response #3

Department staff have made progress over the past decade at reducing the backlog of licensing actions. Using a prioritization process, some actions such as renewals are lower priorities while other such as new licenses and amendments that reflect critical healthcare infrastructure are higher priority. This process ensures that the actions that are overdue are the lowest priority actions that will have limited impact on licensee operations and public health. This allows Department staff to focus on the more time sensitive issues and licensing actions that may have an impact on occupational safety or patient care. During the COVID-19 emergency, staff who normally conduct license reviews had been assisting in the response effort. Department staff are reducing the backlog on a year-over-year basis and will develop a plan to address the remaining backlog.

Recommendation #4

Formalize the written policies and procedures necessary to support the Department's operations and that address changes to regulations, and ensure policy changes, such as changes to inspection schedules, are documented.

Response #4

Department staff are updating existing regulations and documenting processes for inspections, licensing, policy and guidance determinations, and office procedures. Standard Operating Procedures (SOP) are also being documented. Regulation development is our top priority as this will drive changes in our SOPs, inspection and licensing procedures. Many of the program's activities use federal procedures as guidance for how the state should conduct operations, but there are some differences, and these are being included in updated NYS-specific SOPs. Program expects to complete regulatory development in late 2021 and guidance development and SOPs in mid-2022, depending on current events or public health emergencies.

Contributors to Report

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