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State Comptroller

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STATE OF NEW YORK
OFFICE OF THE STATE COMPTROLLER

April 10, 2024

James V. McDonald, M.D., M.P.H.
Commissioner
Department of Health
Corning Tower
Empire State Plaza
Albany, NY 12237

Re: Oversight of Registration, Licensing, and Inspection of Radioactive Materials Facilities and Radiation Equipment Facilities
Report 2023-F-28

Dear Dr. McDonald:

Pursuant to the State Comptroller's authority as set forth in Article V, Section 1 of the State Constitution and Article II, Section 8 of the State Finance Law, we have followed up on the actions taken by officials of the Department of Health (DOH/the Department) to implement the recommendations contained in our initial audit report, *Oversight of Registration, Licensing, and Inspection of Radioactive Materials Facilities and Radiation Equipment Facilities* (Report 2019-S-64).

Background, Scope, and Objective

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 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 the 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.

DOH 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, DOH has established the Bureau of Environmental Radiation Protection (BERP), 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.

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 DOH's program operations every 4 years. DOH must follow NRC's Inspection Manual when performing RAM facility inspections. DOH'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 DOH's operations. Instead, DOH must follow the New York Codes, Rules and Regulations for X-ray and stereotactic equipment inspections. Facilities with mammography equipment fall under the federal Mammography Quality Standards Act (MQSA). DOH must follow MQSA requirements for these inspections. Facilities under the MQSA generally include hospitals, clinics, physician offices, and women's health centers.

The objective of our initial audit, issued September 23, 2021, was to determine if DOH was ensuring that the registration, licensing, and inspection of RAM facilities and radiation equipment facilities were completed as required. The audit covered licensing and inspection records for the period from January 1, 2017 through February 28, 2020 and other information through March 5, 2021. We found that DOH completed 94% of RAM 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. We also found that, of the 259 RAM facility inspections that needed the buffer to be considered inspected on time, 86 (33%) showed the facilities were, at the time of inspection, not in compliance with established standards. For 33 of those 86 inspections (38%), DOH had also found the facility was not in compliance during the prior inspection. Additionally, of the 2,720 radiation equipment facility inspections that needed the buffer to be considered inspected on time, 249 (9%) showed the facilities were, at the time of inspection, not in compliance with established standards. For 55 of those 249 inspections (22%), the facility was found not in compliance with standards during its prior inspection as well. DOH also did not complete all license actions within its 1-year benchmark. For example, as of July 20, 2020, DOH had not completed 55 licensing actions that were beyond the 1-year benchmark.

The objective of our follow-up was to assess the extent of implementation, as of February 2024, of the four recommendations included in our initial audit report.

Summary Conclusions and Status of Audit Recommendations

DOH has made some progress in addressing the problems we identified in the initial audit report; however, more work needs to be done. Of the initial report's four recommendations, one was implemented, one was partially implemented, and two were not implemented.

Follow-Up Observations

Recommendation 1

Ensure that all required inspections are completed on time.

Status – Not Implemented

Agency Action – Since our initial audit, DOH officials advised us that they have continued to work on improving the timeliness of required inspections. DOH has hired additional inspectors, prioritized inspections over other activities, and continued cross-training staff, which officials hope will consolidate inspections in fewer trips, resulting in overall increased productivity. As a result of these efforts, DOH has increased the overall productivity of inspectors and states that it is performing more inspections than ever. According to data provided by DOH officials, inspectors conducted a total of approximately 3,189 inspections between January 2021 and December 2023. While the total number of inspections is similar to the prior 3-year period, the data also shows that the productivity of inspectors has increased. However, DOH officials acknowledged that some inspections continue to exceed established time frames and did not provide us with the information we needed to determine how many of the 3,189 inspections conducted since January 2021 were completed on time. Officials said they will continue to work on improving the overall timeliness of inspections.

Recommendation 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.

Status – Not Implemented

Agency Action – During the initial audit, DOH changed its buffer policy to require the evaluation of compliance history when deciding whether to extend a due date. This policy requires staff to consider inspection history, compliance history, and the public health risks involved with the specific licensees. DOH officials said that staff have continued to follow this policy and document the reason a buffer is used to extend or reduce a facility's inspection time frame. However, DOH did not provide evidence of this. In addition, DOH has not conducted a formal assessment of its overall buffer use and the feasibility of reducing reliance on the buffer, especially for facilities that have had past inspections showing non-compliance since the initial audit. Officials said the use of variable inspection frequency, or a buffer, is the NRC's recommended approach for managing its radioactive materials inspection programs and is consistent with industry standards. However, frequently using the buffer delays equipment inspections, reports, and the timely remediation of issues identified.

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.

Status – Partially Implemented

Agency Action – Since our initial audit, DOH has taken steps to reduce the backlog of pending licensing actions and ensure that future licensing actions are completed within DOH's established 1-year benchmark. DOH has hired additional inspectors who officials expect will, once fully trained, improve the timeliness of completing licensing actions. DOH also developed and issued, in June 2022, a Radioactive Materials Licensing in New York State manual. This manual was created as a resource to, in part, help experienced staff save time and conduct more efficient licensing actions and help newer staff gain the knowledge they need to conduct licensing activities independently. According to newly

implemented metrics, the time it took DOH to process fully completed licensing actions (as of November 2023) has dropped from an average of 71 days in 2022 to 46 days in 2023. As of November 2023, DOH had a backlog of 178 licensing actions, including 74 licensing actions that were beyond the 1-year benchmark.

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.

Status – Implemented

Agency Action – In response to our audit, DOH established several new procedure manuals, including a BERP Inspection Manual in December 2021 and a Radioactive Materials Licensing in New York State manual in June 2022. DOH also reviewed numerous other inspection manuals and updated them, as necessary. The new and updated manuals formalize all of DOH's licensing and inspection policies and procedures and document policy changes. While DOH has drafted updated regulations, they have not yet been passed. DOH officials said that they will update policies and procedures, as necessary, to reflect any changes to regulations once they are officially in place.

Major contributors to this report were Peter Carroll, Kathleen Garceau, and James Rappaport.

DOH officials are requested, but not required, to provide information about any actions planned to address the unresolved issues discussed in this follow-up within 30 days of the report's issuance. We thank DOH management and staff for the courtesy and cooperation extended to our auditors during this follow-up.

Very truly yours,

Andrea LaBarge
Audit Manager

cc: Melissa Fiore, Department of Health