NEW YORK STATE OF OPPORTUNITY. Department of Health

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Acting Executive Deputy Commissioner

December 21, 2021

Honorable Thomas P. DiNapoli
Comptroller
NYS Office of the State Comptroller
110 State Street
Albany, New York 12236

Dear Comptroller DiNapoli:

Pursuant to the provisions of Section 170 of New York State Executive Law, I hereby transmit to you a copy of the New York State Department of Health's comments related to the Office of the State Comptroller's final audit report 2019-S-64 entitled, "Oversight of Registration, Licensing, and Inspection of Radioactive Materials Facilities and Radiation Equipment Facilities."

Please feel free to contact Office of Governmental and External Affairs at (518) 473-1124 with any questions.

Sincerely,

Kristin M. Proud
Acting Executive Deputy Commissioner

Enclosure

cc: Ms. Chun

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

General Comments

The Bureau of Environmental Radiation Protection's routine activities include licensing and inspecting medical, commercial and industrial radioactive materials facilities; radiation producing equipment (x-ray) facility registration and inspection; response to incidents involving radioactive materials and radiation equipment; licensing and discipline of radiologic technologists; nuclear power plant emergency exercises; environmental surveillance and contaminated site activities; providing radon information and distributing low-cost radon detectors; and responding to non-ionizing radiation and electromagnetic field inquiries.

New York State (NYS) is one of 37 states that have agreements with the federal government under the Atomic Energy Act. NYS and other agreement states regulate all sources of radiation in the State, except reactors, federal facilities and large quantities of special nuclear material which are regulated by the U.S. Nuclear Regulatory Commission (NRC). The Department of Labor's radioactive materials program was merged with the Department of Health's program in 2006. The Radioactive Materials Licensing program of the Bureau of Environmental Radiation Protection is responsible for licensing and inspecting approximately 1300 radioactive materials licensees including commercial, medical, academic and government facilities. The NRC audits the NYS program every four years and the last audit indicated that the program met the standards for protection of public health but was found to be behind on regulation adoption and development.

While most x-ray equipment inspections are done under State's jurisdiction, Mammography is performed under contract to the federal government. The Mammography Quality Standards Act (MQSA) is administered by the U.S. Food and Drug Administration (FDA). NYS has a contract with the FDA and performs these inspections in the manner and frequency prescribed by the MQSA contract. NYS has performed these inspections under contract since 1992 and has maintained a satisfactory annual review of all inspectors by the FDA.

Recommendation #1

Ensure that all required inspections are completed on time.

Response #1

The number of overdue inspections has increased during the COVID pandemic due to restrictions on field activities and inspections. While this occurred after the OSC audit period, it presents a significant backlog which will be addressed by three main factors. The first is hiring additional staff, the second will be prioritizing inspections over other activities, and the third will be continued cross training of staff.

The recent removal of a hiring freeze has allowed the program to begin recruiting additional staff to address the backlog. Currently six positions are posted or recently hired, four positions are being requested, and then backfills to replace any of the postings that were promotional will be posted to ensure as many open inspector positions as needed are filled. The effect of adding new staff will not immediately reduce the backlog of inspections as these staff will have to be trained and this will take 6-12 months of didactic and field training before they are able to perform simple inspections independently.

Inspections will be given a high priority as long as the back log remains, however this must be balanced against other essential core activities such as licensing, investigations, and emergency response, which cannot be delayed.

Lastly the cross training of staff allows a more efficient inspection scheduling. In the past, staff were more specialized and may have only performed a few types of inspections. This meant that a facility may have two separate inspections. Cross training has reduced some specialized expertise but has increased inspector throughput by consolidating inspections in fewer trips resulting in an overall increase in productivity.

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 Department's radioactive materials program is scheduled for a review by the U.S. NRC in mid-2022. During this review the Department will ask the U.S. NRC to review the use of the buffer to determine if the way it has been used is inconsistent with how the NRC or other states manage their inspection program and will use their recommendations as to how the program can address any inconsistencies with its use. The Department will continue to use a risk based prioritization based on facility compliance history and the radioactive materials or equipment that they are using.

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. Amendment review uses a prioritization process. Some licensing actions, such as renewals, are given lower priorities while other actions, such as new licenses and amendments that reflect critical healthcare infrastructure, are given a higher priority.

Starting in January 2022, program staff will begin an accelerated review of license amendments and renewals which are over one year old. The effort will focus on weekly review by two or more license reviewers and approval, denial, or request for additional information with a determination to be made within one week.

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

Regulation development is the top priority for the program area as this will drive changes in our Standard Operating Procedures (SOPs) for inspection and licensing procedures. Program staff have drafted updated regulations that will be promulgated in 2022. After these are in place, new SOPs for licensing will be written. Radioactive material licensing and x-ray inspection SOPs will be updated after proposed regulations are passed. It is anticipated that these will be passed in 2022 and those SOPs completed by the end of 2022 or early 2023. The majority of radioactive materials inspection procedures have been written using the U.S. NRC's procedures as a template. Procedures and manuals for processing applications, processing payments and other routine office functions have been updated to reflect current processes and SOPs have been organized in an easily accessible network location. A senior reviewer will review these SOPs in early 2022 for consistency and will organize and post them to the program's SharePoint for easy access by all staff.