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Dear Dr. Sokol, Mr. Vitale, and Ms. Huang:

On June 21, 2018, the Management Review Board (MRB), which consisted of U.S. Nuclear Regulatory Commission (NRC) senior managers and an Organization of Agreement States liaison to the MRB, met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the New York Agreement State Program. The MRB found the New York program adequate to protect public health and safety and not compatible with the NRC's program.

The enclosed final report contains a summary of the IMPEP team's findings (Section 5.0) and recommendations. The review team made two recommendations regarding the performance of the New York Agreement State Program during this review. Based on the results of the current IMPEP review, the next full IMPEP review will take place in approximately 4 years, with a periodic meeting in approximately 1 year.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review. I also wish to acknowledge your continued support for the Agreement State program. I look forward to our agencies continuing to work cooperatively in the future.

Sincerely,

/RA/

Daniel H. Dorman
Acting Deputy Executive Director for Materials, Waste, Research, State, Tribal, Compliance, Administration, and Human Capital Programs
Office of the Executive Director for Operations

Enclosure:
New York Final IMPEP Report

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF THE NEW YORK AGREEMENT STATE PROGRAM

MARCH 12 – 23, 2018

FINAL REPORT

Enclosure

EXECUTIVE SUMMARY

This report presents the results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the New York Agreement State Program. The review was conducted during the period of March 12 – 23, 2018, by a team comprised of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the Commonwealth of Kentucky. Additionally, a team member from the State of Arizona conducted inspector accompaniments prior to the onsite review.

Based on the results of this review, New York was found satisfactory for six of the eight performance indicators reviewed: Status of Materials Inspection Program; Technical Quality of Inspections; Technical Quality of Licensing Actions; Technical Quality of Incident and Allegation Activities; Sealed Source and Device Evaluation Program; and Low-Level Radioactive Waste Disposal Program. The common indicator, Technical Staffing and Training was found satisfactory, but needs improvement. The non-common indicator, Compatibility Requirements was found unsatisfactory. These ratings remain unchanged from the previous IMPEP review, which concluded on March 28, 2014.

When one or more performance indicators is found unsatisfactory, NRC Management Directive 5.6 directs the Management Review Board (MRB) to consider placing the program on Heightened Oversight. At the end of the 2014 IMPEP review, the MRB considered the progress New York made in adopting overdue regulations and New York's performance improvement from unsatisfactory to satisfactory during the review period with respect to the indicator Technical Quality of Incident and Allegation Activities. The 2014 MRB decided to discontinue the period of Heightened Oversight and initiate a period of Monitoring.

As of April 10, 2018, the New York State Department of Health (DOH) was developing rules to adopt NRC regulations by reference; the New York City Department of Health and Mental Hygiene (NYC) was set to adopt compatible rules by October 2018; and the New York State Department of Environmental Conservation (DEC) had filed final rules for the adoption of Title 6 of the New York Codes, Rules and Regulations Part 380 (6 NYCRR 380) "Prevention and Control of Environmental Pollution by Radioactive Materials," which eventually became effective on May 10, 2018. As of June 5, 2018, NYC regulations were approved by the New York City Board of Health for publication and public comment, which keeps it on track to be adopted in October 2018. Additionally, to fill vacancies, the DOH and DEC are required to apply for approval, in the form of a "vacancy waiver" with the State of New York Governor's Office. Both the DOH and DEC have consistently applied for vacancy waivers with the Governor's Office when positions became vacant during the review period. The team factored in the 2014 MRB decision to remove New York from Heightened Oversight and determined that a written performance improvement plan was unnecessary to address the issues involving regulation development and staffing because the DOH was already taking actions to address these issues. The processes for regulation adoption and hiring feature potential delays outside of the DOH and DEC's control. Quarterly monitoring calls would not expedite or facilitate these processes. Therefore, in lieu of Heightened Oversight or Monitoring, the team recommended to the MRB that New York be removed from Monitoring and a periodic meeting be held 1 year from the MRB meeting to discuss the overall status of the program with emphasis on the indicators that were found less than satisfactory, including measuring progress in regulation adoption. The MRB agreed that the period of Monitoring be discontinued with the following condition: The MRB

directed staff to maintain awareness through informal calls with New York with regards to staffing and training and compatibility requirements.

The team made one new recommendation (see Section 5.0) regarding program performance in Technical Quality of Inspections, and determined that two of the three recommendations from the 2014 review regarding the pursuit of vacancy waivers, updating staffing and training qualifications, and additional training for licensing staff should be closed (see Section 2.0). The team determined that the recommendation to make appropriate regulatory changes to resolve NRC-generated comments as noted in regulation review letters, and adopt NRC regulations in accordance with the current NRC policy on adequacy and compatibility should remain open.

Accordingly, the team recommended, and the MRB agreed, that the New York Agreement State Program is adequate to protect public health and safety and not compatible with the NRC's program. The team recommended, and the MRB agreed, that the next IMPEP review take place in 4 years with a periodic meeting in 1 year for the reasons stated above.

1.0 INTRODUCTION

This report presents the results of the review of the New York Agreement State Program radioactive materials safety program. The review was conducted during the period of March 12 – 23, 2018, by a team comprised of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the Commonwealth of Kentucky. Additionally, a team member from the State of Arizona conducted inspector accompaniments in New York City, but did not participate in the onsite review. Team members are identified in Appendix A.

The review was conducted in accordance with the "Agreement State Program Policy Statement," published in the *Federal Register* on October 18, 2017, and NRC Management Directive (MD) 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)," dated February 26, 2004. Preliminary results of the review, which covered the period of March 29, 2014, to March 23, 2018, were discussed with New York managers on the last day of the review.

The New York Agreement State Program is administered by three agencies: (1) the New York State Department of Health (DOH), which has jurisdiction over industrial uses of radioactive materials throughout the State, as well as medical, academic, and research uses outside of New York City; (2) the New York City Department of Health and Mental Hygiene (NYC), which has jurisdiction over medical, academic, and research uses of radioactive materials within the five boroughs of New York City; and (3) the New York State Department of Environmental Conservation (DEC), which has jurisdiction over discharges of radioactive material to the environment, including releases to the air and water, and the land disposal of radioactive wastes. Organization charts for DOH, NYC, and DEC, are available in ADAMS (accession numbers ML18064A180, ML18058A704, and ML18044A167, respectively).

In preparation for the review, a questionnaire addressing the common and applicable non-common performance indicators was sent to New York on September 11, 2017. A copy of the questionnaire is available in the NRC's Agencywide Documents Access and Management System (ADAMS) using accession number ML17249A297. The three agencies (DOH, NYC, and DEC) provided separate questionnaire responses on March 2, February 23, and February 9, 2018, respectively. The questionnaire responses can be found in ADAMS using accession numbers ML18064A182, ML18058A726, and ML18044A153.

A draft of this report was issued to New York on April 25, 2018, for factual comment (ADAMS Accession Number ML18114A213). The three agencies responded to the findings and conclusions separately. NYC responded by letter dated May 18, 2018 (accession number ML18151A740), DEC responded by email dated May 22, 2018 (accession number ML18151A753), and DOH responded via phone call on June 6, 2018. The Management Review Board (MRB) convened on June 21, 2018, to discuss the team's findings.

At the time of the review, New York regulated 1,285 specific licensees (DOH-986 and NYC-299) authorizing possession and use of radioactive materials. Additionally, the

DEC regulated 29 permit holders for radioactive discharges and radioactive waste disposal from all State-regulated radioactive materials licensees. The review focused on the radioactive materials program as it is carried out under the Section 274b (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the State of New York.

The team evaluated the information gathered against the established criteria for each common and applicable non-common performance indicator and made a preliminary assessment of the New York Agreement State Program's performance.

2.0 PREVIOUS IMPEP REVIEW AND STATUS OF RECOMMENDATIONS

The previous IMPEP review concluded on March 28, 2014. The final report is available in ADAMS (accession number ML14261A351). The results of the review and the status of the recommendations are as follows:

Technical Staffing and Training: Satisfactory but Needs Improvement

Recommendation: The review team recommends that the DOH and DEC continue to pursue vacancy waivers and implement a strategy to address current and future staffing vacancies in order to maintain effectiveness, and that NYC should update its staffing and training qualification program to include approved documentation of staff's qualifications. (Section 3.1 of the 2014 IMPEP report)

Status: To fill vacancies, the DOH and DEC are required to apply for approval, in the form of a "vacancy waiver" with the State of New York Governor's Office. A vacancy waiver is an application to the Governor's office that provides justification for filling a position that has been vacant to override the moratorium on new hires. Vacancy waivers can remain under review in the Governor's Office for up to 2 years before the DOH or DEC are permitted to hire personnel to fill the vacant positions. The 2018 IMPEP team identified that the DOH and DEC consistently pursue vacancy waivers in an effort to maintain appropriate staffing levels when an employee leaves or a retirement is imminent. Both agencies continue to implement this strategy and work within New York's labor rules to fill current and future staffing vacancies.

Since the 2014 IMPEP review, NYC has updated its staffing and training qualification program to include documentation of staff's qualifications. NYC developed a qualification journal that is compatible with NRC's Inspection Manual Chapter (IMC) 1248, "Formal Qualifications Program for Federal and State Material and Environmental Management Programs." NYC initiated the use of those qualification journals for its staff to track NRC training, supervised inspections, and in-house training. One staff member has been assigned to maintain the journal and records of employee training.

This recommendation is closed.

Status of Materials Inspection Program: Satisfactory
Recommendation: None

Technical Quality of Inspections: Satisfactory
Recommendation: None

Technical Quality of Licensing Actions: Satisfactory

Recommendation: The review team recommends that NYC (1) provide additional training to technical staff members regarding the technical review of licensing actions, including training to ensure that the staff acquires increased familiarity with the regulations under NYC's equivalent to Title 10 of the *Code of Federal Regulations* (10 CFR) Parts 30, 33, and 35, and applicable licensing guidance documents and license conditions; and (2) take measures to ensure that the NYC's review of licensing actions are complete and well-documented. (Section 3.4 of the 2014 IMPEP report)

Status: The team confirmed a number of actions taken by NYC since the 2014 IMPEP review. These included using a variety of training opportunities, including on-the-job training, NRC-sponsored training, and NYC customized training classes. NYC has implemented a peer review process for all licensing actions to ensure that the actions are complete and well-documented. NYC uses the NUREG-1556, "Consolidated Guidance about Materials Licenses," series and the NRC pre-licensing guidance on applicable licensing actions. NYC has increased staffing and, at the time of the review, had two qualified license reviewers, as well as a third new license reviewer undergoing training. Training for license reviewers has included NRC-sponsored training, 40-hour radiation safety officer training, and other in-house and on-the-job training. In addition, license review procedures have been revised and new forms were created to improve documentation of license actions, peer review, and communications with licensees. At the time of the 2018 IMPEP review, NYC had no backlog of licensing actions.

This recommendation is closed.

Technical Quality of Incident and Allegation Activities: Satisfactory
Recommendation: None

Compatibility Requirements: Unsatisfactory

Recommendation: The review team recommends that the Program make appropriate regulatory changes to resolve NRC-generated comments as noted in regulation review letters, and adopt NRC regulations in accordance with the current NRC policy on adequacy and compatibility (Section 4.1 of the 2014 IMPEP report).

Status: The 2006 and 2011 IMPEP teams recommended that DOH, NYC, and DEC develop and implement an action plan to adopt NRC regulations in accordance with the current NRC policy on adequacy and compatibility. The 2014 IMPEP team determined each agency had developed and implemented an action plan. The DOH and DEC regulation adoption process, which is similar for both agencies, takes approximately 2 to 3 years. NYC uses a different process which takes approximately 6 months to complete, if there are no mitigating factors. NYC was able to clear its backlog, but due to the rulemaking process for both the DOH and DEC, these agencies were not able to clear their backlog of overdue regulations. The 2014 IMPEP team determined that each

agency is cognizant of the requirements to adopt compatible rules, or use legally binding requirements within 3 years of the NRC's effective date, and recommended closing the open recommendation from 2006 and 2011. The MRB agreed; however, the MRB directed the team to open a new recommendation to address New York's continued backlog of overdue regulations in order to be compatible with the NRC's program.

During the current IMPEP review period, 17 regulation amendments became due for adoption by New York (DOH-10, NYC-5, and DEC-2). At the time of the review, all of these regulation amendments were overdue for adoption. Both the DOH and NYC have proposed adopting NRC regulations by reference. The DOH was in the process of developing rules to incorporate NRC regulations by reference; however, the DOH had implemented some license conditions to prevent significant health and safety gaps in New York regulations and to maintain compatibility, e.g., license conditions for 10 CFR Part 35, 37, and 71. These license conditions were not reviewed for compatibility by the NRC before implementation.

During the review period, NYC proposed to repeal and reenact Article 175 of the radiation regulations, which includes the regulation of radioactive material in New York City per the Agreement State Program. In February 2017, NYC submitted proposed regulations to the NRC for review. The NRC issued 16 comments on the proposed regulations in May 2017 and NYC proceeded to promptly resolve the comments. The updated reenactment of Article 175 regulations were submitted to the City Law Department in July 2017 for review. At the time of the 2018 IMPEP review, NYC regulations were still under review at the City Law Department; however, NYC executive management indicated that the regulations would go to the New York City Board of Health in June and could be adopted as early as October 2018. As of June 5, 2018, NYC regulations were approved by the New York City Board of Health for publication and public comment.

The DEC had eight regulation amendments overdue for adoption, six of which dated to the previous IMPEP review period. Of the overdue rules, the DEC incorporated four into the amendment of Title 6 of New York Codes, Rules and Regulations (NYCRR) Part 380 (6 NYCRR 380), "Prevention and Control of Environmental Pollution by Radioactive Materials," which became effective on May 10, 2018. The DEC will adopt two other overdue regulations as the new 6 NYCRR Part 384, "Cleanup Criteria for Remediation of Sites Contaminated with Radioactive Material," which DEC plans to submit for executive approval in 2018. The DEC plans to incorporate the last two overdue rules into 6 NYCRR Part 381, "Transporters of Low-Level Radioactive Waste," which will be developed at a later date.

Given that very little progress was made in adopting regulations over the course of the review period, the team concluded, and the MRB agreed that this recommendation should remain open.

Sealed Source and Device Evaluation Program: Satisfactory
Recommendation: None

Low-Level Radioactive Waste Disposal Program: Satisfactory
Recommendation: None

Overall finding: Adequate to protect public health and safety and not compatible with the NRC's program. Additionally, the MRB chose to discontinue the period of Heightened Oversight and initiate a period of Monitoring.

3.0 COMMON PERFORMANCE INDICATORS

Five common performance indicators are used to review the NRC regional and Agreement State radioactive materials programs. These indicators are: (1) Technical Staffing and Training; (2) Status of Materials Inspection Program; (3) Technical Quality of Inspections; (4) Technical Quality of Licensing Actions; and (5) Technical Quality of Incident and Allegation Activities.

3.1 Technical Staffing and Training

The ability to conduct effective licensing and inspection programs is largely dependent on having a sufficient number of experienced, knowledgeable, well-trained technical personnel. Under certain conditions, staff turnover could have an adverse effect on the implementation of these programs, and could affect public health and safety. Apparent trends in staffing must be explored. Review of staffing also requires consideration and evaluation of the levels of training and qualification. The evaluation standard measures the overall quality of training available to, and taken by, materials program personnel.

a. Scope

The team used the guidance in State Agreements procedure SA-103, “Reviewing the Common Performance Indicator: Technical Staffing and Training,” and evaluated New York’s performance with respect to the following performance indicator objectives:

- A well-conceived and balanced staffing strategy has been implemented throughout the review period.
- Agreement State training and qualification program is compatible with NRC IMC 1248.
- Qualification criteria for new technical staff are established and are followed or qualification criteria will be established if new staff members are hired.
- Any vacancies, especially senior-level positions, are filled in a timely manner.
- There is a balance in staffing of the licensing and inspection programs.
- Management is committed to training and staff qualification.
- Individuals performing materials licensing and inspection activities are adequately qualified and trained to perform their duties.
- License reviewers and inspectors are trained and qualified in a reasonable period of time.

b. Discussion

At the DOH, the radioactive materials program is implemented by the Bureau of Environmental Radiation Protection (the Bureau). The Bureau also has responsibility for radiation-producing equipment. When fully staffed, the Bureau is comprised of the Director, the Associate Director, two Section Chiefs, and 16 staff members which equals 12 full-time equivalents (FTE) to implement the radioactive materials program. Two of the 12 FTE are clerical positions. At the time of the review, there were two vacancies. To fill vacancies, the DOH is required to apply for approval, in the form of a "vacancy waiver" with the State of New York Governor's Office. A vacancy waiver is an application to the Governor's office that provides justification for filling a position that has been vacant to override the moratorium on new hires. The DOH Director applied for vacancy waivers for both positions with the Governor's Office approximately a year before the review. One of the vacancy waivers was approved just prior to the IMPEP review. During the review period, six staff members left the program and four staff members were hired. Four of the six departed employees principally supported the radioactive materials program while the other two were primarily support for the x-ray safety program, although these staff occasionally performed radioactive materials inspections. Of the four staff members newly hired, 0.7 FTE of their combined efforts are committed to the x-ray program.

The Bureau has a training and qualification program compatible with the NRC's IMC 1248. Candidates for employment are required to pass a New York State Civil Service Examination and apply for jobs under strict hiring guidelines consistent with the technical skills required of the position. Candidates are required to have a minimum of a Bachelor of Science degree. The Bureau uses on-the-job training to supplement course work so that individuals may broaden their work experience. Staff members are assigned increasingly complex duties as they progress through the qualification process. Training is implemented through a mentoring program with a senior staff person who assigns inspections and licensing actions in accordance with a staff member's expertise. The NRC-sponsored training attendance is tracked in an excel spreadsheet. The Bureau also maintains a spreadsheet of the license types that each employee is authorized to inspect. The Bureau conducts a 2-day annual meeting in October that covers a host of regulatory and technical topics and is part of the Bureau's continuing education program.

The DOH and DEC are required to have travel authorizations for NRC-sponsored training approved by the State of New York Governor's office. Delays in approving these travel authorizations have resulted in several late withdrawals from NRC training courses by DOH personnel (e.g., less than 1 week before the scheduled class). These withdrawals have delayed the DOH staff's completion of technical qualifications. The Bureau's management contacted the NRC about this issue and a letter was sent from the NRC to DOH management explaining the impact of these withdrawals. The DEC has not utilized NRC-sponsored training recently; therefore, this has not been an issue for the DEC. NYC is not subject to this approval process.

The team identified performance issues involving the backlog of licensing actions that would indicate that DOH did not have adequate staffing. At the time of the 2014 IMPEP,

there were 187 renewal applications that had not been processed and were older than 1 year. At the time of the periodic meeting on May 5, 2016, the number of renewals that were older than 1 year had been reduced to 150. At the time of this review, the team identified that DOH had 331 outstanding licensing actions that had not been started: 157 renewals, 13 Part 37 actions, and 161 amendments. Forty-one amendment requests and 83 renewal applications were greater than 1 year old (see Section 3.4 for additional details). Despite the backlog of licensing actions, the DOH was implementing a triage system where the supervisor prioritized licensing actions from a public health and safety perspective. The team did not identify any instances where the backlog was causing the DOH to provide inadequate regulatory oversight with respect to the protection of public health and safety. The team did not identify issues in DOH's inspection program related to staffing levels.

In addition, as described in Section 4.1, New York was found not compatible with the NRC's program because of the number of overdue regulations. Minimal progress was made by the DOH to address the overdue regulations over the review period. The Bureau Director informed the team that one reason for the lack of progress toward compatibility with NRC's program could be attributed to a lack of resources.

The NYC staff is comprised of the Director of the Office of Radiological Health, who has responsibility for the radioactive materials program and radiation-producing equipment, the Unit Chief of Radioactive Materials, and six staff members which equals 6.75 FTE for the radioactive materials program when fully staffed. At the time of the review, there was one vacancy for a license reviewer. This vacancy was created the week of the IMPEP review when a license reviewer was promoted to the position of Unit Chief of Radioactive Materials. During the review period, three staff members left the NYC program and four staff members were hired. The Director of the Office of Radiological Health left the program in March 27, 2017, and was replaced immediately by the former Unit Chief of Radioactive Materials who also continued to act as the Unit Chief of Radioactive Material until that position was filled in March 2018.

The NYC training and qualification program is compatible with the NRC's IMC 1248. Employees are required to have a minimum of a Bachelor of Science degree and are encouraged to attend NRC-sponsored training. The current NYC management is committed to training and the most recent hire has attended four NRC training courses in less than a year. Attendance at training courses is tracked in an excel spreadsheet along with the completion of specific regulatory study topics, supervised inspections, and other supplemental training. NYC also has on-the-job training to supplement course work so that individuals may broaden their work experience. Staff members are assigned increasingly complex duties as they progress through the qualification process. Licensing and inspection training and qualification is implemented by a mentoring program with a senior staff member reviewing and monitoring the work of a junior staff member. In May 2016, a consultant was hired to provide 24 hours of radioactive materials continuing education training for license reviewers and inspectors.

At the DEC, the Radiation Control Permit Section (RCPS) has a supervisor and three staff members plus one vacancy which equals 5.0 FTE when fully staffed. There were no changes in personnel since the last IMPEP review. An Environmental Radiation

Specialist (ERS) 2 position became vacant via retirement just prior to the end of the previous IMPEP review. In 2016, the DEC obtained a vacancy waiver which enabled the DEC to promote an ERS1 staff member to the vacant ERS2 position. As a result, the DEC had a vacant ERS1 position since 2016. The position will be filled through the New York State Civil Service process, which includes applying for vacancy waivers with the State of New York Governor's office. The RCPS staff issues permits for radioactive material discharges to the environment, so the staff training is limited to those technical classes in IMC 1248 which directly relate to discharges, licensing, and inspection. All staff members are fully trained to both review permit applications and to inspect permits that are issued. All staff members take refresher and supplementary training. Staff training includes new inspectors accompanying more experienced lead inspectors; the new inspectors then become the lead inspector while being accompanied by a more experienced inspector.

c. Evaluation

The team determined that, during the review period, New York met the performance indicator objectives listed in Section 3.1.a., with three exceptions:

- A well-conceived and balanced staffing strategy was not implemented throughout the review period by the DOH.
- The DOH license reviewers and inspectors were not always trained and qualified in a reasonable period of time.
- Any vacancies, especially senior-level positions, were not always filled by the DOH in a timely manner.

Based on the IMPEP evaluation criteria in MD 5.6, the team recommended that New York's performance with respect to the indicator, Technical Staffing and Training, be found satisfactory, but needs improvement.

d. MRB Decision

The MRB agreed with the team's recommendation and found New York's performance with respect to this indicator to be satisfactory, but needs improvement.

3.2 Status of Materials Inspection Program

Periodic inspections of licensed operations are essential to ensure that activities are being conducted in compliance with regulatory requirements and consistent with good safety practices. The frequency of inspections is specified in IMC 2800, "Materials Inspection Program," and is dependent on the amount and kind of material, the type of operation licensed, and the results of previous inspections. There must be a capability for maintaining and retrieving statistical data on the status of the inspection program.

a. Scope

The team used the guidance in State Agreements procedure SA-101, "Reviewing the Common Performance Indicator: Status of the Materials Inspection Program," and evaluated New York's performance with respect to the following performance indicator objectives:

- Initial inspections and inspections of Priority 1, 2, and 3 licensees are performed at the frequency prescribed in IMC 2800.
- Candidate licensees working under reciprocity are inspected in accordance with the criteria prescribed in IMC 1220, "Processing of NRC Form 241, Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, and Offshore Waters, and Inspection of Agreement State Licensees Operating Under 10 CFR 150.20."
- Deviations from inspection schedules are normally coordinated between technical staff and management.
- There is a plan to perform any overdue inspections and reschedule any missed or deferred inspections; or a basis has been established for not performing any overdue inspections or rescheduling any missed or deferred inspections.
- Inspection findings are communicated to licensees in a timely manner (30 calendar days, or 45 days for a team inspection, as specified in IMC 0610, "Nuclear Material Safety and Safeguards Inspection Reports").

b. Discussion

Inspection frequencies for DOH and NYC are the same as similar license types in the NRC's IMC 2800. During the review period, DOH and NYC collectively performed 1,055 Priority 1, 2, 3, and initial inspections. A total of 29 of 805 Priority 1, 2, and 3 inspections and 10 of 250 initial inspections were conducted overdue for an overdue rate of 3.7 percent for the review period.

A sampling of 58 DOH and NYC inspection reports indicated that three inspection findings were communicated to the licensees beyond New York's goal of 30 days after the inspection exit. All three of these reports were issued by the DOH. The overdue documentation was issued approximately 2 weeks beyond the goal of 30 days following the inspection in each case.

The DOH inspected 8.8 percent of candidate reciprocity licensees in 2014 (5 out of 57), 16.3 percent in 2015 (7 out of 43), 18.9 percent in 2016 (10 out of 53), and 20.5 percent in 2017 (9 out of 44). The DOH self-identified reciprocity inspections as a weakness and placed greater focus and resources on completing these inspections. The result was improved performance in 2016 and 2017.

Reciprocity records for 2014 could not be produced by NYC. Neither the number of reciprocity requests granted nor the number of reciprocity inspections performed in 2014 were available for review by the team. The staff indicated that the missing documents were the result of a change in management in 2014 and poor transition between

managers. In all other years of the review period, NYC performed inspections of 100 percent of candidate licensees: two out of two in 2015; four out of four in 2016; and three out of three in 2017. Therefore, the collective performance for the New York Agreement State Program regarding reciprocity inspections during the review period was 8.8 percent in 2014, 20.0 percent in 2015, 24.6 percent in 2016, and 25.5 percent in 2017.

Since the focus of the inspections conducted by the DEC is solely on environmental discharges, the inspection frequencies are not based on the NRC's IMC 2800. Instead, the inspection frequencies are based on the magnitude of environmental discharges. The DEC performed 79 permit inspections since the last IMPEP review. All were conducted on time, or ahead of the required inspection date. Inspection of permits is performed at a frequency determined by RCPS policy, based on the quantity of effluent authorized for release by the permit. Documentation for seven permit inspections was reviewed, and results of all were issued within 30 days after the inspection exit. Reciprocity inspections are not applicable to the DEC.

c. Evaluation

The team determined that, during the review period, New York met the performance indicator objectives listed in Section 3.2.a., and, based on the criteria in MD 5.6, recommended that New York's performance with respect to the indicator, Status of Materials Inspection Program, be found satisfactory.

d. MRB Decision

The MRB agreed with the team's recommendation and found New York's performance with respect to this indicator to be satisfactory.

3.3 Technical Quality of Inspections

Inspections, both routine and reactive, provide assurance that licensee activities are carried out in a safe and secure manner. Accompaniments of inspectors performing inspections, and the critical evaluation of inspection records, are used to assess the technical quality of an Agreement State's inspection program.

a. Scope

The team used the guidance in State Agreements procedure SA-102, "Reviewing the Common Performance Indicator: Technical Quality of Inspections," and evaluated New York's performance with respect to the following performance indicator objectives:

- Inspections of licensed activities focus on health, safety, and security.
- Inspection findings are well-founded and properly documented in reports.
- Management promptly reviews inspection results.
- Procedures are in place and used to help identify root causes and poor licensee performance.

- Inspections address previously identified open items and violations.
- Inspection findings lead to appropriate and prompt regulatory action.
- Supervisors, or senior staff as appropriate, conduct annual accompaniments of each inspector to assess performance and assure consistent application of inspection policies.
- For programs with separate licensing and inspection staffs, procedures are established and followed to provide feedback information to license reviewers.
- Inspection guides are consistent with NRC guidance.
- An adequate supply of calibrated survey instruments is available to support the inspection program.

b. Discussion

The team evaluated inspection reports, enforcement documentation, inspection field notes, and interviewed inspectors for 65 radioactive materials inspections (DOH-32, NYC-26 and DEC-7), conducted during the review period. The casework reviewed included inspections conducted by inspectors from each of the New York agencies, and covered various license types including: academic and medical broad scope; medical institutions with written directives, including unsealed radioiodine therapy, high dose rate remote afterloader therapy, microspheres, intravascular brachytherapy, permanent or temporary implant brachytherapy, and gamma knife therapy; medical institutions without written directives; veterinary; well-logging; waste broker; service provider; cyclotron; fixed gauge; portable gauge; industrial radiography; self-shielded irradiator; nuclear pharmacy; and 10 CFR Part 37 for radioactive materials quantities of concern.

The team accompanied 13 Program inspectors (DOH-6, NYC-3, and DEC-4) between October 6, 2017, and February 22, 2018. The accompaniments are identified in Appendix B. During the accompaniments, the inspectors demonstrated appropriate inspection techniques and knowledge of the regulations, and conducted performance-based inspections. The inspectors were trained, well-prepared for inspections, and thorough in their audits of the licensees' radiation safety programs. The inspectors conducted interviews with appropriate personnel, observed licensed operations, conducted confirmatory measurements, and utilized good health physics practices. The inspections were adequate to assess radiological health, safety, and security at the licensed facilities.

The team noted that all three New York agencies have a policy of performing annual supervisory accompaniments of each inspector. Based on a review of records provided by NYC and DEC, the team concluded that each inspector was accompanied by their supervisor at least once each year during the review period. At DOH, the team noted that only three inspectors were accompanied in calendar years 2014 and 2015, while nine inspectors were accompanied in calendar year 2016, and 10 inspectors were accompanied in 2017. The DOH self-identified this issue and DOH management committed to maintaining an adequate level of annual accompaniments in the future.

Based on the evaluation of casework, the team noted that inspections performed by all three New York agencies covered all aspects of the licensee's radiation safety

programs. The team found that inspection reports were thorough, complete, consistent, and of high quality, with sufficient documentation to ensure that a licensee's performance with respect to health, safety, and security was acceptable. The documentation supported violations, recommendations made to licensees, the effectiveness of corrective actions taken to resolve previous violations, and discussions held with licensees during exit interviews. Each New York agency issued either a letter or e-mail indicating a clear inspection or a Notice of Violation (NOV) to the licensee, which details the results of the inspection. When each New York agency issued an NOV, the licensee was required to provide a written response with corrective actions for the violations cited within 30 days. The team also identified that reports and findings were reviewed by the appropriate DOH, NYC, or DEC managers.

Inspection procedures and techniques utilized by all three New York agencies were evaluated by the team and were determined to be consistent with the inspection guidance outlined in the NRC's IMC 2800. Specific guidance for the various license types/activities was also included in the respective agency procedure manuals and/or inspection checklists. The team determined that 10 CFR Part 37 security inspection files were stored in a secure location for all three agencies. The inspection files were marked as containing sensitive information or to withhold from the public. The team noted that NYC does not mark its file folders as containing security-related information; however, inspection checklists for 10 CFR Part 37 inspections, containing sensitive security information, are marked to be withheld from the public.

The team identified that seven inspections conducted by NYC indicated that the licensees returned radioactive material, specifically nuclear medicine doses to the radiopharmacy; however, the transportation section of NYC's inspection checklist was marked as "not applicable." After discussing this issue with NYC inspectors, the team learned that compliance with certain Department of Transportation (DOT) regulations for radioactive materials returned to the radiopharmacy were not being inspected, e.g., training requirements for shippers and verification of package contamination levels. The team recommended, and the MRB agreed, that NYC inspectors obtain additional training regarding the application of DOT regulations to material licensee inspections and take steps to properly perform associated inspections.

The team confirmed that all three New York agencies have ample supplies of radiation survey instruments such as Geiger-Mueller meters, scintillation detectors, ion chambers, micro-R meters, and neutron detectors, to support its inspection program. The DOH also has portable multi-channel analyzers (MCAs) located in offices across New York, which are used to analyze samples and wipes for alpha, beta, and gamma radiation. The DEC also has portable MCAs located in Albany and its Buffalo Regional office. Instruments were calibrated at least annually in-house or by an outside vendor. Each New York agency used databases to track each instrument, its current location, and the next calibration date. The portable instruments used during the inspector accompaniments completed by the IMPEP team prior to the onsite review were operational and calibrated.

c. Evaluation

The team determined that, during the review period, New York met the performance indicator objectives listed in Section 3.3.a., and, based on the criteria in MD 5.6, recommended that New York's performance with respect to the indicator, Technical Quality of Inspections, be found satisfactory.

The team believed that factoring in all the information presented, the satisfactory rating was the most applicable since no performance issues were observed during team accompaniments of the inspectors. In addition, New York has a policy of conducting annual inspector accompaniments and two of the three agencies conducted 100 percent annual accompaniments and the third agency self-identified a shortcoming in this area and showed improvement in compliance during the IMPEP review period.

d. MRB Decision

The MRB agreed with the team's recommendation and found New York's performance with respect to this indicator to be satisfactory.

3.4 Technical Quality of Licensing Actions

The quality, thoroughness, and timeliness of licensing actions can have a direct bearing on public health and safety, as well as security. An assessment of licensing procedures, actual implementation of those procedures, and documentation of communications and associated actions between the New York licensing staff and regulated community is a significant indicator of the overall quality of the licensing program.

a. Scope

The team used the guidance in State Agreements procedure SA-104, "Reviewing the Common Performance Indicator: Technical Quality of Licensing Actions," and evaluated New York's performance with respect to the following performance indicator objectives:

- Licensing action reviews are thorough, complete, consistent, and of acceptable technical quality with health, safety, and security issues properly addressed.
- Essential elements of license applications have been submitted and elements are consistent with current regulatory guidance (e.g., financial assurance, increased controls, pre-licensing guidance).
- License reviewers, if applicable, have the proper signature authority for the cases they review independently.
- License conditions are stated clearly and can be inspected.
- Deficiency letters clearly state regulatory positions and are used at the proper time.
- Reviews of renewal applications demonstrate a thorough analysis of a licensee's inspection and enforcement history.
- Applicable guidance documents are available to reviewers and are followed (e.g., NUREG-1556 series, pre-licensing guidance, regulatory guides, etc.).

- Licensing practices for risk-significant radioactive materials are appropriately implemented including increased controls and fingerprinting orders (Part 37 equivalent).
- Documents containing sensitive security information are properly marked, handled, controlled, and secured.

b. Discussion

During the review period, DOH and NYC collectively performed 3,618 radioactive materials licensing actions. The team evaluated 54 of those licensing actions. The licensing actions selected for review included 7 new applications, 22 amendments, 11 renewals, 10 terminations, 3 denials, and 1 variance. The team evaluated casework which included the following license types and actions: broad scope, medical diagnostic and therapy, accelerator, commercial manufacturing and distribution, industrial radiography, research and development, academic, nuclear pharmacy, gauge, panoramic and self-shielded irradiator, well-logging, service provider, decommissioning, financial assurance, and notifications. The casework sample represented work from 15 license reviewers.

The team noted that DOH's licensing actions were of acceptable technical quality with sufficient attention to health, safety, and security issues. License tie-down conditions were stated clearly and were supported by information contained in the file. Deficiency letters clearly stated regulatory positions, were used at the proper time, and identified deficiencies in the licensees' documents. At the time of the 2018 IMPEP review, the DOH had a backlog of 331 outstanding license actions, including 161 amendments and 157 renewals with 41 amendments and 83 renewals pending over 1 year. These numbers represent a slight increase from 29 amendments, and a slight decrease from the 187 renewal actions pending for more than 1 year identified during the 2014 IMPEP review.

The DOH continues to make efforts to address its renewal backlog such as utilizing a quick review process (an administrative process which extends the license expiration date, where applicable) while ensuring adequate protection of public health and safety by continuing to perform inspections. In addition, the DOH was implementing a triage system where the supervisor prioritized licensing actions from a public health and safety perspective. The team did not identify any instances where the backlog was causing the DOH to provide inadequate regulatory oversight with respect to the protection of public health and safety.

At the time of the review, NYC reported having approximately 299 specific radioactive materials licenses. During the review period, NYC performed 784 license actions. There was no backlog noted during the review period. The team found licensing actions to be thorough, complete, consistent, and of high quality with health, safety, and security issues properly addressed. License tie-down conditions were stated clearly and were supported by information contained in the file. Deficiency letters clearly stated regulatory positions, were used at the proper time, and identified deficiencies in the licensees' documents. Terminated licensing actions were well documented, showing appropriate transfer and survey records. The team determined that NYC performs transfer of control

by terminating the existing license and issuing a new license. NYC performance with regard to licensing demonstrated that the corrective actions taken in response to the 2014 IMPEP recommendations have been effective, i.e., NYC provided additional training to technical staff members regarding the technical review of licensing actions and took measures to ensure that NYC's review of licensing actions were complete and well-documented.

At the DEC, the Radiation Control Permit Section (RCPS) performed 47 permit actions since the last IMPEP. In addition, RCPS staff reviewed seven permit applications which were determined to not require a permit. The team reviewed seven permit actions, including one new air permit, five renewals (one incinerator and four air permits), and one air permit modification, representing the work of three permit reviewers. The team determined the actions were of high quality. The RCPS staff used staff-developed guidance provided to applicants for typical air permits, and a separate guidance document for cyclotron applicants for an air permit. Two internal documents were developed since the last IMPEP: guidance for treating multiple stacks as a single release point; and a technical basis document for determining when stack monitoring results are sufficient to demonstrate compliance with the constraint rule.

c. Evaluation

The team determined that, during the review period, New York met the performance indicator objectives listed in Section 3.4.a., and, based on the criteria in MD 5.6, recommended that New York*'s* performance with respect to the indicator, Technical Quality of Licensing Actions, be found satisfactory.

d. MRB Decision

The MRB agreed with the team's recommendation and found New York's performance with respect to this indicator to be satisfactory.

3.5 Technical Quality of Incident and Allegation Activities

The quality, thoroughness, and timeliness of response to incidents and allegations of safety concerns can have a direct bearing on public health and safety. An assessment of incident response and allegation investigation procedures, actual implementation of these procedures, internal and external coordination, and investigative and followup actions, are a significant indicator of the overall quality of the incident response and allegation programs.

a. Scope

The team used the guidance in State Agreements procedure SA-105, "Reviewing the Common Performance Indicator: Technical Quality of Incident and Allegation Activities," and evaluated New York's performance with respect to the following performance indicator objectives:

- Incident response, investigation, and allegation procedures are in place and followed.
- Response actions are appropriate, well-coordinated, and timely.
- On-site responses are performed when incidents have potential health, safety, or security significance.
- Appropriate followup actions are taken to ensure prompt compliance by licensees.
- Followup inspections are scheduled and completed, as necessary.
- Notifications are made to the NRC Headquarters Operations Center for incidents requiring a 24-hour or immediate notification to the Agreement State or NRC.
- Incidents are reported to the Nuclear Material Events Database (NMED).
- Allegations are investigated in a prompt, appropriate manner.
- Concerned individuals are notified of investigation conclusions.
- Concerned individuals' identities are protected, as allowed by law.

b. Discussion

During the review period, 155 (DOH-138, NYC-12, and DEC-5) incidents were reported to New York, of which 42 were reportable to the NRC. The team evaluated 28 radioactive materials incidents, which included seven events involving lost/stolen radioactive material, one potential overexposure, 17 medical events, one event involving damaged equipment, and two events involving leaking sources. The appropriate New York agency dispatched inspectors for onsite followup for 15 of the cases reviewed.

The team reviewed each agency's implementation of its incident and allegation processes, including written procedures for handling incident and allegation response, file documentation, and notification of incidents to the NRC Headquarters Operations Officer for inclusion in NMED. When a notification of an incident or allegation is received, the respective New York agency's managers review the information, determine its health and safety significance, and decides on the appropriate level of initial response. The team found that inspectors from all three agencies properly evaluated each event, interviewed involved individuals, and thoroughly documented their findings. Enforcement actions were taken when appropriate.

In regards to the reporting of events to the NRC, if the event meets the NRC reporting thresholds as established in NMSS Procedure SA-300, the appropriate New York agency notified the NRC in a prompt manner, with the exception of six incidents (DOH-2 and NYC-4) where five events were reported to the NRC approximately 6 days late and one incident was reported 79 days late.

During the review period, 16 allegations (DOH-11, NYC-3, and DEC-2) were received by New York. The team evaluated the effectiveness of the three New York agencies' response to 13 allegations during the review period, including nine allegations (DOH-7, NYC-1, and DEC-1) referred to New York by the NRC. The team concluded that, with one exception, all three agencies took prompt and appropriate actions in response to concerns raised. Staff documented the investigations of concerns, retained all necessary documentation to appropriately close the allegation, and notified concerned individuals of the conclusion of an investigation. The exception involved one allegation

that was referred to the NYC by the NRC on September 12, 2014. The NRC forwarded the allegation information to the managers of the NYC program at the time, but both managers left the agency prior to the IMPEP review and were not interviewed. The team contacted NRC Region I for additional support or information, but no additional information was available. The team concluded that the current NYC management was not aware of the concerns nor could they find any documentation or records involving this allegation or NYC's response. The team accepted NYC management's explanation that the allegation must have been dispositioned by previous management because no further inquiries regarding the allegation were received by NYC or the NRC.

c. Evaluation

The team determined that, during the review period, New York met the performance indicator objectives listed in Section 3.5.a., and, based on the criteria in MD 5.6, recommended that New York's performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, be found satisfactory.

d. MRB Decision

The MRB agreed with the team's recommendation and found New York's performance with respect to this indicator to be satisfactory.

4.0 NON-COMMON PERFORMANCE INDICATORS

Four non-common performance indicators are used to review Agreement State programs: (1) Compatibility Requirements; (2) Sealed Source and Device (SS&D) Evaluation Program; (3) Low-Level Radioactive Waste Disposal (LLRW) Program; and (4) Uranium Recovery Program. The NRC's Agreement with New York retains regulatory authority for a uranium recovery program; therefore, only the first three non-common performance indicators applied to this review.

4.1 Compatibility Requirements

State statutes should authorize the State to establish a program for the regulation of agreement material and provide authority for the assumption of regulatory responsibility under the agreement. The statutes must authorize the State to promulgate regulatory requirements necessary to provide reasonable assurance of protection of public health, safety, and security. The State must be authorized through its legal authority to license, inspect, and enforce legally binding requirements, such as regulations and licenses. NRC regulations that should be adopted by an Agreement State for purposes of compatibility or health and safety should be adopted in a time frame so that the effective date of the State requirement is not later than 3 years after the effective date of the NRC's final rule. Other program elements, as defined in Appendix A of State Agreements procedure SA-200, "Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements," that have been designated as necessary for maintenance of an adequate and compatible program, should be adopted and implemented by an Agreement State within 6 months following NRC designation.

a. Scope

The team used the guidance in State Agreements procedure SA-107, "Reviewing the Non-Common Performance Indicator: Compatibility Requirements," and evaluated New York's performance with respect to the following performance indicator objectives. A complete list of regulation amendments can be found on the NRC Web site at the following address: https://scp.nrc.gov/regtoolbox.html.

- The Agreement State program does not create conflicts, duplications, gaps, or other conditions that jeopardize an orderly pattern in the regulation of radioactive materials under the Atomic Energy Act, as amended.
- Regulations adopted by the Agreement State for purposes of compatibility or health and safety were adopted no later than 3 years after the effective date of the NRC regulation.
- Other program elements, as defined in SA-200 that have been designated as necessary for maintenance of an adequate and compatible program, have been adopted and implemented within 6 months of NRC designation.
- The State statutes authorize the State to establish a program for the regulation of agreement material and provide authority for the assumption of regulatory responsibility under the agreement.
- The State is authorized through its legal authority to license, inspect, and enforce legally binding requirements such as regulations and licenses.
- Impact of sunset requirements, if any, on the State's regulations.

b. Discussion

New York became an Agreement State on October 15, 1962. There are three separate agencies regulating ionizing radiation in the State of New York: DOH, NYC, and DEC. The DOH legislative authority to administer its portion of the Agreement is granted in New York Public Health Law, Article 2, Title II, Sections 201 and 225. The NYC regulatory authority is delegated from the DOH under Part 16 of the New York State Health Sanitary Code which provides for delegation to local governments when covering greater than two million individuals. The local legislative authority for NYC's portion of the Agreement State program is granted in Chapter 22 of the New York City Charter, specifically Section 556(c)(11). This regulatory authority is implemented by NYC through Article 175 of the New York City Health Code. Articles 1, 3, 17, 19, 29, and 37 of the Environmental Conservation Law provide the DEC with the authority to implement its radiation program. The DEC regulations are found in 6 NYCRR Chapter IV, Subchapter C, Parts 380, 381, 382 and 383, and apply to environmental releases and disposal of radioactive material. The DEC requires a permit for environmental releases of radioactive material, including releases to ground or surface water, releases to the air above a specified threshold, incineration, and environmental studies. These regulations also cover the transportation of LLRW shipments into, within, and through New York State.

The three agencies reported to the team that no legislation affecting the radiation control programs was passed during the review period. The team noted that New York's rules and regulations are not subject to "sunset" laws.

The DOH and DEC regulation adoption processes are similar and take approximately 2 to 3 years. The NYC uses a different process that takes approximately 6 months to complete, if there are no mitigating factors. The public, the NRC, other agencies, and potentially impacted licensees and registrants are offered an opportunity to comment during each process.

At the DOH, once proposed regulations are developed within the Bureau, it typically takes approximately 1 year to complete internal reviews before transmitting a proposed rule to the Governor's office for review and approval. The Governor's office has been taking 1 to 2 years to complete its review and approval before being sent to the Public Health Council for review. Once the proposed rules are reviewed by the Public Health Council, they are published in the New York State Register for a mandatory 45-day public comment period. When the public comment period is completed, and if there are no substantive changes needed, the proposed rules and resolution of comments are reviewed by the Public Health Council and published in the State Register as final rules with an effective date.

The DEC follows a similar process to the DOH; however, there is no Public Health Council or Environmental Review Board involvement. At the DEC, rules are developed in conjunction with a program attorney. This process can take anywhere from 3 months to a year for more complex rules. Once the rules are developed, the DEC Office of General Counsel performs a review which can take about 1 to 2 months. After that, the proposed rules go to the DEC Executive Commissioner for review, which for the 6 NYCRR Part 380 amendments, took approximately 1 year. After leaving the DEC, the proposed rules go to the Governor's Office for review. For the 6 NYCRR 380 review, the Governor's office review took 2 years. The proposed rules then go out for a 30 to 90-day public comment period during which time a public hearing is held. After the public comment period and comments are resolved, the DEC has 1 year from the public hearing date to file the final rules with the New York Department of State. For the 6 NYCRR 380 amendments, the public hearing date was May 25, 2017. The final rules were filed with the New York Department of State on April 10, 2018 and became effective on May 10, 2018.

The NYC follows a different process. The NYC develops a regulation package and sends it to the New York City mayor's office and the City Law Department for review and approval. Once the rules are approved by the mayor's office and the City's Law Department, they are placed on the Department's Board of Health agenda. The Board of Health meets quarterly in March, June, September, and December. The first time that it is presented with proposed rules, the Board of Health determines whether to approve them for publication on the City's proposed rules website and in the City Record (a newspaper which publishes City agencies' proposed and adopted rules) at that point, the rules are open for general public comment. Once the Board approves for publication, the proposed rule is also disseminated to various stakeholders, the media, and City officials. The agency also holds a public hearing on the proposed rule, usually about

30 days after the Board has approved it for publication. The overall public comment period is usually 60 days.

During the review period, 17 regulation amendments became due for adoption by New York (DOH-10, NYC-5, and DEC-2). At the time of the review, these regulation amendments had not been adopted and were all overdue. Prior to the review period, several regulation amendments were not adopted by the due date and several outstanding comments on those amendments were unresolved. Since both DOH and NYC proposed and worked on the revisions to adopt NRC regulations by reference, neither program worked on individual NRC amendments that were due or past due. The DEC had worked on individual NRC amendments and was in the process of adopting them during the review period.

At the time of the 2018 IMPEP review, the DOH was in the process of developing rules to incorporate NRC regulations by reference. The DOH had implemented some license conditions to prevent significant health and safety gaps in the regulations and to maintain compatibility, e.g., license conditions for 10 CFR Parts 35, 37, and 71. These license conditions were not reviewed for compatibility by the NRC before implementation.

During the review period, NYC proceeded to adopt NRC regulations by reference by repealing and reenacting Article 175 of the NYC Health Code, which includes the regulation of radioactive material in New York City per the Agreement State Program. In 2016, NYC developed and submitted the proposed Article 175 revisions to the NRC for review. The NRC issued 16 comments on the proposed regulations in May 2017, and NYC proceeded to promptly resolve the comments. The updated reenactment of Article 175 regulations were submitted to the New York City Law Department in July 2017 for review. At the time of the review, the regulations were still under review at the New York City Law Department; however, NYC management indicated that the regulations would go to the New York City Board of Health in June and could be adopted as early as October 2018. As of June 5, 2018, NYC regulations were approved by the New York City Board of Health for publication and public comment.

The DEC had a total of eight regulation amendments overdue for adoption at the time of the review, six of which dated to the previous IMPEP review period. Of the overdue rules, four are incorporated into the amendment of 6 NYCRR 380, “Prevention and Control of Environmental Pollution by Radioactive Materials,” which became effective on May 10, 2018. Two other overdue regulations will be adopted as the new 6 NYCRR Part 384, which is expected to be submitted for executive approval in 2018. The last two overdue rules are to be incorporated into 6 NYCRR Part 381, which will be developed later.

c. Evaluation

The team determined that, during the review period, New York met the performance indicator objectives listed in Section 4.1.a., with one exception:

- Regulations adopted by the Agreement State for purposes of compatibility or health and safety were not adopted within 3 years after the effective date of the NRC regulation.

Based on the IMPEP evaluation criteria in MD 5.6, the team recommended that New York's performance with respect to the indicator, Compatibility Requirements, be found unsatisfactory.

d. MRB Decision

The MRB agreed with the team's recommendation and found New York's performance with respect to this indicator to be unsatisfactory.

4.2 SS&D Evaluation Program

Adequate technical evaluations of SS&D designs are essential to ensure that SS&Ds will maintain their integrity and that the design is adequate to protect public health and safety. NUREG-1556, Volume 3, "Consolidated Guidance about Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration," provides information on conducting SS&D reviews and establishes useful guidance for teams. Under this guidance, three sub elements: Technical Staffing and Training, Technical Quality of the Product Evaluation Program, and Evaluation of Defects and Incidents Regarding SS&D's, are evaluated to determine if the SS&D program is satisfactory. Agreement States with authority for SS&D evaluation programs who are not performing SS&D reviews are required to commit in writing to having an SS&D evaluation program in place before performing evaluations.

a. Scope

The team used the guidance in State Agreements procedure SA-108, "Reviewing the Non-Common Performance Indicator: Sealed Source and Device Evaluation Program," and evaluated New York's performance with respect to the following performance indicator objectives:

Technical Staffing and Training

- A well-conceived and balanced staffing strategy has been implemented throughout the review period.
- Qualification criteria for new technical staff are established and are being followed or qualification criteria will be established if new staff members are hired.
- Any vacancies, especially senior-level positions, are filled in a timely manner.
- Management is committed to training and staff qualification.
- Individuals performing SS&D evaluation activities are adequately qualified and trained to perform their duties.
- SS&D reviewers are trained and qualified in a reasonable period of time.

Technical Quality of the Product Evaluation Program

- SS&D evaluations are adequate, accurate, complete, clear, specific, and consistent with the guidance in NUREG-1556, Volume 3.

Evaluation of Defects and Incidents

- SS&D incidents are reviewed to identify possible manufacturing defects and the root causes of these incidents.
- Incidents are evaluated to determine if other products may be affected by similar problems. Appropriate action and notifications to the NRC, Agreement States, and others, as appropriate, occur in a timely manner.

b. Discussion

Technical Staffing and Training

The SS&D program is administered by the DOH. At the time of the review, New York had two staff members qualified to perform SS&D reviews. Both reviewers have attended the NRC SS&D Workshop. There were no changes to the staff who perform SS&D evaluations during the review period and, at the time of the review, there were no vacancies. New York has a training program equivalent to NRC training requirements listed in the NRC's IMC 1248, Appendix D.

Technical Quality of the Product Evaluation

New York has three SS&D licensees. The team evaluated the sole SS&D action DOH processed during the review period. The action included an amendment to an existing registration certificate and featured changes to the dimensions of a registered sealed source. The reviewer performed a complete and technically accurate review, evaluated the new submitted prototype test results, and was able to identify the shortcoming of the application. The review was thorough and completed in a timely manner. The casework indicated that staff followed the guidance in NUREG 1556 Vol.3, Rev. 2, and completed the Safety Evaluation Checklist.

Evaluation of Defects and Incidents Regarding SS&Ds

The team evaluated both incidents involving New York SS&D registered products that occurred during the review period. Neither of the incidents were related to manufacturing or design of the sources/devices manufactured or distributed by a licensee with a SS&D registered by New York. The team found that DOH properly evaluated each event, took appropriate action, and documented its findings.

c. Evaluation

The team determined that, during the review period, New York met the performance indicator objectives listed in Section 4.2.a., and, based on the criteria in MD 5.6,

recommended that New York's performance with respect to the indicator, Sealed Source and Device Evaluation Program, be found satisfactory.

d. MRB Decision

The MRB agreed with the team's recommendation and found New York's performance with respect to this indicator to be satisfactory.

4.3 Low-Level Radioactive Waste (LLRW) Disposal Program

The objective is to determine if New York LLRW disposal program is adequate to protect public health and safety. Five sub-elements are used to make this determination: (1) Technical Staffing and Training; (2) Status of LLRW Inspection Program; (3) Technical Quality of Inspections; (4) Technical Quality of Licensing Actions; and (5) Technical Quality of Incident and Allegation Activities.

a. Scope

The team used the guidance in State Agreements procedure SA-109, "Reviewing the Non-Common Performance Indicator: Low-Level Radioactive Waste Disposal Program," and evaluated New York's performance with respect to the following performance indicator objectives:

Technical Staffing and Training

- Qualified and trained technical staff are available to license, regulate, control, inspect, and assess the operation and performance of the LLRW disposal facility.
- Qualification criteria for new LLRW technical staff are established and are followed or qualification criteria will be established if new staff members are hired.
- Any vacancies, especially senior-level positions, are filled in a timely manner.
- There is a balance in staffing the LLRW licensing and inspection programs.
- Management is committed to training and staff qualification.
- Individuals performing LLRW licensing and inspection activities are adequately qualified and trained to perform their duties.
- LLRW license reviewers and inspectors are trained and qualified in a reasonable period of time.

Status of LLRW Inspection Program

- The LLRW facility is inspected at prescribed frequencies.
- Statistical data on the status of the inspection program are maintained and can be retrieved.
- Deviations from inspection schedules are coordinated between LLRW technical staff and management.
- There is a plan to perform any overdue inspections and reschedule any missed or deferred inspections; or a basis has been established for not performing any overdue inspections or rescheduling any missed or deferred inspections.

- Inspection findings are communicated to licensees in a timely manner.

Technical Quality of Inspections

- Inspections of LLRW licensed activities focus on health, safety, and security.
- Inspection findings are well-founded and properly documented in reports.
- Management promptly reviews inspection results.
- Procedures are in place and used to help identify root causes and poor licensee performance.
- Inspections address previously identified open items and violations.
- Inspection findings lead to appropriate and prompt regulatory action.
- Supervisors, or senior staff as appropriate, conduct annual accompaniments of each LLRW inspector to assess performance and assure consistent application of inspection policies.
- Inspection guides are consistent with NRC guidance.
- An adequate supply of calibrated survey instruments is available to support the inspection program.

Technical Quality of Licensing Actions

- Licensing action reviews are thorough, complete, consistent, and of acceptable technical quality with health, safety, and security issues properly addressed.
- Applicable LLRW guidance documents are available to reviewers and are followed (e.g., pre-licensing guidance, regulatory guides, etc.).
- Essential elements of license applications have been submitted and elements are consistent with current NRC or Agreement State regulatory guidance for describing the isotopes and quantities used, qualifications of authorized users, facilities, equipment, locations of use, operating and emergency procedures, and any other requirements necessary to ensure an adequate basis for the licensing action, e.g., financial assurance, increased controls/Part 37, etc.
- LLRW license reviewers, if applicable, have the proper signature authority for the cases they review independently.
- License tie-down conditions are stated clearly and can be inspected.
- Deficiency letters clearly state regulatory positions and are used at the proper time.
- Reviews of renewal applications demonstrate a thorough analysis of a licensee's inspection and enforcement history.
- Licensing practices for risk significant radioactive materials are appropriately implemented including increased controls and fingerprinting orders (Part 37 equivalent).
- Documents containing sensitive security information are properly marked, handled, controlled, and secured.

Technical Quality of Incident and Allegation Activities

- LLRW incident response, investigation, and allegation procedures are in place and followed.

- Response actions are appropriate, well-coordinated, and timely.
- On-site responses are performed when incidents have potential health, safety or security significance.
- Appropriate followup actions are taken to ensure prompt compliance by licensees.
- Followup inspections are scheduled and completed, as necessary.
- Notifications are made to the NRC Headquarters Operations Center for incidents requiring a 24-hour or immediate notification to the Agreement State or NRC.
- Incidents are reported to the NMED.
- Allegations are investigated in a prompt, appropriate manner.
- Concerned individuals are notified of investigation conclusions.
- Concerned individuals' identities are protected, as allowed by law.

b. Discussion

New York does not have any active LLRW sites. The DEC's Radioactive Materials Management Section (RMMS) oversees two closed land burial facilities at locations where LLRW was buried in the past in accordance with regulations at the time of burial. The State-licensed Disposal Area (SDA) located at West Valley is authorized under a land burial permit to monitor and maintain the SDA facility. The Cornell Radioactive Disposal Site (RDS) performs monitoring and maintenance of the facility under a Consent Order issued by the State of New York. The RDS also is authorized by a water permit to release effluent water.

Technical Staffing and Training

The RMMS has two qualified staff members currently performing oversight of the two closed land burial sites. Other qualified staff in RMMS perform work not related to activities under the Agreement. At the time of the review, there was one vacancy in the RMMS. There were no changes in the staff members who oversee the closed land burial sites since the last IMPEP. The RMMS training program for the staff performing oversight of the two closed land burial sites is equivalent to NRC training requirements listed in IMC 1248, Appendix E for both initial and refresher training.

Status of LLRW Disposal Inspection Program

The RMMS staff performed 12 inspections during the review period. The review determined that RMMS completed the inspections in accordance with the frequency in the NRC's IMC 2800. The more complex land burial site, the West Valley SDA, is inspected a minimum of twice each year; the smaller, less complex site, the Cornell RDS, is inspected annually.

Inspection findings for the LLRW disposal program were communicated by formal correspondence to the licensee within 30 days following the inspection.

Technical Quality of Inspections

On October 6, 2017, the team accompanied two inspectors and a supervisor at the Cornell RDS. Under the Consent Order issued to Cornell University, site security, environmental monitoring, and facility posting of the Cornell RDS were observed.

The team evaluated two inspection files, which included hydrogeological, radiological, security, and environmental hazards, and determined that the inspection reports were thorough, complete, consistent, and had sufficient documentation to ensure that licensee performance with respect to health, safety and security was acceptable. The findings were well-founded, supported by regulations, and were appropriately documented.

Technical Quality of Licensing Actions

The RMMS completed one land burial permit action during the review period: the renewal of the West Valley SDA land burial permit. The review was thorough and completed in a timely manner.

Technical Quality of Incident and Allegation Activities

The team evaluated the one incident and all three allegations that RMMS received during the review period. All three allegations were referred to the State of New York by the NRC and were determined to involve activities under RMMS oversight. The incident and allegations were not related to either land burial site, but were evaluated by RMMS because the nature of the issues best fell under RMMS oversight. The DEC has written procedures for the handling, review, analysis, response and follow-up of incidents and allegations. These procedures were undergoing revision at the time of the review.

The single incident was a request for assistance from another State agency. Two of the three allegations referred by the NRC were related to issues and facilities with which RMMS already was familiar. RMMS's response to the single incident was adequate and appropriate follow-up actions were taken with all three allegations.

c. Evaluation

The team determined that, during the review period, New York met the performance indicator objectives listed in Section 4.3.a., and, based on the criteria in MD 5.6, recommended that New York performance with respect to the indicator, Low-Level Radioactive Waste Disposal Program, be found satisfactory.

d. MRB Decision

The MRB agreed with the team's recommendation and found New York's performance with respect to this indicator to be satisfactory.

5.0 SUMMARY

As noted in Sections 3.0 and 4.0 above, New York's performance was found satisfactory for six out of eight performance indicators reviewed, satisfactory but needs improvement for the performance indicator Technical Staffing and Training, and unsatisfactory for the performance indicator Compatibility Requirements. The MRB agreed with the team's sole recommendation regarding New York's performance and agreed that two of the three recommendations from the 2014 IMPEP review should be closed. The MRB agreed with the team that the recommendation from 2014 IMPEP review regarding regulation development should remain open.

When one or more performance indicators is found unsatisfactory, NRC Management Directive 5.6 directs the MRB to consider placing the program on Heightened Oversight. At the end of the 2014 IMPEP review, the MRB considered the progress New York made in adopting overdue regulations and New York's performance improvement from unsatisfactory to satisfactory during the review period with respect to the indicator Technical Quality of Incident and Allegation Activities. The 2014 MRB decided to discontinue the period of Heightened Oversight and initiate a period of Monitoring.

As of April 10, 2018, the DOH was developing rules to adopt NRC regulations by reference; NYC was set to adopt compatible rules by October 2018; and the DEC had filed final rules for the adoption of 6 NYCRR 380, "Prevention and Control of Environmental Pollution by Radioactive Materials," which eventually became effective on May 10, 2018. As of June 5, 2018, NYC regulations were approved by the New York City Board of Health for publication and public comment, which keeps it on track to be adopted in October 2018. Additionally, to fill vacancies, the DOH and DEC are required to apply for approval, in the form of a "vacancy waiver" with the State of New York Governor's Office. Both the DOH and DEC have consistently applied for vacancy waivers with the Governor's Office when positions became vacant during the review period. The team factored in the 2014 MRB decision to remove New York from Heightened Oversight and determined that a written performance improvement plan was unnecessary to address the issues involving regulation development and staffing because the DOH was already taking actions to address these issues. The processes for regulation adoption and hiring feature potential delays outside of the DOH and DEC's control. Quarterly monitoring calls would not expedite or facilitate these processes. Therefore, in lieu of Heightened Oversight or Monitoring, the team recommended to the MRB that New York be removed from Monitoring and a periodic meeting be held 1 year from the MRB meeting to discuss the overall status of the program with emphasis on the indicators that were found less than satisfactory, including measuring progress in regulation adoption. The MRB agreed that the period of Monitoring be discontinued with the following condition: The MRB directed staff to maintain awareness through informal calls with New York with regards to staffing and training and compatibility requirements.

Accordingly, the team recommended, and the MRB agreed, that the New York Agreement State Program is adequate to protect public health and safety and not compatible with the NRC's program. Based on the results of the current IMPEP review, the team recommended, and the MRB agreed, that the next full IMPEP review will take place in 4 years, with a periodic meeting in 1 year.

Below are the team's recommendations, as mentioned in the report, for evaluation and implementation by New York:

1. The team recommends that the NYC inspectors obtain additional training regarding the application of DOT regulations to material licensee inspections and take steps to properly perform associated inspections (Section 3.3).

2. The team recommends that the Program make appropriate regulatory changes to resolve NRC-generated comments as noted in regulation review letters, and adopt NRC regulations in accordance with the current NRC policy on adequacy and compatibility (Section 4.1 of the 2014 IMPEP report).

LIST OF APPENDICES

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	**Areas of Responsibility**
Binesh Tharakan, Region IV	Team Leader Compatibility Requirements
John Miller, Region I	Technical Staffing and Training Status of Materials Inspection Program DOH Inspector Accompaniments
Robin Elliott, Region I	Technical Quality of Inspections DOH Inspector Accompaniments
Angela Wilbers, Kentucky	Technical Quality of Licensing Actions
Zahid Sulaiman, Region III	Technical Quality of Incident and Allegation Activities
Lymari Sepulveda, NMSS	Sealed Source and Device Evaluation Program
Betsy Ullrich, Region I	Low-Level Radioactive Waste Disposal Program DEC Common Indicators DEC Inspector Accompaniments
Brian Goretzki, Arizona	NYC Inspector Accompaniments

APPENDIX B

INSPECTION ACCOMPANIMENTS

The following inspection accompaniments were performed prior to the on-site IMPEP review:

Accompaniment No.: 1	Permit No.: NA – Consent Order
Permit Type: Land Burial	Priority: 1
Inspection Date: 10/6/17	Inspector: JA and KM

Accompaniment No.: 2	License No.: 91-3079-01
License Type: Medical, written directive required	Priority: 3
Inspection Date: 12/11/17	Inspector: MR

Accompaniment No.: 3	License No.: 91-3018-01
License Type: Medical, written directive required	Priority: 3
Inspection Date: 12/12/17	Inspector: OA

Accompaniment No.: 4	License No.: 91-2902-01
License Type: Medical, written directive required	Priority: 3
Inspection Date: 12/13/17	Inspector: JL

Accompaniment No.: 5	Permit No.: 181-3
Permit Type: Air	Priority: 2
Inspection Date: 12/19/17	Inspector: TF

Accompaniment No.: 6	Permit No.: 53-3
Permit Type: Air	Priority: 3
Inspection Date: 1/30/18	Inspector: FF

Accompaniment No.: 7	License No.: C3244
License Type: Fixed gauge	Priority: 5
Inspection Date: 2/5/18	Inspector: NK

Accompaniment No.: 8	License No.: C2610
License Type: Portable gauge	Priority: 5
Inspection Date: 2/6/18	Inspector: MSu

Accompaniment No.: 9	License No.: C3034
License Type: Radiography	Priority: 1
Inspection Date: 2/15-16/18	Inspector: AB

Accompaniment No.: 10	License No.: 1195
License Type: Medical, no written directive required	Priority: 5
Inspection Date: 2/20/18	Inspector: MS

Accompaniment No.: 11	License No.: 437
License Type: Medical, HDR	Priority: 2
Inspection Date: 2/21/18	Inspector: JK

Accompaniment No.: 12	License No.: 5124
License Type: Medical, no written directive required	Priority: 5
Inspection Date: 2/22/18	Inspector: JC