UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

October 3, 2014

Nathan Graber, M.D., M.P.H.
Director
Center for Environmental Health
Empire State Plaza-Corning Tower-Room 1619
Albany, NY 12237

Dear Dr. Graber:

On August 4, 2014, the Management Review Board (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 U.S. Nuclear Regulatory Commission's (NRC) program.

Section 5.0, page 18 of the enclosed final report contains a summary of the IMPEP team's findings and recommendations. The review team determined that the recommendations from the 2011 IMPEP review, regarding reciprocity inspections, development of an action plan to adopt NRC regulations, and incident reporting and incident procedures should be closed. The review team made three recommendations regarding program performance in technical staffing, quality of licensing, and compatibility requirements. We request your written response to the recommendations in the report within 30 days from receipt of this letter. Your response to the recommendations should be submitted to Laura Dudes, Director, Division of Materials Safety and State Agreements. The MRB suggests the Program carefully review the IMPEP report sections on Technical Staffing and Training, Technical Quality of Licensing Actions, and Compatibility Requirements as it prepares the responses to the recommendations. Based on the results of the current IMPEP review, the next full review of the New York Agreement State Program will take place in approximately 4 years from the current IMPEP, with a periodic meeting tentatively scheduled for March 2016.

The MRB commends the Program for progress made under the indicator Technical Quality of Incident and Allegations Activities, where performance was improved from unsatisfactory to satisfactory during the review period, and the progress made in adopting several overdue rules. As a result, the MRB directed that the period of Heightened Oversight be discontinued and a period of Monitoring be initiated.

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/

Roy P. Zimmerman
Acting Deputy Executive Director for
Materials, Waste, Research, State, Tribal and
Compliance Programs
Office of the Executive Director for Operations

Enclosure:
New York Final IMPEP Report

cc: Cheryl Rogers, WI
Organization of Agreement States
Liaison to the MRB

Stephen Gavitt, CHP, Director
Bureau of Environmental Radiation Protection

Robert Dansereau, Asst. Director
Bureau of Environmental Radiation Protection

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

October 3, 2014

Mr. Robert W. Schick
New York State Department of
Environmental Conservation
625 Broadway, 11th Floor
Albany, NY 12233

Dear Mr. Schick:

On August 4, 2014, the Management Review Board (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 U.S. Nuclear Regulatory Commission's (NRC) program.

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Roy P. Zimmerman
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Enclosure:
New York Final IMPEP Report

cc: Cheryl Rogers, WI
Organization of Agreement States
Liaison to the MRB

Timothy Rice, Chief
Radiological Sites Section
Remedial Bureau A

Sandra Hinkel, Chief
Radiation Control Permits Section
Remedial Bureau

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

October 3, 2014

Mr. Christopher Boyd
Assistant Commissioner
Bureau of Environmental Sciences
and Engineering
42-09 28th Street, 14th Floor CN#56
Long Island City, NY 11101

Dear Mr. Boyd:

On August 4, 2014, the Management Review Board (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 U.S. Nuclear Regulatory Commission's (NRC) program.

Section 5.0, page 18 of the enclosed final report contains a summary of the IMPEP team's findings and recommendations. The review team determined that the recommendations from the 2011 IMPEP review, regarding reciprocity inspections, development of an action plan to adopt NRC regulations, and incident reporting and incident procedures should be closed. The review team made three recommendations regarding program performance in technical staffing, quality of licensing, and compatibility requirements. We request your written response to the recommendations in the report within 30 days from receipt of this letter. Your response to the recommendations should be submitted to Laura Dudes, Director, Division of Materials Safety and State Agreements. The MRB suggests the Program carefully review the IMPEP report sections on Technical Staffing and Training, Technical Quality of Licensing Actions, and Compatibility Requirements as it prepares the responses to the recommendations. Based on the results of the current IMPEP review, the next full review of the New York Agreement State Program will take place in approximately 4 years from the current IMPEP, with a periodic meeting tentatively scheduled for March 2016.

The MRB commends the Program for progress made under the indicator Technical Quality of Incident and Allegations Activities, where performance was improved from unsatisfactory to satisfactory during the review period, and the progress made in adopting several overdue rules. As a result, the MRB directed that the period of Heightened Oversight be discontinued and a period of Monitoring be initiated.

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/

Roy P. Zimmerman
Acting Deputy Executive Director for
Materials, Waste, Research, State, Tribal and
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Office of the Executive Director for Operations

Enclosure:
New York Final IMPEP Report

cc: Cheryl Rogers, WI
Organization of Agreement States
Liaison to the MRB

Geoffrey Korir, Director
Office of Radiological Health

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF THE NEW YORK AGREEMENT STATE PROGRAM

MARCH 17–28, 2014

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 17–28, 2014, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Florida.

Based on the results of this review, New York's performance was found satisfactory for the indicators Status of the Materials Inspection Program, Technical Quality of Inspection, Technical Quality of Incidents and Allegations, Sealed Source and Device Evaluation Program, and Low-level Radioactive Waste Disposal Program. The indicator, Technical Staffing and Training was found satisfactory, but needs improvement, and remains unchanged from the previous IMPEP review. The indicator, Compatibility Requirements was found unsatisfactory and remains unchanged from the previous IMPEP review. Progress has been made on this indicator, but the State has not yet addressed a number of overdue regulation amendments and outstanding NRC comments regarding earlier regulation packages. The indicator, Technical Quality of Licensing Actions, was found satisfactory, but needs improvement by the IMPEP team. However, the Management Review Board (MRB) determined this indicator should be found satisfactory.

The review team made three recommendations regarding program performance in technical staffing, technical quality of licensing, and compatibility requirements, and determined that the six recommendations from the 2011 IMPEP review, regarding reciprocity inspections, development of an action plan to adopt NRC regulations, and incident reporting and incident procedures should be closed.

Accordingly, the review team recommended, and the MRB agreed, that the New York Agreement State Program is adequate to protect public health and safety and is not compatible with the NRC's program. Considering the progress New York made under the indicator Technical Quality of Incident and Allegations (i.e., performance was improved from unsatisfactory to satisfactory during the review period) and the progress made in adopting several overdue rules, the review team recommended, and the MRB agreed, that the period of Heightened Oversight be discontinued and a period of Monitoring be initiated. The review team recommended and the MRB agreed that the next IMPEP review take place in approximately 4 years.

1.0 INTRODUCTION

This report presents the results of the review of the New York Agreement State Program. The review was conducted during the period of March 17–28, 2014, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Florida. Team members are identified in Appendix A. The review was conducted in accordance with the "Implementation of the Integrated Materials Performance Evaluation Program and Rescission of Final General Statement of Policy," published in the *Federal Register* on October 16, 1997, and NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)," dated February 26, 2004. Preliminary results of the review, which covered the period of June 16, 2011, to March 27, 2014, were discussed with New York managers on the last day of the review.

A draft of this report was provided to New York for factual comment on April 30, 2014. New York responded to the findings and conclusions of the review by (1) e-mail dated May 14, 2014, from Sandra Hinkel, Chief, Radiation Control Permit Section, NYS Department of Environmental Conservation; (2) e-mail dated June 3, 2014, from Stephen Gavitt, Director, Bureau of Environmental Radiation Protection; and (3) letter dated June 4, 2014, Christopher Boyd, Assistant Commissioner, Bureau of Environmental Sciences and Engineering. Copies of the State's responses are included as an Attachment to this report. A Management Review Board (MRB) met on August 4, 2014, to consider the proposed final report. The MRB found the New York Agreement State Program adequate to protect public health and safety and not compatible with the NRC's program.

The New York Agreement State Program (the Program) is currently 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 disposal of radioactive wastes in the ground. Organization charts for the three agencies are included as Appendix B.

At the time of the review, the Program regulated 1,349 specific licenses authorizing possession and use of radioactive materials, and 30 permits for radioactive discharges and radioactive waste disposals 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.

In preparation for the review, a questionnaire addressing the common and applicable non-common performance indicators was sent to the New York agencies on May 6, 2013. Each agency provided an electronic response to the questionnaire–DEC on February 12, 2014; DOH on March 7, 2014; and NYC on March 11, 2014. A copy of the respective questionnaire responses can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Numbers ML14070A275, ML14070A282, and ML14072A041.

The review team's general approach for conduct of this review consisted of (1) examination of the Program's responses to the questionnaires, (2) review of applicable New York statutes and regulations, (3) analysis of quantitative information from the Program's databases, (4) technical review of selected regulatory actions, (5) field accompaniments of 11 inspectors, and (6) interviews with staff and managers. The review team evaluated the information gathered against the established criteria for each common and the applicable non-common performance indicator and made a preliminary assessment of the Program's performance.

Section 2.0 of this report covers the State's actions in response to recommendations made during previous reviews. Results of the current review of the common performance indicators are presented in Section 3.0. Section 4.0 details the results of the review of the applicable non-common performance indicators, and Section 5.0 summarizes the review team's findings.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on June 16, 2011, the review team made six recommendations regarding the New York's Agreement State Program's performance. The status of the recommendations is as follows:

Recommendation 1: "The review team recommended that DOH develop and implement a process to track reciprocity inspections to ensure at least 20 percent of candidate licensees for reciprocity are inspected. (Section 3.2)"

Status: Since the June 2011 IMPEP, DOH implemented the use of a tracking system which allows for tracking and completion of reciprocity inspections. The review of New York DOH reciprocity records confirmed an electronic tracking system was developed which allows for tracking completion of reciprocity inspections. Staff was able to provide printout lists of reciprocity inspections with correlating data for the entire review period showing that the DOH performed inspections of at least 20 percent of the candidate licensees for reciprocity. This recommendation is closed.

Recommendation 2: "The review team recommended that DOH develop comprehensive incident response and allegation procedures, and ensure that reportable incidents are reported to the NRC Operations Center in accordance with the timelines identified in FSME Procedure SA-300. (Section 3.5)"

Status: Based on a review of the DOH incident and allegation procedures, the review team determined that DOH developed comprehensive incident response and allegation procedures which include the event reporting timelines identified in SA-300. In addition, based on a review of selected NMED casework, the review team determined that DOH is reporting incidents to the NRC Operations Center in accordance with the timelines identified in SA-300. This recommendation is closed.

Recommendation 3: "The 2006 IMPEP review team recommended that DOH, NYC, DEC develop and implement an action plan to adopt NRC regulations in accordance with the current NRC policy on adequacy and compatibility. (Open recommendation from the 2006 and 2011 IMPEP reviews)."

Status: The team determined that each agency developed and implemented an action plan to adopt the NRC regulations in accordance with current NRC policies on adequacy and compatibility. Each NY agency had developed and implemented an action plan as directed by the recommendation. The NYC agency was able to clear its backlog, but due to an arduous rulemaking process for both DOH and DEC, these agencies were not able to clear their backlog of overdue regulations. The 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. This recommendation is closed.

Recommendation 4: "The review team recommended that NYC respond to each incident received in accordance with its established Incident Response Procedure. (Section 3.5)"

Status: Since the 2011 IMPEP review, NYC revised its Incident Response Procedure and has trained the staff on the contents of the revised procedure. Program managers reminded the staff to follow the established protocol for medical events reported to NYC and to follow the proper sequence of events to close out all incidents reported to NYC. Based on a review of selected casework files, the review team determined that NYC responded to each incident received in accordance with its established Incident Response Procedure. This recommendation is closed.

Recommendation 5: "The review team recommended that NYC modify its Incident Response Procedure to add timely notifications to the NRC Operations Center in accordance with the timelines identified in SA-300. (Section 3.5)"

Status: The NYC manager stated that program staff was made aware of and instructed to review the reporting requirements as listed in SA-300. The Incident Response Procedure was modified to add the requirement for timely notifications. Based on a review of the NYC Incident Response Procedure, the review team determined that the procedure has been updated to include information on timely notifications to the NRC Operations Center in accordance with the timelines identified in SA-300. This recommendation is closed

Recommendation 6: "The review team recommended that NYC evaluate all incident statistical information received from licensees, both retrospectively and prospectively, and follow up in a manner to ensure that each incident is properly evaluated for health, safety, and security implications. (Section 3.5)"

Status: During the 2011 IMPEP review, NYC performed the retrospective review of the incident statistical information received from licensees. Twelve medical events were identified, two of which were initially determined to be reportable to the NRC. The NYC reported these events to the NRC on June 15, 2011. Subsequent to the 2011 IMPEP review, NYC determined that one of the two events reported to the NRC was actually not reportable. Based on a review of selected casework and discussions with NYC inspection staff, the review team determined that NYC evaluates each incident for health, safety and security implications and follows up in an appropriate manner. This recommendation is closed.

3.0 COMMON PERFORMANCE INDICATORS

Five common performance indicators are used to review 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

Issues central to the evaluation of this indicator include staffing level and staff turnover, as well as the technical qualifications and training histories of the staff for each of the New York agencies. To evaluate these issues, the review team examined the respective agency's response to the IMPEP questionnaire relative to the indicator, interviewed management and staff, reviewed job descriptions and training records, and considered any workload backlogs.

The NYC radioactive materials program is administered by the Office of Radiological Health (ORH) which is staffed by the Office Director, the Unit Chief, and six technical staff members totaling 5.4 full-time equivalents (FTE). Over the review period, there were three vacancies, the Office Director position and two technical staff positions. Since the retirement of the Office Director in the fall of 2013, management of the ORH is being conducted by the Assistant Commissioner of Environmental Sciences and Engineering until a replacement is hired. The ORH has interviewed candidates for the vacancies and has extended offers of employment for the Director position and one technical position. During the review period, one technical position was eliminated. Subsequent to the onsite review, an offer was accepted for the Director's position and one technical staff position. The new Office Director started in June 2014. The new technical staff member has a background in radiation producing equipment and will allow the two current Radiation Scientist II staff to be cross-trained to perform material inspections and licensing to focus more of their effort on those activities and complete the training after a dedicated mentoring period. This will assist the agency in addressing the loss of three long-term staff that supported the radioactive materials program.

At the time of the review, the materials inspectors were fully qualified, and the license reviewers were fully qualified and have full signatory authority for licensing actions. The ORH, however, provides cross qualification training to its X-ray inspectors to best leverage resources. Currently two x-ray inspectors are working on materials qualifications for inspection and licensing. Since the 2011 IMPEP, the NYC staff has attended NRC technical training courses, which is an improvement over the previous review period.

The ORH requires a bachelor's degree in engineering, physical, or biological sciences for all technical positions. NYC has written qualifications requirements which include the minimum casework reviews and training courses for full qualification. The review team discussed with NYC managers the need to fully document its technical staff's training qualifications, i.e. course and casework completion dates and management sign-off.

The DEC Radiation Program Staff consists of two branches, the Radiation Control Permit Section and the Radiological Sites Section which totals 7.8 FTE for Agreement State work. There are two vacancies in the Radiological Sites Section, one of which was eliminated during the review period. The DEC and DOH both face difficulties in hiring due to State budget

constraints and a hiring freeze. Positions are often eliminated once they are vacated. The agency is required to request a waiver in order to fill vacancies. The waiver process is lengthy, and requires approval through multiple State offices. The team determined that DEC staff is balanced between permitting and inspection functions. The DEC maintains a Radiation Program Staff Training Requirements which are consistent with the NRC requirements for training and qualification. With the exception of one person, all DEC staff are fully qualified. There is management support for staff training and qualification. The DEC has one field inspector located in the Buffalo office. Since the employee is not yet qualified, the section chief for the Radiological Sites Section is performing field work at the West Valley site until this employee is fully qualified and can inspect independently. Travel logistics and State travel restrictions make it difficult for this employee to travel to the Albany central office for training.

The DOH radioactive materials program is administered by the Bureau of Environmental Radiation Protection and consists of the Office Director, the Environmental Radon/Emergency Response Section, the Radioactive Materials Section, the Radiation Equipment/X-ray Section, and the Inspection and Enforcement Section. Currently, there are 11.9 FTE that support the radioactive materials program. There are four DOH Regions. In the Western Region, there is one staff member in Buffalo and one in Rochester. In the Central region, there are two staff members in Syracuse. On Long Island, there are two staff members, and in New York City, there are two staff. There are currently three vacancies in the Radioactive Materials Program including the Chief, Radioactive Materials Section and two Associate Radiological Health Specialists. These positions were vacated during the review period. Additional vacancies also exist in the other sections of the Bureau of Environmental Radiation Protection. Since the last IMPEP, DOH has requested eight waivers to fill vacancies from the last review period. Four positions were approved and DOH hired two trainees, one experienced Radiation Health Specialist, and promoted one individual.

The DOH has a documented training plan for technical staff that is consistent with the requirements in the NRC's formal qualification and training procedure. The DOH also has on-the-job training to supplement course work so that individuals may broaden their work experience. All technical staff has at minimum, Bachelor's degrees in the sciences. Staff members are assigned increasingly complex duties as they progress through the qualification process. Licensing training and qualification is implemented by a mentoring program with a senior staff person leading the group and assigning licensing actions in accordance with their expertise and complexity of the action. Candidates for employment are required to pass a New York State Civil Service Examination and then apply for jobs under strict hiring guidelines consistent with the technical skills required of the position. This system appears rigorous and thorough in hiring competent staff. The review team concluded that the Program's training program is adequate to carry out its regulatory duties and noted that Program management is supportive of staff training opportunities.

The review team observed backlogs in licensing actions and inspection reporting as detailed in Sections 3.3 and 3.4 of the report. These backlogs have increased over the prior review period. The review team found no instances where the backlogs compromised health, safety and security, but the review team determined that insufficient staffing levels attributed to the increasing backlogs. Both the DOH and DEC have managed their chronic staffing shortages. Given the restricted hiring and waiver process for New York State agencies, coupled with a

lengthy training and qualification process for technical staff, the review team is concerned that any additional losses in staff could severely impact both DOH and DEC's performance.

Based on the review team's assessment of the technical staffing and training process for the NYC, and taking into consideration that NYC has new hires and other staff undergoing the training process, the review team determined that NYC should memorialize its training qualifications program. The review team made two recommendations: The review team recommended that the NYC update its training qualification program to be consistent with IMC 1248, "Formal Qualification Program for Federal and State Material and Environmental Management Programs," and apply this program to all technical staff currently going through the qualification process and all new staff that are hired. Second, the review team recommended that DOH and DEC should develop and implement a strategy to address current and future staffing vacancies in order to maintain the effectiveness and efficiency of the Program. The MRB discussed the recommendations and directed that the recommendations be combined and revised as follows: 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.

Based upon the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that New York's performance with respect to this indicator, Technical Staffing and Training, be found satisfactory, but needs improvement.

3.2 Status of Materials Inspection Program

The review team focused on five factors while reviewing this indicator: inspection frequency, overdue inspections, initial inspections of new licenses, timely dispatch of inspection findings to licensees, and performance of reciprocity inspections. The review team's evaluation was based on the Program's responses to the questionnaire relative to this indicator, data gathered from agency databases, examination of completed inspection casework, and interviews with management and staff for each agency.

The review team verified that New York's inspection frequencies for all types of radioactive material licenses are as frequent or more frequent as similar license types listed in Inspection Manual Chapter (IMC) 2800, "Materials Inspection Program." The review team confirmed that Increased Control inspections are conducted in conjunction with routine health and safety inspections.

The Program conducted 388 Priority 1, 2, and 3 inspections during the review period, based on the inspection frequencies established in IMC 2800. Only four of these inspections were conducted overdue by more than 25 percent of the inspection frequency prescribed in IMC 2800. In addition, the Program performed 108 initial inspections during the review period. Thirteen of the initial inspections were conducted overdue. As required by IMC 2800, initial inspections should be conducted within 12 months of license issuance. The team discussed the late initial inspections with the DOH inspection manager and determined the causes were due to lack of resources and travel restrictions for the DOH agency. The Program is cross training x-ray and materials inspectors to improve efficiency. Overall, the review team calculated that the Program performed 3.3 percent of its inspections overdue during the review period.

The review team evaluated the Program's timeliness in providing inspection findings to licensees. A review of the Program's database printouts indicated 79 out of 281 (28 percent) inspection reports were communicated to the licensees beyond the Program's goal of 30 days after the inspection. Nearly all (78) of the late inspections reports were observed in the DOH agency. The review team noted that the inspection reports issued beyond 30 days is an increase over the 20 percent of inspection reports issued beyond 30 days from the 2011 IMPEP review. The team discussed the late inspections reports with the inspection manager and determined the primary cause is attributed to late transmittal of compliance letters by the inspectors. In 2014, DOH implemented a monthly inspection reporting QA process that requires each inspector to submit a report listing the inspections performed and their status to materials management. The DOH also conducts a conference call every other week to discuss issues, unusual observations, and inspection findings.

During the review period, the Program granted 164 reciprocity permits, 34 of which were inspected. The review team determined that the Program met the NRC's criteria of inspecting 20 percent of candidate licensees operating under reciprocity in each year of the review period.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that New York's performance with respect to the indicator, Status of Materials Inspection Program, be found satisfactory.

3.3 Technical Quality of Inspections

The review team evaluated inspection reports, enforcement documentation, inspection field notes, and interviewed inspectors for 35 radioactive materials inspections (DOH-14, NYC-13, DEC-8), 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 institutions, medical institutions with written directives including unsealed radioiodine therapy, high dose rate remote afterloader therapy, permanent or temporary implant brachytherapy, and gamma knife therapy, medical institutions without written directives, portable gauge, industrial radiography, panoramic and self-shielded irradiators, nuclear pharmacy, and increased security controls for radioactive materials quantities of concern (Increased Controls). Appendix C lists the inspection casework files reviewed, with case-specific comments, as well as the results of the inspector accompaniments.

Based on the evaluation of casework, the review team noted that inspections covered all aspects of the licensee's radiation safety programs. The review 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 and safety 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. The Program issued to the licensee, either a letter indicating a clear inspection or a Notice of Violation (NOV), in letter format or as an attachment, which detailed the results of the inspection. When the Program issued an NOV, the licensee was required to provide a written response with corrective actions for the violations cited within 30 days. The review team also noted that reports and findings were reviewed by Program managers

The inspection procedures and techniques utilized by the Program were evaluated by the review team and were determined to be consistent with the inspection guidance outlined in IMC 2800. Specific guidance for the various license types/activities was also included in the respective agency procedures manuals and/or inspection checklists.

The review team determined that Program Increased Controls security inspection files were stored in a secure location. The inspection files were marked as containing sensitive information or withhold from the public. The review team noted that NYC agency does not mark its files folders as containing security-related information; however, inspection checklists for Increased Controls inspections, containing sensitive security information, are marked to be withheld from the public.

The review team accompanied 11 Program inspectors (DOH-6, NYC-3, and DEC-2) during the periods of July 16 to August 30, 2013. The inspectors were accompanied during health and safety inspections of medical institutions with the following uses: written directives including unsealed radioiodine therapy, high dose rate remote afterloader therapy, permanent or temporary implant brachytherapy, and gamma knife therapy. Other accompaniments included medical institutions without written directives, industrial radiography, Increased Controls, and disposal site and discharge permittees. The accompaniments are identified in Appendix C. During the accompaniments, the inspectors demonstrated appropriate inspection techniques, knowledge of the regulations, and conducted performance-based inspections. The inspectors were trained, well-prepared for the inspection, 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 and safety and security at the licensed facilities.

The review team noted that the Program has a policy of performing annual supervisory accompaniments of each inspector. Based on a review of records provide by each agency, the review team concluded that each inspector was accompanied by their supervisor at least once a year during the review period for the NYC and DEC agencies. The team noted that only 7 of 18 staff in the DOH program were accompanied in calendar year 2012, and 12 of 18 in calendar year 2013. The DOH self-identified this issue and DOH inspection management developed an accompaniment checklist, implemented discussing the accompaniment status at monthly supervisor meetings, and added inspector accompaniments to supervisor performance appraisal plans.

The review team noted that the Program has an ample supply of radiation survey instruments such as Geiger-Mueller (GM) meters, scintillation detectors, ion chambers, micro-R meters, and neutron detectors to support its inspection program. The Program also had portable multi-channel analyzers located in offices across the State which are used to analyze samples and wipes for alpha, beta, and gamma radiation. Instruments were calibrated at least annually, or as needed, by an outside vendor for instrument service and calibration and/or had an in-house capability to perform instrument calibrations. The Program uses databases to track each instrument, its current location, and next calibration date. The portable instruments used during the inspector accompaniments were operational and calibrated.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that the State of New York's performance with respect to the indicator, Technical Quality of Inspections, be found satisfactory.

3.4 Technical Quality of Licensing Actions

The review team examined completed licensing casework and interviewed license reviewers for 30 specific licensing actions. Licensing actions were reviewed for completeness, consistency, proper radioisotopes and quantities, qualifications of authorized users, adequacy of facilities and equipment, adherence to good health physics practices, financial assurance, operating and emergency procedures, appropriateness of license conditions, and overall technical quality. The casework was also reviewed for timeliness, use of appropriate deficiency letters and cover letters, reference to appropriate regulations, supporting documentation, consideration of enforcement history, pre-licensing visits, peer/supervisory review, and proper signatures.

The licensing casework was selected to provide a representative sample of licensing actions completed by the Program during the review period. Licensing actions selected for evaluation included 4 new licenses, 3 renewals, 1 decommissioning, 5 termination actions, 1 financial assurance, 12 amendments, and 4 permits. Files reviewed included a cross-section of license types: industrial radiography, medical diagnostic, medical therapy including permanent implant brachytherapy and stereotactic radiosurgery, nuclear pharmacy, and broad scope licensees. The casework sample represented work from thirteen license reviewers (DOH-7, NYC-2, DEC-4). The casework for the DEC permit reviewers is presented in Section 4.3.3. A list of the licensing casework evaluated with case-specific comments is provided in Appendix D.

Licensing actions are all tracked via Program databases. Licensing actions are received by the Program via mail, fax, or electronic mail. Licensing actions are assigned to a reviewer and subsequently updated in the Program's databases with the status and assignment of the licensing action. The licensing staff uses formal correspondence for technical notices or deficiencies. Routinely staff used electronic mail and phone calls to follow up with deficiency notices. Licenses are issued for a 10 year period under a timely renewal system. In NYC all license reviewers have signature authority for licensing actions. In DOH, the Radioactive Materials Section Chief has signature authority, and performs a technical and supervisory review on all licensing actions before issuance to the licensee. The DOH Bureau Director and Assistant Director also have signature authority for licensing actions.

The DOH enters licensing information into a primary database upon receipt, but requires the original documents from the licensee before a license action is approved. The licensing manager performs a preliminary review of the actions and assigns the licensing action in accordance with its complexity and modality. After the reviewer completes the review, the licensing manager performs a second technical and supervisory review on all licensing actions before issuance to the licensee. The administrative staff then process and dispatch signed licenses. At the time of the review there were 92 licensing actions (52 renewals and 40 amendments) waiting to be reviewed and signed by the licensing manager. There was a backlog of 29 amendments, and 187 renewal requests greater than one year at the time of the review. The review team noted that the number of renewal requests greater than one year is an increase over the 73 renewals in backlog noted during the 2011 IMPEP review. The DOH indicated that the licensing actions in backlog are triaged for priority. The review team noted the

administrative process creates a constraint on the issuance of licensing actions and increasing backlog is cause for concern.

The review team evaluated the Program's application of the financial assurance requirements. The review team verified that the proper financial assurance documentation was on file and that the information was appropriately protected.

The review team assessed the Program's implementation of pre-licensing guidance. The review team found that the casework reviewed, including four new licenses and two change of ownership requests, had the documentation to support a basis of confidence that the radioactive material would be used as requested.

The review team examined the Program's licensing practices in regard to requests for risk significant radioactive materials (i.e. Increased Controls and Fingerprinting Orders). The review team determined that the Program has a licensing procedure to identify new and amended licenses that should be subject to additional security measures. While the Program did not always document this process, the team did not identify any new or amended licenses that were missing the required license conditions and concluded that the Program added legally binding license conditions to the licenses that met the criteria for Increased Controls, including fingerprinting, as appropriate.

The review team found that the licensing actions from DOH were 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. Follow up requests were fully documented in the license files. Deficiency letters clearly stated regulatory positions, were used at the proper time, and identified substantive deficiencies in the licensees' documents. Terminated licensing actions were well documented, showing appropriate transfer and survey records. License reviewers use licensing guides and/or NRC NUREG-1556 series guidance documents, policies, checklists, and standard license conditions specific to the type of licensing actions to ensure consistency in licenses, and review enforcement history during the license renewal process.

The review team identified a few licensing actions from NYC which had incomplete evaluations of health and safety issues and a lack of technical quality (see Appendix D). The review team determined that NYC did not review the licensee's enforcement history during the license renewal process in two cases reviewed. Since there have been staff losses during the review period and considering the NYC's cross training initiative, the review team expressed to current staff that license renewals are opportunities for the staff to review the licensee's history and to evaluate the historical licensing and inspection documentation and to perform a quality assurance assessment of the license file. In one instance, a case for a terminated license was reviewed; however, the licensing case file did not contain any supporting documentation regarding the termination. In another case, applicable and current guidance were not adhered to for a license renewal request from a veterinary clinic. The review did not identify that the renewal application lacked all the radiation safety program procedures that should have been added as tie-down conditions. The review also identified two instances where licensing actions for NYC medical use licensees were authorized with incomplete documentation of the training and experience of a Radiation Safety Officer.

Since the last review, the team observed that NYC had implemented the use of the checklists from the NUREG -1556 series as well as the pre-licensing guidance. However, the review team found that license reviewers identified deficiencies in applications, but documentation of the resolution of addressed deficiencies was not found in the files. In addition, license reviewers accept the use of older and superseded licensing guidance by applicants. The review team discussed, with the NYC management and staff, the importance of fully documenting licensees' responses to license application deficiencies, noting that a complete and well documented licensing action assists the inspectors and demonstrates the steps taken by the license reviewer and the licensee, in order to issue an amended license.

The review team discussed the identified licensing deficiencies with NYC management and suggested additional technical licensing training for the NYC staff as an adjunct to any licensing training already received. The review team recommends that NYC (1) provide additional training to technical staff members regarding technical review of licensing actions, including training to ensure that the staff acquires increased familiarity with the regulations under New York City's equivalent to 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.

Based on the IMPEP evaluation criteria, the review team recommended that New York's performance with respect to the indicator, Technical Quality of Licensing Actions, be found satisfactory, but needs improvement. The IMPEP team based its recommendation on the observation that some licensing actions did not fully address health and safety concerns and there were repeated problems with thoroughness, completeness, consistency, technical quality, and adherence to existing guidance in licensing actions. The MRB acknowledged the IMPEP team's findings, yet concluded that New York's performance with respect to the indicator, Technical Quality of Licensing Actions, be found satisfactory. The MRB found that licensing issues presented by the IMPEP team were central to the NYC agency and not reflective of the entire Program; some of the licensing weaknesses observed during the onsite review were resolved during the MRB meeting and were attributed to staff training which the MRB believed would be resolved with the new performance recommendations made under the indicators, Technical Staffing and Training, and Technical Quality of Licensing Actions. The MRB also took into consideration that the NYC agency had made some improvements in licensing since the last review with the incorporation of pre-licensing guidance and use of the NUREG-1556 series licensing guidance.

3.5 Technical Quality of Incident and Allegation Activities

In evaluating the effectiveness of the Program's actions in responding to incidents and allegations, the review team examined the Program's responses to the questionnaire relative to this indicator, evaluated selected incidents reported for New York in the Nuclear Material Events Database (NMED) against those contained in the Program's files, and evaluated the casework for radioactive materials incidents. A list of the incident casework examined, with case-specific comments, may be found in Appendix E. The review team also evaluated the Program's response to allegations involving radioactive materials, including allegations transferred to New York by the NRC during the review period.

The review team examined the Program's implementation of its incident and allegation processes, including written procedures for handling allegations and incident response, file documentation, notification of incidents to the NRC Headquarters Operations Center, and the use of NMED software. When notification of an incident or an allegation is received, the Program's managers review the event information and determine the appropriate level of initial response.

The review team identified a total of 105 incidents that were reported to the Program during the review period. The review team identified 32 radioactive material incidents in NMED for New York (DOH-23, NYC-9, and DEC-0) which were reported during the review period. Nine of the reported incidents involved events which had occurred during the previous IMPEP review period and were not reported to the NRC as required. These incidents were subsequently reported to the NRC within two weeks of the end of the 2011 IMPEP review. The review team evaluated the casework for eight non-reportable incidents for New York and determined that the events were correctly categorized as non-reportable by the Program.

The 13 reported incidents selected for review included the following categories: lost/stolen radioactive material, potential overexposure, medical event, and/or damaged equipment. The review team determined that the Program's response to incidents was complete and comprehensive. Initial responses were prompt and well-coordinated, and the level of effort was commensurate with the health and safety significance. The Program dispatched inspectors for on-site investigations in seven of the cases reviewed and took suitable enforcement and follow-up actions. If the incident met the reporting thresholds, as established in the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-300 "Reporting Material Events," the State notified the NRC Headquarters Operations Center and entered the information into NMED, in a prompt manner with the exception of two incidents which were reported to NRC approximately 2 months late. In addition, the review team identified one medical event for the NYC agency which had not been reported to the NRC and appeared to meet the NRC reporting requirements. After discussions between the review team and the NYC Radioactive Materials Chief, the NYC agency indicated that NYC will review the event and report the information to NRC if it determines that the event meets the NRC reporting criteria.

In evaluating the effectiveness of the Program's response to allegations, the review team evaluated the completed casework for 12 allegations (DOH-6, NYC-5, and DEC-1) including 7 that the NRC transferred to New York during the review period. The review team concluded that the Program took prompt and appropriate actions in response to concerns raised. The review team noted that the Program documented the investigations of concerns and retained all necessary documentation to appropriately close the allegations. The Program notified the concerned individuals of the conclusion of its investigations. The review team determined that the Program adequately protected the identity of concerned individuals.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that New York's performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, be found 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 Evaluation Program, (3) Low-Level Radioactive Waste Disposal Program, and (4) Uranium Recovery Program. The NRC's Agreement with New York does not relinquish regulatory authority for a uranium recovery program; therefore, only three non-common performance indicators applied to this review.

4.1 Compatibility Requirements

4.1.1 Legislation

New York became an Agreement State on October 15, 1962. There are three separate agencies regulating ionizing radiation in the State of New York: NYC, DOH, and DEC. The 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(s). The NYC regulatory authority is delegated from DOH under Part 16 of the New York State Health Code which provides for delegation to local governments when covering greater than two million individuals. 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. Articles 1, 3, 17, 19, 29, and 37 of the Environmental Conservation Law provide 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 release of radioactive material to the environment, including the disposal of radioactive material, for all radioactive material. These regulations also cover the transportation and manifesting of Low-Level Radioactive Waste (LLRW) shipments into, within, and through New York State. The DEC's regulatory adoption process takes approximately two years to complete if there are no mitigating factors.

The agencies reported to the IMPEP team that no legislation affecting the radiation control programs was passed during the review period.

4.1.2 Program Elements Required for Compatibility

The review team evaluated New York's response to the questionnaire relative to this indicator, reviewed the status of regulations required to be adopted by the State under the Commission's adequacy and compatibility policy, and verified the adoption of regulations with data obtained from the State Regulation Status Sheet (SRS) that FSME maintains. Interviews were conducted with staff, and files were reviewed to confirm the use of license conditions in lieu of regulations. The review team found that New York provides the opportunity for public comment during the regulatory adoption process. The regulations are not subject to sunset provisions. Both the DOH and DEC regulatory adoption processes take approximately two years to complete if there are no mitigating factors. The NYC regulatory promulgation process takes approximately one year to complete depending on the complexity of the rule.

During the review period, the Program made progress in adopting overdue rules. There were 31 rules overdue for adoption (DOH–13, NYC–12, DEC–6) at the start of the review period. Appendix F summarizes the status of each NRC amendment (e.g., Regulation Amendment

Tracking System (RATS) identification number for each New York agency in the Program for the current IMPEP review period). The Program submitted 20 rule packages as final rules (13 regulation amendments, 3 legally binding license conditions, and 4 partial regulation amendments) to the NRC for a compatibility review. Current NRC policy requires that Agreement States adopt certain equivalent regulations or legally-binding requirements no later than 3 years after they become effective. All of the final rules were several years overdue for adoption at the time they were submitted. The NRC's compatibility review resulted in nine final rules (DOH–3, NYC–6, DEC–0) with comments that identified corrections needed in order to fully address the compatibility designations of these final rules. These comments need to be addressed by the Program in upcoming rulemaking activities to avoid gaps, conflicts, and duplications between New York's regulations and other regulatory programs nationally. Furthermore, from the SRS sheet for each agency, the IMPEP team observed there are 10 outstanding comment letters (DOH–5, NYC–4, DEC-1) from prior IMPEP review periods that still need to be addressed. At the time of this review, there were nine NRC amendments overdue for adoption, and six final regulations adopted by the Program with unresolved comments (Appendix F).

The 2006 and 2011 IMPEP review teams recommended that DOH, NYC, DEC develop and implement an action plan to adopt NRC regulations in accordance with the current NRC policy on adequacy and compatibility. The IMPEP team determined each agency had developed and implemented an action plan as directed by the recommendation. The NYC agency was able to clear its backlog, but due to an arduous rulemaking process for both DOH and DEC, these agencies were not able to clear their backlog of overdue regulations. The 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 recommendation. The MRB agreed; however, the MRB directed the team open a new recommendation to address the Program's continued backlog of overdue regulations in order to be compatible with the NRC's program. 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.

A complete list of regulation amendments can be found on the NRC website at the following address: http://nrc-stp.ornl.gov/rss_regamendents.html.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that New York's performance with respect to the indicator, Compatibility Requirements, be found unsatisfactory.

4.2 Sealed Source and Device Evaluation Program

The regulatory responsibility for the Sealed Source and Device (SS&D) Evaluation Program resides with DOH. In reviewing this indicator, the review team used three sub-elements to evaluate DOH's performance regarding the SSD Evaluation Program. These sub-elements were (1) Technical Staffing and Training, (2) Technical Quality of the Product Evaluation Program, and (3) Evaluation of Defects and Incidents Regarding SS&Ds.

In assessing the DOH SS&D evaluation activities, the review team examined the information provided in response to the IMPEP questionnaire and evaluated the SS&D registry sheets and supporting documents processed during the review period. The team also evaluated SS&D staff training, the use of guidance documents and procedures, and interviewed the staff and management involved in SS&D evaluations.

4.2.1. Technical Staffing and Training

The SS&D safety evaluation responsibilities are distributed between two reviewers. Both reviewers have attended the NRC SS&D Workshop. The DOH does not have a formal SS&D qualification program. The DOH has used on-the-job training for new reviewers with oversight from the qualified SS&D reviewers. The DOH also does not have a set number of reviews to be conducted by each individual prior to being considered qualified to independently perform reviews. This is primarily due to the infrequent SS&D applications or amendment requests.

The review team interviewed the reviewers and found them to be familiar with the SS&D safety evaluation process, as well as guidance and reference documents. The review team determined that the reviewers are qualified to review and sign SS&D registrations and that the DOH has a sufficient number of qualified reviewers to adequately handle the workload.

4.2.2 Technical Quality of the Product Evaluation Program

During the review period, DOH processed one SS&D action. The action was an ownership change and the addition of a new device. There were no inactivations of SS&D registrations or emerging technology evaluations processed during the review period. The review team evaluated the action processed during the review period. The SS&D certificate evaluated by the review team may be found in Appendix G.

The casework review indicated that staff followed NRC guidance during the review process to ensure that licensees submit the information necessary to support the product. The tie-down conditions on the certificates were stated clearly and are enforceable. Deficiency letters clearly stated regulatory positions and were used at the appropriate time. A concurrence review was performed by a second SS&D qualified reviewer.

In assessing the DOH's SS&D evaluation activities, the review team examined information contained in the questionnaire response and interviewed program staff and managers. The review team confirmed that the DOH follows the recommended guidance from the NRC SS&D Workshop, NUREG-1556 Series Guidance, applicable and pertinent American National Standards Institute (ANSI) standards and Military Standards, ISO-9001 and NY regulations, statutes, policies and procedures.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

The DOH was not aware of any defects or incidents involving sources and devices evaluated by the agency. The review team confirmed the lack of defects or incidents by a search of NMED and case files.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that New York's performance with respect to the indicator, Sealed Source and Device Evaluation Program, be found satisfactory.

4.3 Low-level Radioactive Waste Disposal Program

In reviewing this indicator, the review team used five sub-elements to evaluate New York's performance regarding the low-level radioactive waste (LLRW) disposal program. These sub-elements were (1) Technical Staffing and Training, (2) Status of LLRW Disposal Inspection, (3) Technical Quality of Inspections, (4) Technical Quality of Licensing Actions, and (5) Technical Quality of Incident and Allegation Activities. Performance of the Technical Staffing and Training and Technical Quality of Incident and Allegation Activities sub-elements are included in the discussions of the respective common performance indicators in sections 3.1 and 3.5.

New York has two former radioactive waste disposal sites: the State-licensed Disposal Area (SDA) on the Western New York Nuclear Service Center at West Valley (West Valley site), and the University of Cornell Radiation Disposal Site (RDS) in Lansing.

The SDA has been owned by the State of New York since its creation in 1963, and was operated by Nuclear Fuel Services from inception until they turned over control of the site to the New York State Energy Research and Development Authority (NYSERDA) in 1976. Disposal of radioactive wastes was originally authorized by DOH. In 1974, regulation of the site passed from DOH to the newly created DEC Radiation program. In 1975, DEC required the closure of the SDA due to uncontrolled leachate releases. At SDA, approximately 2.4 million cubic feet of waste received from various places such as nuclear power plants, government facilities, industries, waste brokers, decontamination companies, and the adjacent West Valley spent nuclear fuel reprocessing center were placed in 14 parallel disposal trenches capped with compacted native clay. With the exception of two smaller special purpose trenches, the trenches range from approximately 350 to nearly 700 feet in length and were approximately 33 feet wide and 20 feet deep. In addition to the trenches, the SDA contains three excavated lagoons (now filled) which were formerly used to manage water pumped from the trenches during operation.

Currently NYSERDA holds one Part 380 permit for the SDA from the DEC, which regulates monitoring and maintenance of the facility. The NYSERDA also holds a radioactive materials license from DOH for the SDA.

Disposal operations at the Cornell RDS occurred between 1956 and 1978. The trenches cover an area roughly 290 by 300 feet in size. Wastes were buried in narrow trenches 6 to 12 feet deep. LLRW radioactive laboratory wastes were disposed of at the RDS, including scintillation solvents such as paradioxane. Cornell currently operates under a broad scope radioactive materials license from DOH.

The RDS has been closed pursuant to a closure plan developed under a Consent Order issued by DEC. As part of the conditions of that Consent Order, Cornell operates a groundwater treatment system for the non-radioactive contaminants that collects and discharges minute amounts of radionuclides incidental to the non-radioactive treatment system. Those radioactive

discharges are regulated by a substantive Part 380 discharge permit. The DEC plans to issue a substantive Part 380 permit for ongoing monitoring and maintenance of the RDS before the Consent Order is terminated. When the Consent Order is terminated, any substantive permits issued under the Order will convert to stand-alone Part 380 permits.

4.3.1 Status of Low-level Radioactive Waste Disposal Inspection Program

The review team focused on three factors while reviewing this sub-element. These include the inspection frequency, overdue inspections or any deviations from the schedule, and timely dispatch of inspection findings to the permittee. The review team's evaluation was based on the DEC's questionnaire response relative to this indicator, examination of inspection casework, and interviews with management and staff.

The DEC has a one year inspection frequencies at West Valley and the Cornell sites. The review team confirmed that DEC inspected both sites annually. They also inspected the West Valley site annually for a special inspection which focused on obtaining environmental samples.

The DEC inspected the West Valley site four times during the review period of June 17, 2011, to March 28, 2013. West Valley was inspected November 2011, August 2012, May 2013, and November 2013. Cornell was inspected December 2011, November 2012, and January 2014. The December 2011 inspection was beyond the year plus 3 months mark as the last inspection was performed July 2010. The DEC has maintained the inspection frequency since this variance.

The review team determined that the inspection findings for the LLRW disposal program were typically communicated by formal correspondence to the permittee within 30 days following the inspection.

4.3.2 Technical Quality of Inspections

The review team assessed the quality of LLRW disposal program inspections by evaluating inspector performance during the accompaniments and reviewing inspection field notes, completed reports, inspection procedures and the staff's follow-up to previous inspection findings, as well as regulatory actions taken and annual supervisory accompaniments.

On August 13 and 14, 2013, one review team member accompanied two inspectors at the West Valley facility, as indicated in Appendix C. The inspectors were well prepared and thorough during their limited review of the LLRW disposal site. Under the LLRW permit, site security, environmental monitoring, and facility posting were observed. Inspectors conducted proper entrance and exit interviews with permittee managers and safety staff. Inspectors also conducted interviews with non-supervisory site personnel during the course of the inspection to ascertain perspective on permittee commitment to safety and training. During the accompaniments, the inspectors demonstrated appropriate performance-based inspection techniques and knowledge of the regulations. The inspections were adequate to assess the safety and radiological hazards at the LLRW disposal facility.

Based on an evaluation of five inspection files, the review team determined that the inspection reports were thorough, complete, consistent, and had sufficient documentation to ensure that

permittee's performance with respect to health, safety and security were acceptable. The team determined that the inspectors had not been documenting inspection information about most of the security requirements on the West Valley site. Through interview, it was determined that the inspector had observed security practices but had not documented these observations. The inspection findings were well-founded, supported by regulations and were appropriately documented. Based on interviews and review of documentation, the review team concluded that the inspectors reviewed the previous inspection report and discussed past inspection findings with other inspectors and the Radiological Sites Section Chief, in preparation for an inspection. Inspectors followed-up on previous inspection findings during the subsequent inspection.

Currently the Cornell inspection responsibility is assigned to an inspector from the Central Office. The Radiological Sites Section Chief is performing the inspections at the West Valley site until an individual in the Buffalo Office gains the experience at the site and then will perform the inspections. The individual is estimated to start independent inspections at the site in 2015 which will allow the Section Chief to perform inspector accompaniments at West Valley.

4.3.3 Technical Quality of Licensing Actions

The team reviewed six permit actions that had been completed during the review period including an amendment and a renewal. A listing of the permitting casework reviewed can be found in Appendix D.

The review team determined that the examined permitting actions were thorough, complete, consistent, and of acceptable technical quality. The license conditions, including the tie-down conditions, were clearly stated and supported by information contained in the file and enforceable. Many of the amendments were issued by a Letter Modification to the Permit.

The review team reviewed the 2012 Annual Report Cornell University Radiation Disposal Site – Chemical Disposal Site of March 2013, which is a requirement of the permit. The team reviewed the Quarterly Report for the State-licensed Disposal Area and the NYSERDA – Maintained Areas of the Western New York, Nuclear Service Center (WNYNSC) dated July 1-Sepember 30, 2013, and the NYSERDA SDA at West Valley 2011 Annual Report, both are required by the permit. The review team found that health and safety issues were properly addressed as part of the licensing action.

The review team concluded that the New York's permitting process was thorough, complete, consistent, and of acceptable quality.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that New York's performance with respect to the indicator, Low-level Radioactive Waste Disposal Program, be found satisfactory.

5.0 SUMMARY

As noted in Sections 3.0 and 4.0 above, New York's performance was found satisfactory for the indicators, Status of the Materials Inspection Program, Technical Quality of Inspections, Technical Quality of Licensing Actions, Technical Quality of Incidents and Allegations, SS&D

Evaluation Program, and LLRW Disposal Program. The indicator, Technical Staffing and Training, was found satisfactory, but needs improvement. The indicator, Compatibility Requirements was found unsatisfactory. These indicators remain unchanged from the previous IMPEP review. Progress has been made on the indicator, Compatibility Requirements, but the State has not yet addressed a number of outstanding NRC comments regarding earlier regulation packages. In addition, there are nine regulation amendments overdue for adoption by the Program. The indicator, Technical Quality of Incidents and Allegations Activities, improved from the last review. The IMPEP team recommended that Technical Quality of Licensing Actions be found satisfactory, but needs improvement. The MRB directed this indicator be found satisfactory since the issues were central to one agency and not reflective of overall program performance. Additionally, some of the examples of licensing weaknesses were resolved during the MRB meeting.

The review team made three recommendations regarding program performance in technical staffing, quality of licensing, and compatibility requirements. The review team determined that the recommendations from the 2011 IMPEP review, regarding reciprocity inspections, development of an action plan to adopt NRC regulations, and incident reporting and incident procedures should be closed.

Accordingly, the review team recommended, and the MRB agreed, that that the New York Agreement State Program is adequate to protect public health and safety and is not compatible with the NRC's program. Considering the progress the Program made under the indicator Technical Quality of Incident and Allegations Activities, where performance was improved from unsatisfactory to satisfactory during the review period, and the progress made in adopting several overdue rules, the review team recommended, and the MRB agreed, that the period of Heightened Oversight be discontinued and a period of Monitoring be initiated. The review team recommended, and the MRB agreed, that the next IMPEP review take place in approximately 4 years.

RECOMMENDATIONS

1. 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)

2. The review team recommends that NYC (1) provide additional training to technical staff members regarding technical review of licensing actions, including training to ensure that the staff acquires increased familiarity with the regulations under NYC's equivalent to 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)

3. 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)

LIST OF APPENDICES

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

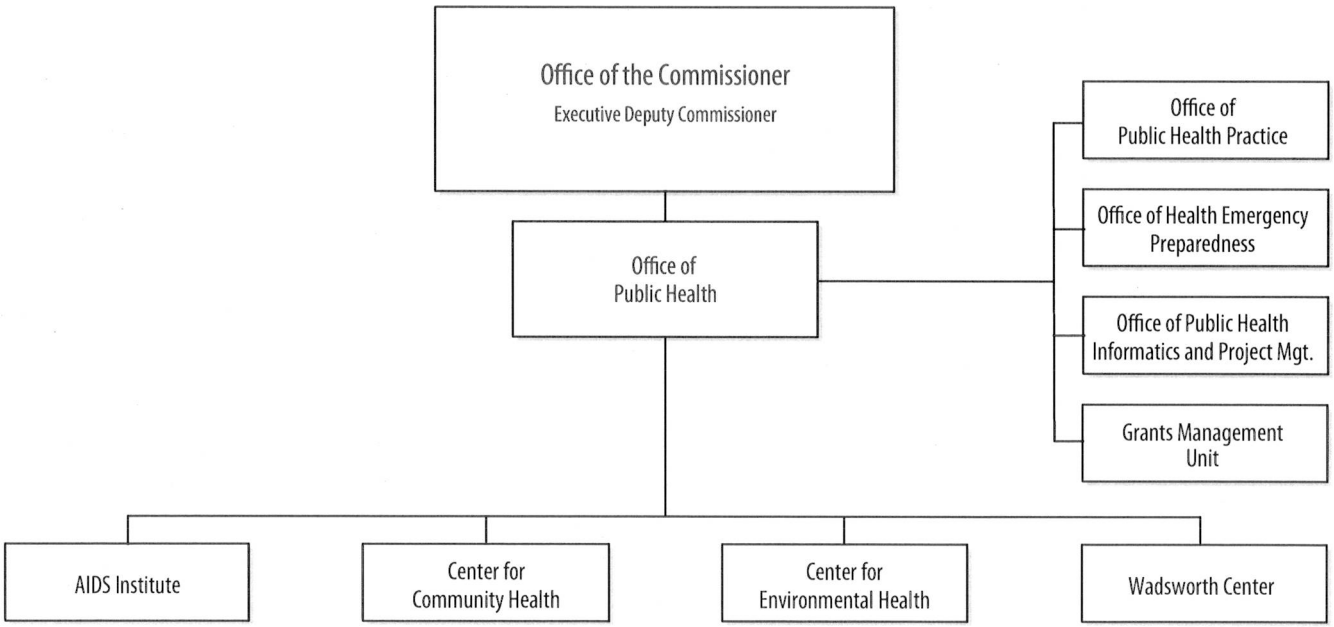
Name	**Area of Responsibility**
Lisa Dimmick, FSME	Team Leader, Compatibility (DOH, DEC, NYC)
Donna Janda, RI	Technical Quality Incidents and Allegations (DOH, DEC, NYC) Inspector Accompaniments (DEC)
Ken Lambert, RIII	Technical Quality of Inspection Program (DOH and NYC)
Lizette Roldan-Otero, RIV	Technical Quality of Licensing (DOH and NYC)
Joe O'Hara, FSME	Staffing and Training (DOH, DEC, NYC)
Jerry Bai, State of Florida	Status of the Materials Inspection Program (DOH & NYC)
Maria-Arribas-Colon, FSME	Sealed Source & Device Program, (DOH)
Dennis Lawyer, RI	Low Level Waste Program (DEC)
Anthony Gaines, RIV	Inspector Accompaniments (DOH, NYC)

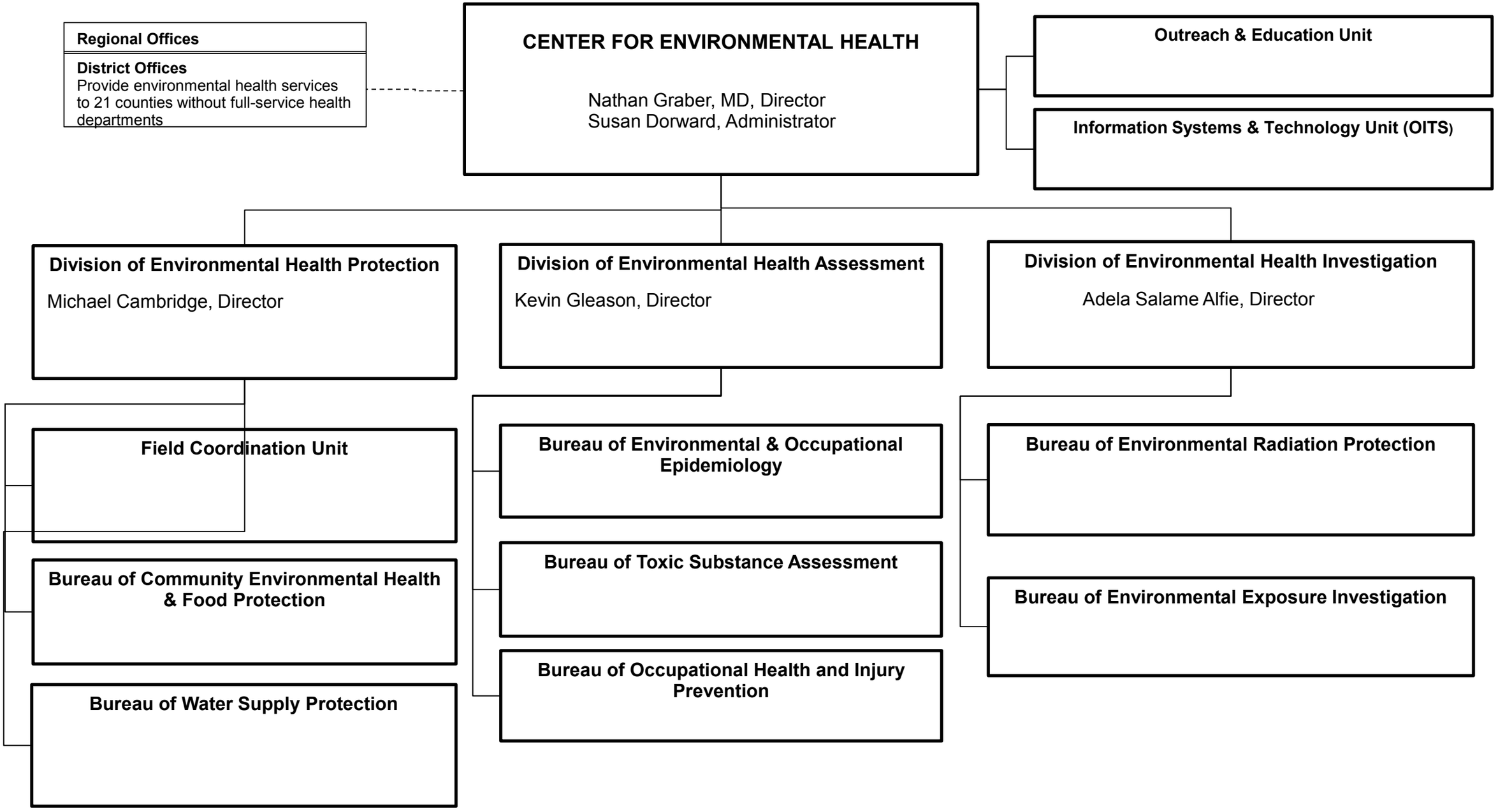
APPENDIX B

NEW YORK ORGANIZATION CHARTS

ADAMS ACCESSION NO(S).:
ML14119A153 – New York DOH
ML14119A158 – New York City DHMH
ML14070A270 – New York DEC

Organization of Public Health Programs
New York State Department of Health




Regional Offices
District Offices
Provide environmental health services to 21 counties without full-service health departments
CENTER FOR ENVIRONMENTAL HEALTH
Nathan Graber, MD, Director
Susan Dorward, Administrator
Outreach & Education Unit
Information Systems & Technology Unit (OITS)
Division of Environmental Health Protection
Michael Cambridge, Director
Division of Environmental Health Assessment
Kevin Gleason, Director
Division of Environmental Health Investigation
Adela Salame Alfie, Director
Field Coordination Unit
Bureau of Community Environmental Health & Food Protection
Bureau of Water Supply Protection
Bureau of Environmental & Occupational Epidemiology
Bureau of Toxic Substance Assessment
Bureau of Occupational Health and Injury Prevention
Bureau of Environmental Radiation Protection
Bureau of Environmental Exposure Investigation

Bureau of Environmental Radiation Protection

Office of the Director

Name	Title
Stephen Gavitt	Director
Robert Dansereau	Assistant Director
Ilham Almahamid	Research Scientist
Martha Harvey	Administrative Officer
Barbara Fabbie	Secretary
Janaki Krishnamoorthy	Associate Radiological Health Specialist
Lynn Schriner	Secretary

Radiation Equipment/ X-ray Section

Name	Title
Alex Damiani	Chief
Michael Dreibelbis	Associate Radiological Health Specialist
Gerald O'Connor	Associate Radiological Health Specialist
Dennis Ludlum	Associate Radiological Health Specialist
David O'Hehir	Associate Radiological Health Specialist
Mary Furan	Senior Radiological Health Specialist
Trevor Thayer	Research Scientist
Cynthia Stephenson	Public Health Rep
Misako Dreibelbis	Clerk
Jacklyn Veiga	Clerk

X-ray facility registration & inspection; Radiologic Technologist Licensing

Environmental Radon/ Emergency Response Section

Name	Title
Cynthia Costello	Chief
Jerry Collins	Associate Radiological Health Specialist
Nicole Frisino-Napoli	Secretary

Radon Outreach/Radiological Emergency Response/Environmental Monitoring

Radioactive Materials Section

Name	Title
Daniel Samson	Acting Chief
Charles Burns	Associate Radiological Health Specialist
Michael Harmon	Associate Radiological Health Specialist
Michael Soucie	Associate Radiological Health Specialist
Desmond Gordon	Associate Radiophysicist
Mohammad Chaudhry	Associate Radiophysicist
Marc Sullivan	Senior Radiological Health Specialist
Karen Stankus	KBS 2/9

Radioactive material licensing and inspection

Inspection and Enforcement Section

Name	Title
Robert Snyder	Chief
Sara Koch (WRO)	Associate Radiological Health Specialist
Vidya Goyal (CNYRO)	Associate Radiological Health Specialist
Michele Kehoe	Associate Radiological Health Specialist
Brajesh Kothari (MARO)	Associate Radiophysicist
Andrew Bass (MARO)	Associate Radiological Health Specialist
Nelson Warren (MARO)	Associate Radiological Health Specialist
Mai Tran (WRO)	Associate Radiological Health Specialist
William Kelleher (CNYRO)	Associate Radiological Health Specialist
Sam Plesac (WRO)	Senior Radiological Health Specialist
William Hom (MARO)	Senior Radiological Health Specialist

X-ray and radioactive material facility inspections/incident investigations

Board of Health
Fund for the Public Health in New York
Advisory Boards:
-Health and Mental Hygiene Advisory Council
-Community Services Board/Mental Hygiene Advisory Board
-Federation for Mental Health, Mental Retardation and Alcoholism Services
-Local Early Intervention Coordinating Council
-HIV/AIDS Community Planning
-NYC Commission on HIV/AIDS

NYC Department of Health and Mental Hygiene
Table of Organization

Mary Bassett, MD, MPH
Commissioner

Barbara Sampson, MD, PhD
Acting Chief Medical Examiner

Community Services Board
and
Federation for Mental Health,
Mental Retardation and
Alcoholism Services

Emiko Otsubo, MSW
Chief of Staff

Patsy Yang, DrPH
Executive Deputy Commissioner &
Chief Operating Officer

Thomas Merrill, JD
General Counsel

Employment Law Unit
Institutional Review Board
Legal Affairs

Alcohol & Drug Use, Prevention, Care & Treatment
Children, Youth and Families
Clinical Affairs
Developmental Disabilities
Early Intervention
Mental Health
MH Administration

Adam Karpati, MD, MPH
Executive Deputy Commissioner
Mental Hygiene

Communicable Diseases
HIV/AIDS
Immunization
Public Health Laboratory
STD Prevention & Control
Tuberculosis Control

Jay Varma, MD
Deputy Commissioner
Disease Control

Child Care
Environmental Disease Prevention
Environmental Emergency Preparedness & Response
EH Division Management
Environmental Sciences & Engineering
Environmental Surveillance & Policy
Food Safety and Community Sanitation
Veterinary & Pest Control Services

Daniel Kass, MSPH
Deputy Commissioner
Environmental Health

EPI Division Management
Epidemiology Services
Provider Education Program
Public Health Training
Vital Statistics
World Trade Center Health Registry

Carolyn Greene, MD
Deputy Commissioner
Epidemiology

Correctional Health Services
HCAI Administration
HCAI IT Initiatives
Primary Care Access and Planning
Primary Care Information Project

Amanda Parsons, MD, MBA
Deputy Commissioner
Health Care Access and Improvement

Chronic Disease Prevention and Tobacco Control
District Public Health Offices
Maternal, Infant and Reproductive Health
School Health

Susan Kansagra, MD, MBA
Deputy Commissioner
Health Promotion and Disease Prevention

Communications
Intergovernmental
OEA Administration
Public Affairs
TCNY

Sam Miller, MPA
Associate Commissioner
External Affairs

Administration and Operations

Julie Friesen, MS
Deputy Commissioner
Administration

Clinical Quality Management & Improvement/Employee Health
Facilities Planning & Administrative Services
Human Resources & Labor Relations
Occupational Safety & Health
Operations

Sandy Rozza
Deputy Commissioner
Finance

Agency Chief Contracting Officer
Budget & Revenue
Controller

Jian Liu, MS
Deputy Commissioner
Chief Information Officer

Application Development & Database Administration
IT Administration
IT Solutions & Delivery
IT Security & Business Continuity
Network Technology & Telecommunications Services
Public Health Informatics & Data Services

Marisa Raphael, MPH
Deputy Commissioner
Emerg. Preparedness & Response

Agency Preparedness and Response
Grant Management & Administration
Healthcare System Readiness
Policy, Community Resilience and Response

Sara Packman, CPA, MBA
Assistant Commissioner
Audit Services

Audit Services
Medicaid Compliance Program

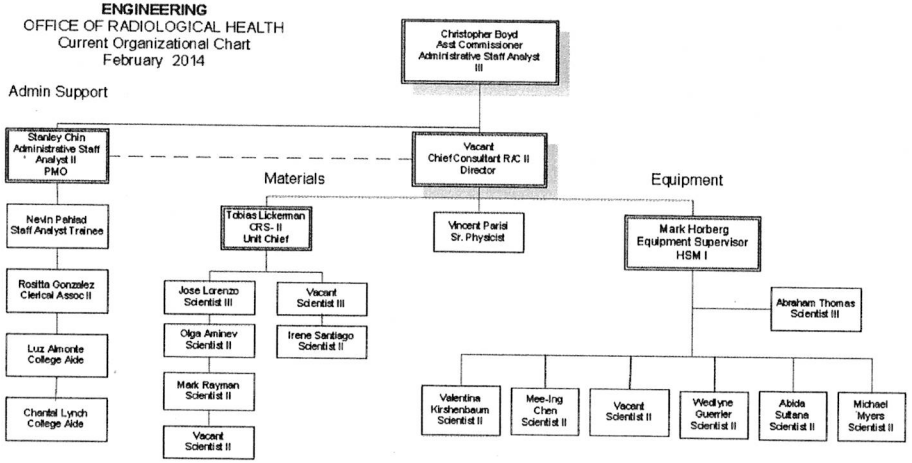
Linda Adamson, MPP
Executive Director
Planning and Program Analysis

Measurement Evaluation
Data Use and Strategic Analysis

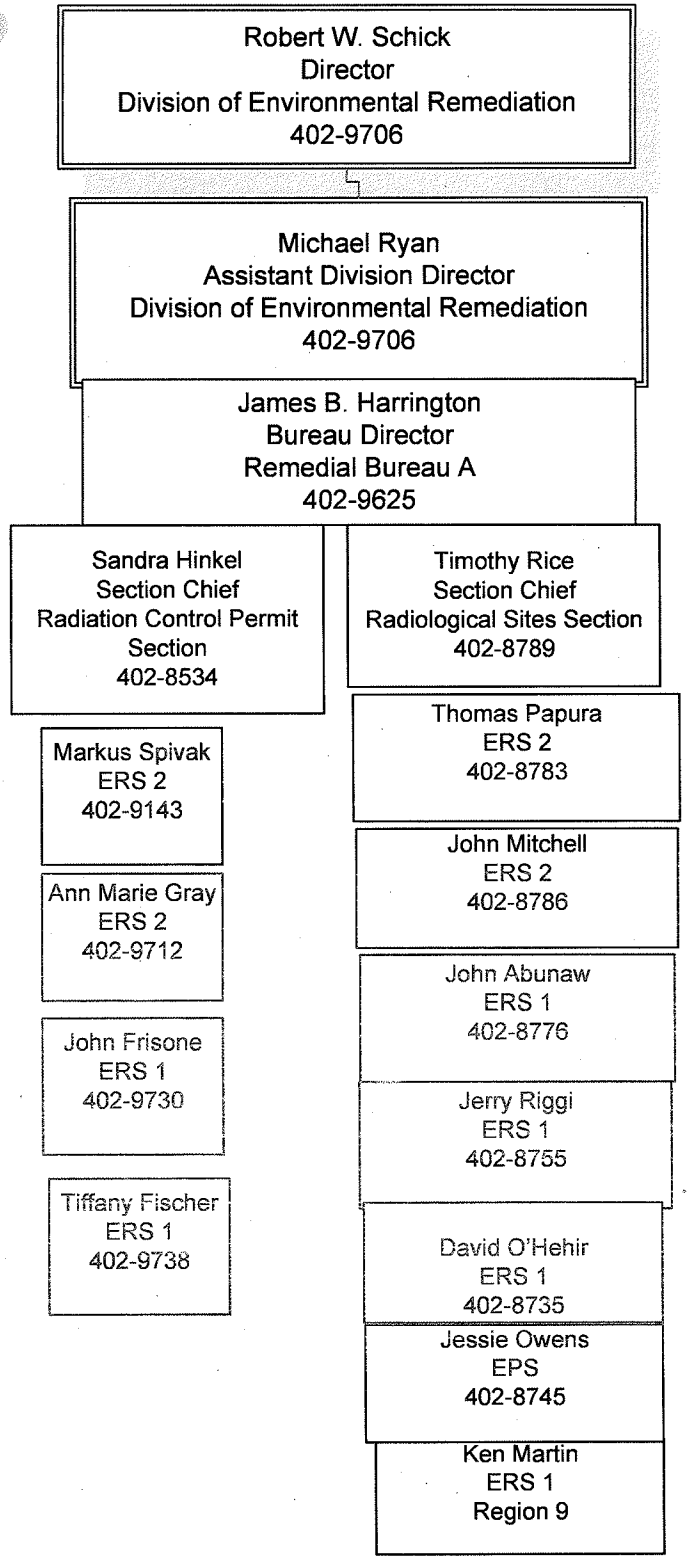
February 2014

BUREAU OF ENVIRONMENTAL SCIENCES & ENGINEERING

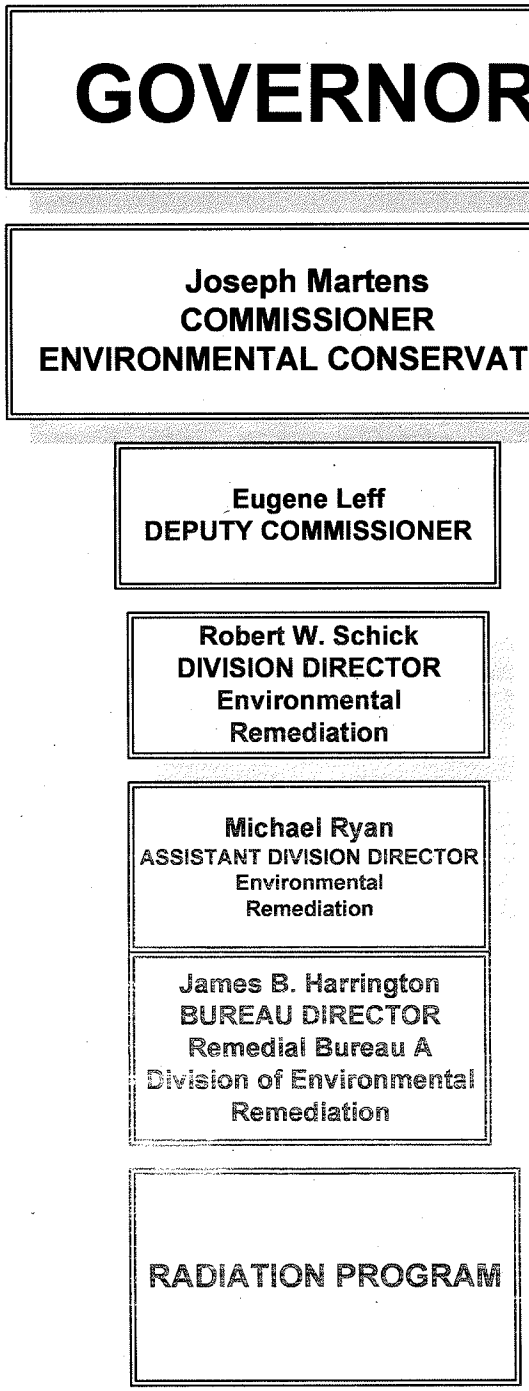
OFFICE OF RADIOLOGICAL HEALTH
Current Organizational Chart
February 2014



NYS DEC RADIATION PROGRAM STAFF



4/15/2013



Updated on 08/26/13

APPENDIX C

INSPECTION CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS

New York City Department of Health and Mental Hygiene

File No.: 1
Licensee: Rockefeller University — License No.: 74-2989-02
Inspection Type: Routine, unannounced — Priority: 2
Inspection Date: 8/20/12 — Inspector: JL

Comment: The licensee's response to the violations was not in the file.

File No.: 2
Licensee: Rentrop, K. Peter - M.D. — License No.: 91-3262-01
Inspection Type: Routine, unannounced — Priority: 5
Inspection Date: 3/14/13 — Inspector: MR

File No.: 3
Licensee: Bergmann, Steven - M.D. — License No.: 91-3379-01
Inspection Type: Routine, unannounced — Priority: 5
Inspection Date: 1/4/13 — Inspector: JL

File No.: 4
Licensee: Memorial Sloan Kettering — License No.: 75-2968-01
Inspection Type: Routine, unannounced — Priority: 2
Inspection Date: 6/19/13 — Inspector: OA

File No.: 5
Licensee: Columbia Presbyterian Medical Center — License No.: 75-2878-01
Inspection Type: Routine, unannounced — Priority: 2
Inspection Date: 8/2/11 — Inspector: EC

Comment: Inspection documentation issued to the licensee 48 days after the inspection.

File No.: 6
Licensee: New York Presbyterian Hospital — License No.: 75-2960-04
Inspection Type: Routine, unannounced — Priority: 2
Inspection Date: 7/16/12 — Inspector: JL

File No.: 7
Licensee: Columbia Presbyterian Medical Center — License No.: 93-2878-05
Inspection Type: Routine, unannounced — Priority: 2
Inspection Date: 8/29/12 — Inspector: OA

File No.: 8
Licensee: NYCHCC North Central Bronx Hospital — License No.: 91-3211-01
Inspection Type: Routine, unannounced — Priority: 3
Inspection Date: 2/21/12 — Inspector: MR

File No.: 9
Licensee: Stevens, Ronald – M.D. — License No.: 91-3467-01
Inspection Type: Routine, unannounced — Priority: 5
Inspection Date: 1/10/14 — Inspector: JL

File No.: 10
Licensee: University Hospital of Brooklyn at LICH — License No.: 91-3501-01
Inspection Type: Routine, unannounced — Priority: 3
Inspection Date: 8/18/11 — Inspector: EC

File No.: 11
Licensee: Wyckoff Heights Hospital — License No.: 91-2846-01
Inspection Type: Routine, unannounced — Priority: 3
Inspection Date: 5/2/11 — Inspector: JH

File No.: 12
Licensee: Rockefeller University — License No.: 75-2989-01
Inspection Type: Increased Controls, unannounced — Priority: 2
Inspection Date: 10/11/12 — Inspector: MR

File No.: 13
Licensee: Memorial Sloan-Kettering Cancer Research Center — License No.: 74-2968-01 and 02
Inspection Type: Increased Controls, unannounced — Priority: 2/3
Inspection Date: 8/13/13 and 9/18/13 — Inspector: MR

New York State Department of Health

File No.: 14
Licensee: North Shore University Hospital — License No.: 1016
Inspection Type: Routine, unannounced — Priority: 2
Inspection Date: 12/16-18/13 — Inspector: CB

File No.: 15
Licensee: Columbia University — License No.: 537-2
Inspection Type: Routine, announced — Priority: 3
Inspection Date: 4/17/13 — Inspector: CB

File No.: 16
Licensee: Entec Consultants, Inc. — License No.: C2630
Inspection Type: Routine, unannounced — Priority: 1
Inspection Date: 1/17 and 23 /13 — Inspector: AC

File No.: 17
Licensee: Corning Hospital — License No.: 421

Inspection Type: Routine, unannounced — Priority: 2
Inspection Date: 12/7/11 — Inspector: SK

Comment: Inspection documentation issued to the licensee 179 days after the inspection.

File No.: 18
Licensee: Westchester Medical Center — License No.: 586
Inspection Type: Routine, unannounced — Priority: 2
Inspection Date: 11/21/13 — Inspector: JK

File No.: 19
Licensee: Steris Isomedix Services, Inc. — License No.: C2583
Inspection Type: Routine, unannounced — Priority: 1
Inspection Date: 12/16/11 — Inspector: BK

Comment: Letter to licensee and inspection checklist were not in the file.

File No.: 20
Licensee: Cardinal Health — License No.: C2364
Inspection Type: Routine, unannounced — Priority: 2
Inspection Date: 12/13/13 — Inspector: DG

Comment: Inspection documentation issued to the licensee 63 days after the inspection.

File No.: 21
Licensee: Rolex Watch USA, Inc. — License No.: C0263
Inspection Type: Routine, announced — Priority: 2
Inspection Date: 10/11/12 — Inspector: BK

File No.: 22
Licensee: Dobbs Ferry Pavilion — License No.: 2960
Inspection Type: Routine, unannounced — Priority: 1
Inspection Date: 11/30/12 — Inspector: DS

File No.: 23
Licensee: North Shore University Hospital at Plainview — License No.: 1153
Inspection Type: Routine, unannounced — Priority: 3
Inspection Date: 11/28/12 — Inspector: MK

File No.: 24
Licensee: Eastern Testing & Inspection, Inc. License No.: C2438
Inspection Type: Routine, unannounced Priority: 1
Inspection Date: 12/15 and 22/11 Inspector: AB

Comment: Inspection documentation issued to the licensee 34 days after the inspection.

File No.: 25
Licensee: NYSERDA, West Valley License No.: C0382
Inspection Type: Routine, announced Priority: 5
Inspection Date: 06/15/11 Inspector: SK

Comment: Inspection documentation issued to the licensee 56 days after the inspection.

File No.: 26
Licensee: A.M.P. Radiation Oncology License No.: 5556
Inspection Type: Initial, announced Priority: 5
Inspection Date: 08/14/13 Inspector: CB

File No.: 27
Licensee: NCM USA Bronx, LLC License No.: C5496
Inspection Type: Reactive, announced Priority: 2
Inspection Date: 08/12 and 15/13 Inspector: MS

New York State Department of Environmental Conservation

File No.: 28
Permitee: New York State Energy Research and Development Authority (NYSERDA) Permit No.: 9-0422-00011/00011
Inspection Type: Special and Announced Priority: 1
Inspection Date: 5/21-22/13 Inspector: DO

File No.: 29
Permitee: NYSERDA Permit No.: 9-0422-00011/00011
Inspection Type: Routine and Announced Priority: 1
Inspection Date: 8/13-14/13 Inspector: DO

File No.: 30
Permitee: NYSERDA Permit No.: 9-0422-00011/00011
Inspection Type: Special and Announced Priority: 1
Inspection Date: 11/20/13 Inspector: TR

File No.: 31
Permitee: Cornell University Permit No.: NA
Inspection Type: Routine and Announced Priority: 1
Inspection Date: 12/22/11 Inspector: DO

File No.: 32
Permitee: Cornell University Permit No.: NA

Inspection Type: Routine and Announced — Priority: 1
Inspection Date: 10/27-28/12 — Inspector: DO

File No.: 33
Permitee: Cardinal Health Nuclear Pharmacy Services — Permit No.: 1-282402219/00001
Inspection Type: Routine and Unannounced — Priority: 3
Inspection Date: 4/20/12 — Inspector: AG

File No.: 34
Permitee: SUNY at Buffalo — Permit No.: 9-1402-00680/00029
Inspection Type: Routine and Unannounced — Priority: 3
Inspection Date: 8/28-29/13 — Inspector: AG

File No.: 35
Permitee: NRD LLC — Permit No.: 9-1446-0018/00001
Inspection Type: Routine and Announced — Priority: 3
Inspection Date: 12/18-19/13 — Inspector: JF

INSPECTOR ACCOMPANIMENTS

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

New York State Department of Health

Accompaniment No.: 1
Licensee: Adirondack Diagnostic Imaging — License No.: 3290
Inspection Type: Routine, Unannounced — Priority: 3
Inspection Date: 8/19/13 — Inspector: DS

Accompaniment No.: 2
Licensee: St. Peter's Health Partners, Medical Associates, P.C. — License No.: 5565
Inspection Type: Routine, Unannounced — Priority: 5
Inspection Date: 8/20/13 — Inspector: RS

Accompaniment No.: 3
Licensee: Cardiology Consultants of Rockland, P.C. — License No.: 3287
Inspection Type: Routine, Unannounced — Priority: 5
Inspection Date: 8/21/13 — Inspector: AC

Accompaniment No.: 4
Licensee: Able Testing and Inspection, Inc. — License No.: C2555
Inspection Type: Routine, Announced — Priority: 1
Inspection Date: 8/22/13 — Inspector: DG

Accompaniment No.: 5
Licensee: St. Peter's Hospital — License No.: 1073-2
Inspection Type: Routine, Unannounced — Priority: 2
Inspection Date: 8/23/13 — Inspector: CB

Accompaniment No.: 6
Licensee: Island Diagnostic Imaging Associates, PLLC — License No.: 5114
Inspection Type: Routine, Unannounced — Priority: 5
Inspection Date: 08/27/13 — Inspector: MK

New York City Department of Health and Mental Hygiene

Accompaniment No.: 7
Licensee: The New York Community Hospital — License No.: 91-2991-01
Inspection Type: Routine, Unannounced — Priority: 3
Inspection Date: 08/28/13 — Inspector: MR

Accompaniment No.: 8
Licensee: Columbia-Presbyterian Medical Center — License No.: 93-2878-05
Inspection Type: Routine, Unannounced — Priority: 2
Inspection Date: 08/29/13 — Inspector: OA

Accompaniment No.: 9
Licensee: Staten Island University Hospital — License No.: 91-2840-01
Inspection Type: Routine, Unannounced — Priority: 2
Inspection Date: 08/30/13 — Inspector: JL

New York State Department of Environmental Conservation

Accompaniment No.: 10
Licensee: University of Rochester Lab for Laser Energetics — Permit No.: 8-2699-00059/00003
Inspection Type: Routine, Announced — Priority: 3
Inspection Date: 7/16/13 — Inspector: TF

Accompaniment No.: 11
Licensee: NYSERDA SDA — Permit No.: 9-0422-00011/00011
Inspection Type: Routine, Announced — Priority: 1
Inspection Date: 8/13 and 14/13 — Inspector: DO

APPENDIX D

LICENSE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1
Licensee: Daniel Amen, M.D./Amen Clinics Inc. License No.: 91-3475-01
Type of Action: New Amendment No.: NA
Date Issued: 09/27/12 License Reviewer: IS/DH

File No.: 2
Licensee: Daniel Amen, M.D./Amen Clinics Inc. License No: 91-3475-01
Type of Action: Amendment Amendment No.: 01
Date Issued: License Reviewer: IS

Comment: The reviewer improperly added an individual as a RSO to the license. The proposed RSO did not meet the qualification requirements in accordance with 175.103(j)(5), and 175.103(j)(1), respectively.

File No.: 3
Licensee: Hari Ashamalla, M.D./All City Ambulatory Surgery Ctr. License No.: 91-3402-01
Type of Action: Termination Amendment No.: 03
Date Issued: 02/11/14 License Reviewer: IS

File No.: 4
Licensee: Columbia Presbyterian Medical Center License No.: 75-2878-01
Type of Action: Amendment Amendment No.: 38
Date Issued: 03/07/14 License Reviewer: IS

File No.: 5
Licensee: Van-Hong Nguyen, M.D./Marathon Medical, PC License No.: 91-3457-01
Type of Action: Termination/Change of Ownership Amendment No.: 1
Date Issued: 01/15/14 License Reviewer: IS

File No.: 6
Licensee: Van-Hong Nguyen, M.D./ License No.: 91-5399-01
Mount Sinai Marathon Medical, PC
Type of Action: New/Change of Ownership Amendment No.: NA
Date Issued: 01/15/14 License Reviewer: IS

File No.: 7
Licensee: Memorial Sloan Kettering License No.: 75-2968-01
Type of Action: Amendment Amendment No.: 17
Date Issued: 08/16/13 License Reviewer: DH

File No.: 8
Licensee: Montefiore Medical Center License No.: 75-2885-01
Type of Action: Amendment Amendment No.: 38 & 39
Date Issued: in 2012 License Reviewer: DH

File No.: 9
Licensee: Montefiore Medical Center License No.: 75-2885-01
Type of Action: Amendment Amendment No.: 45
Date Issued: 03/12/14 License Reviewer: IS

File No.: 10
Licensee: NY Presbyterian Hospital/ License No.: 93-2878-05
Columbia University Med Center
Type of Action: Amendment Amendment No.: 15
Date Issued: 03/03/14 License Reviewer: IS

Comment: The reviewer improperly added an individual as an RSO to the license. There was no supporting documentation to show the RSO had received or was going to receive training regarding the radiation safety aspects of the gamma knife.

File No.: 11
Licensee: Bhumi, Sarat License No.: 91-3342-01
Type of Action: Renewal Amendment No.: 3
Date Issued: 07/03/12 License Reviewer: DH

Comment: Review did not demonstrate a thorough analysis of the licensee's inspection and enforcement history. The license reviewer did not adhere to the applicable and current guidance for this review.

File No.: 12
Licensee: Bhumi, Sarat License No.: 91-3342-01
Type of Action: Termination Amendment No.: 4
Date Issued: License Reviewer: DH

Comment: Team member could not evaluate the termination because the file lacked the supporting documentation for the termination request.

File No.: 13
Licensee: The Animal Medical Center License No.: 52-2899-02
Type of Action: Renewal Amendment No.: 10
Date Issued: 01/15/14 License Reviewer: IS

Comment: The license reviewer did not adhere to the applicable and current guidance for this review. Review did not demonstrate a thorough analysis of the licensee's inspection and enforcement history. The review was not thorough, complete, clear, and of poor technical quality.

File No.: 14
Licensee: Sheehan Memorial Hospital License No.: 1847
Type of Action: Termination Amendment No.: 18
Date Issued: 06/25/12 License Reviewer: MH

File No.: 15
Licensee: Adelphi University License No.: 45
Type of Action: Renewal Amendment No.: 22
Date Issued: 02/09/12 License Reviewer: AC

File No.: 16
Licensee: Syracuse University License No.: 40
Type of Action: Amendment/Decommission Amendment No.: 29
Date Issued: 02/20/13 License Reviewer: DS

File No.: 17
Licensee: Cardinal Health License No.: C2613
Type of Action: Termination Amendment No.: 16
Date Issued: 09/03/13 License Reviewer: MS

File No.: 18
Licensee: TEI Analytical Services, Inc. License No.: C5547
Type of Action: New Amendment No.:
Date Issued: 02/21/13 License Reviewer: DG

File No.: 19
Licensee: Windsong Radiology Group, P.C. License No.: 3051
Type of Action: Amendment Amendment No.: 37
Date Issued: 03/08/13 License Reviewer: JK

File No.: 20
Licensee: WIndsong Radiology Group, P.C. License No.: 3051
Type of Action: Amendment Amendment No.: 35
Date Issued: License Reviewer: JK

File No.: 21
Licensee: AMP Radiation Oncology License No.: 5584
Type of Action: New Amendment No.:
Date Issued: 7/25/13 License Reviewer: RD

File No.: 22
Licensee: AMP Radiation Oncology License No.: 5584
Type of Action: Amendment Amendment No.: 01
Date Issued: 9/10/13 License Reviewer: RD

File No.: 23
Licensee: AMP Radiation Oncology License No.: 5584
Type of Action: Amendment Amendment No.: 02
Date Issued: 12/26/13 License Reviewer: DS

File No.: 24
Licensee: Northern Westchester Hospital Center License No.: 585
Type of Action: Amendment Amendment No.: 81
Date Issued: 02/26/14 License Reviewer: JK

Comment: The preceptor dates were not correct. The NRC Form had dates that were longer than the time the preceptor was at the hospital. Clarification on the dates should have been requested.

File No.: 25
Licensee: Mount Sinai North Shore Medical Group License No.: 5539
Type of Action: Amendment Amendment No.: 4
Date Issued: 03/14/14 License Reviewer: MH

File No.: 26
Licensee: Steris Isomedix Services, Inc. License No.: C2583
Type of Action: Financial Assurance Amendment No.: 4
Date Issued: 03/22/12 License Reviewer: MH

File No.: 27
Permitee: NYSERDA Permit No.: 9-0422-00011/00011
Type of Action: Amendment Amendment No.: NA
Date Issued: Letter of Modification to the Permit written on 10/11/2013, 12/14/2013, 12/19/2013 and 1/13/2014. Permit Reviewer: DO

File No.: 28
Permitee: Cornell University Permit No: NA (Under Consent Order)
Type of Action: Renewal Amendment No.: NA
Date Issued: Currently Pending Issue Permit Reviewer: DO

File No.: 29
Permitee: NRD LLC Permit No.: 9-1446-00018
Type of Action: Renewal Amendment No.: NA
Date Issued: 5/23/2013 Permit Reviewer: JF

File No.: 30
Permitee: SUNY at Buffalo Permit No.: 9-1402-00680/00029
Type of Action: Amendment Amendment No.: NA
Date Issued: 11/18/2013 Permit Reviewer: AG

File No.: 31
Permitee: Cardinal Health
Permit No.: 1-2824-02719/00001
Type of Action: Renewal
Amendment No.: NA
Date Issued: 10/1/12013
Permit Reviewer: AG

File No.: 32
Permitee: University of Rochester
Permit No.: 8-2699-00059/00003
Type of Action: Renewal
Amendment No.: NA
Date Issued: 12/21/2012
Permit Reviewer: TF

APPENDIX E

INCIDENT CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1
Licensee: Memorial Sloan Kettering Cancer Center
Date of Incident: 06/29/11
Investigation Date: 09/21/11
License No.: 75-2968-01
NMED No.: 120588
Type of Incident: Medical Event
Type of Investigation: Site

File No.: 2
Licensee: Mount Sinai Medical Center
Date of Incident: 09/20/12
Investigation Date: 09/25/12
License No.: 75-2909-04
NMED No.: 120588
Type of Incident: Medical Event
Type of Investigation: Site

File No.: 3
Licensee: Montefiore Medical Center
Date of Incident: 03/22/13
Investigation Date: 7/8/13
License No.: 75-2885-01
NMED No.: 130384
Type of Incident: Overexposure
Type of Investigation: Site

File No.: 4
Licensee: Memorial Sloan Kettering Cancer Center
Date of Incident: 11/21/13
Investigation Date: 12/13/13
License No.: 75-2968-01
NMED No.: 140003
Type of Incident: Medical Event
Type of Investigation: Site

File No.: 5
Licensee: Integrated Medical Professionals
Date of Incident: 02/14/14
Investigation Date: 03/07/14
License No.: 5335
NMED No.: 140109
Type of Incident: Lost/Stolen RAM
Type of Investigation: Site

File No.: 6
Licensee: Materials Testing Lab, Inc.
Date of Incident: 10/23/12
Investigation Date: 10/24/12
License No.: C2274
NMED No.: 120634
Type of Incident: Lost/Stolen RAM
Type of Investigation: Phone

File No.: 7
Licensee: Redacted License No.: Redacted
Date of Incident: 10/13/11 NMED No.: 110574
Investigation Date: 10/14/11 Type of Incident: Medical Event
Type of Investigation: Phone/Email

File No.: 8
Licensee: Callanan Industries License No.: G14553
Date of Incident: 05/09/12 NMED No.: 120302
Investigation Date: 05/09/12 Type of Incident: Lost/Stolen RAM
Type of Investigation: Phone

File No.: 9
Licensee: Steris Isomedix Services, Inc. License No.: C2583
Date of Incident: 12/27/13 NMED No.: 140017
Investigation Date: 12/30/13 & 02/06/14 Type of Incident: Equipment Failure
Type of Investigation: Phone/Letter

File No.: 10
Licensee: Eastman Kodak Company License No.: C1347
Date of Incident: 10/27/07 NMED No.: 110330
Investigation Date: 10/29/07 & 11/28/11 Type of Incident: Lost/Stolen RAM
Type of Investigation: Phone/Email

Comment: Event occurred during previous IMPEP review period and identified during 2011 IMPEP as not reported to NRC. Event reported to NRC on 07/01/11.

File No.: 11
Licensee: Redacted License No.: Redacted
Date of Incident: 03/25/13 NMED No.: 130176
Investigation Date: 04/05/13 & 06/06/13 Type of Incident: Medical Event
Type of Investigation: Phone

File No.: 12
Licensee: Roswell Park Cancer Institute License No.: 2923
Date of Incident: 07/12/13 NMED No.: 130470
Investigation Date: 09/20/13 Type of Incident: Lost/Stolen RAM
Type of Investigation: Letter/Next Inspection

File No.: 13
Licensee: NCM USA Bronx, LLC License No.: C5496
Date of Incident: 07/15/13 NMED No.: 130353
Investigation Date: 08/12 & 8/15/13 Type of Incident: Overexposure
Type of Investigation: Site

APPENDIX F

REGULATION STATUS REVIEW

RATS ID	Description	Agency		State Status
1991-4	Notification of Incidents," 10 CFR Parts 20, 30, 31, 34, 39, 40, and 70 amendments (56 FR 64980), that became effective on October 15, 1991 and was due for Agreement State adoption by **October 15, 1994.**	DOH	1/28/2000	**Open** Regulations adopted but unresolved comments.
		NYC	12/5/2011 comments	
		DEC	NA	
1993-1	Decommissioning Recordkeeping and License Termination: Documentation Additions," 10 CFR Parts 30 and 40 amendments (58 FR 39628), that became effective on October 25, 1993 and was due for Agreement State adoption by **October 25, 1996.**	DOH	1/28/2000	**Closed**
		NYC	9/22/2011	
		DEC	NA	
1996-3	Termination or Transfer of Licensed Activities: Recordkeeping Requirements," 10 CFR Parts 20, 30, 40, 61, and 70 amendments (61 FR 24669), that became effective on June 17, 1996 and was due for Agreement State adoption by **June 17, 1999.**	DOH	2/20/14 (LC)	**Closed**
		NYC	6/12/2006	
		DEC	NA	
1995-7	Medical Administration of Radiation and Radioactive Materials," 10 CFR Parts 20 and 35 amendments (60 FR 48623), that became effective on October 20, 1995, and was due for Agreement State adoption by **October 20, 1998. Only Part 20 provisions need to be adopted.**	DOH		**Open**
		NYC	10/20/1998	
		DEC	NA	
1994-3	Timeliness in Decommissioning Material Facilities," 10 CFR Parts 30, 40, and 70 amendments (59 FR 36026), that became effective on August 15, 1994 and was due for Agreement State adoption by **August 15, 1997.**	DOH	1/28/2000	**Open**
		NYC	6/12/2006	
		DEC		
1995-5	Radiation Protection Requirements: Amended Definitions and Criteria," 10 CFR Parts 19 and 20 amendments (60 FR 36038), that became effective on August 14, 1995, and was due for Agreement State adoption by **August 14, 1998.**	DOH		**Open**
		NYC	2/23/2007	
		DEC		

1997-6	Radiological Criteria for License Termination," 10 CFR Parts 20, 30, 40, and 70 amendments (62 FR 39057), that became effective on August 20, 1997, and was due for Agreement State adoption by **August 20, 2000.**	DOH	2/20/2014 (LC)	**Open**
		NYC	2/23/2007	
		DEC		
1998-5	Minor Corrections, Clarifying Changes, and a Minor Policy Change," 10 CFR Parts 20, 30, 40, and 70 amendments (63 FR 39477, 63 FR 45393), that became effective on October 26, 1998, and was due for Agreement State adoption by **October 26, 2001.**	DOH		**Open**
		NYC	6/12/2014	
		DEC		
1998-6	Transfer for Disposal and Manifests: Minor Technical Conforming Amendment," 10 CFR Part 20 amendment (63 FR 50127), that became effective on November 20, 1998 and was due for Agreement State adoption by **November 20, 2001.**	DOH	NA	**Closed**
		NYC	6/12/2014	
		DEC	2/28/2006	
1998-1	Deliberate Misconduct by Unlicensed Persons," 10 CFR Parts 30, 40, and 70 amendments (63 FR 1890, 63 FR 13773), that became effective on February 12, 1998, and was due for Agreement State adoption by **February 12, 2001.**	DOH	6/19/2013 (LC) comments	**Open** Legally binding requirements adopted but unresolved comments.
		NYC	6/12/2006	
		DEC	4/25/2006	
2002-1	Revision of the Skin Dose Limit," 10 CFR Part 20 amendment (67 FR 16298), that became effective on April 5, 2002, and was due for Agreement State adoption by **April 5, 2005**.	DOH		**Open**
		NYC	6/1/2006	
		DEC	NA	
2002-2	Medical Use of Byproduct Material," 10 CFR Parts 20, 32, and 35 amendments (67 FR 20249), that became effective on April 24, 2002, and was due for Agreement State adoption by **October 24, 2005.**	DOH	8/8/2013 Comments Part 35 only	**Open** Regulations adopted but unresolved comments and partial rule adoption.
		NYC	6/12/2014	
		DEC	NA	
2005-2	Medical Use of Byproduct Material-Recognition of Specialty Boards," 10 CFR Part 35 amendment (70 FR 16336, 71 FR 1926), that became effective on April 29,	DOH	8/8/2013	**Closed**
		NYC	6/12/2014	

	2005, and was due for Agreement State adoption by **April 29, 2008**	DEC	NA	
2006-1	"Minor Amendments," 10 CFR Parts 20, 30, 32, 35, 40, and 70 amendments (71 FR 15005), that became effective on March 27, 2006, and was due for Agreement State adoption by **March 27, 2009**.	DOH	8/8/2013 Comments Part 35 only	**Open** Regulations adopted but unresolved comments and partial rule adoption.
		NYC	7/7/2011 Comments	
		DEC	NA	
2007-1	"Medical Use of Byproduct Material – Minor Corrections and Clarifications," 10 CFR Parts 32 and 35 amendments (72 FR 45147, 72 FR 54207), that became effective on October 29, 2007 and were due for Agreement State adoption on **October 29, 2010**	DOH	8/8/2013 Part 35 only	**Open** Regulations adopted but unresolved comments and partial rule adoption
		NYC	7/7/2011 Comments	
		DEC	NA	
2007-2	Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements," 10 CFR Parts 30, 31, 32, and 150 amendments (72 FR 58473), that became effective on December 17, 2007 and was due for Agreement State adoption by **December 17, 2010.**	DOH		**Open**
		NYC	6/12/2014 Comments	
		DEC	NA	
2007-3	Requirements for Expanded Definition of Byproduct Material," Parts 20, 30, 31, 32, 33, 35, 61, and 150 amendments (72 FR 55864), that became effective on November 30, 2007 and was due for Agreement State adoption by **November 30, 2010**.	DOH	8/8/2013 Part 35 only	**Open**
		NYC	6/12/2014 Comments	
		DEC		
2008-1	Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent," 10 CFR Parts 19 and 20 amendments (72 FR 68043), that became effective February 15, 2008 and was due for Agreement State adoption by **February 15, 2011.**	DOH		**Open**
		NYC	6/12/2014	
		DEC		
2009-1	Medical Use of Byproduct Material – Authorized User Clarification," 10 CFR Part 35 amendment (74 FR 33901), that became effective on September 28, 2009 and is due for Agreement State adoption by **September 28, 2012.**	DOH	8/8/2013	**Open** Regulations adopted but unresolved comments
		NYC	4/24/2013 Comments	
		DEC	NA	

APPENDIX G

SEALED SOURCE AND DEVICE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1
Registry No.: NY-1210-D-103-B SS&D Type: ECD
Applicant Name: Inficon, Inc. Type of Action: Ownership change and new ECD Model
Date Issued: 7/13/2012 SS&D Reviewers: DS, DG

ATTACHMENT(S)

May 14, 2014 Letter from Sandra Hinkle
New York DEC Response to the Draft Report
ADAMS Accession No.: ML14136A386

June 3, 2014 Email from Stephen Gavitt
New York DOH Response to the Draft Report
ADAMS Accession No.: ML14157A217

June 4, 2014 Letter from Christopher Boyd
New York City DHMH Response to the Draft Report
ADAMS Accession No.: ML14161A566

NRC Comment Resolution - REVISED
ADAMS Accession No.: ML14266A285

Comments on the IMPEP Review of the New York Agreement State Program
March 17-28, 2014 Draft Report
Submitted by the NYS Department of Environmental Conservation

3.0 COMMON PERFORMANCE INDICATORS

Page 4, last paragraph, first sentence and throughout: change "Radiation Sites Section" to "Radiological Sites Section."

Page 4, last paragraph: change "Positions are almost always eliminated once they are vacated" to "Positions are often eliminated…"

Page 5, second sentence, states "New York State employee travel restrictions make it difficult for this employee to travel to Albany for training." These travel restrictions have been eased by that regional employee's administration; the primary difficulty is the long distance (over 8 hours round trip) and overnight hotel costs for this employee to travel to Albany to obtain training with the radiation program staff, all of whom are located in the Albany Central Office.

4.0 NON-COMMON PERFORMANCE INDICATORS

Page 12, 4.0, second sentence contains a typo: "The NRC's Agreement with New York does not relinquish regulatory authority for a r uranium recovery program…"

Page 12, 4.1.1, first paragraph, next to last sentence states "These regulations also cover the transportation and manifestation of LLRW shipments…" Change the word "manifestation" to "manifesting."

Page 16, 4.1.2: the web link/page name provided appears to include a typo. The stated link is "rss regamendents.html" – was it meant to say "rss regamendments.html"?

4.3 Low-level Radioactive Waste Disposal Program

Page 18, second paragraph, change "the State-Licensed Disposal Area (SDA)" to "the State-licensed Disposal Area (SDA)." Although this may appear to be a minor correction, it is important to prevent migration of names and terms related to this site.

Page 18, fourth paragraph, first sentence, insert the words "Part 380" between the words "one" and "permit." This clarification is necessary because NYSERDA also holds non-radiological DEC permits for the SDA.

Page 18, fourth paragraph: change "The NYSERDA also holds a radioactive materials license from DOH for the West Valley Site" to "NYSERDA also holds a radioactive materials license from the DOH for the SDA." This clarification is needed because NYSERDA does not hold a DOH license for the whole 3,300 acres of the West Valley Site, just for the SDA.

Page 19, first paragraph states "…Cornell operates a groundwater treatment system for non-radioactive contaminants." Following "contaminants," add "that collects and discharges minute amounts of radionuclides incidental to the non-radioactive treatment system. Those radioactive discharges are regulated by a substantive Part 380 discharge permit."

Page 19, first paragraph also states "DEC plans to issue a substituent Part 380 permit before the remedial activates by the consent order have ended." Reword that sentence to instead state "DEC plans to issue a substantive Part 380 permit for ongoing monitoring and maintenance of the RDS before the Consent Order is terminated. When the Consent Order is terminated, any substantive permits issued under the Order will convert to stand-alone Part 380 permits."

Page 19, 4.3.2, second paragraph: change the terms "license" and "licensee" to "permit" and "permittee." This clarification is needed because DEC issues permits, not licenses.

Page 19, 4.3.2, second paragraph also refers to "pre-operational environmental monitoring." This is not an accurate statement, as the site is in an interim closure status; ongoing environmental sampling would therefore not be considered to be pre-operational.

Page 20, 4.3.3, third paragraph, second sentence: refers to a "NYSERDA-SLD Area at West Valley 2011 Annual Report." Correct this reference to refer to the "NYSERDA State-licensed Disposal Area (SDA)."

Page 20, fourth paragraph: change the term "licensing" to "permitting."

RECOMMMENDATIONS

Page 22, recommendation 4 states "The 2006 IMPEP review team recommended that DOH, NYC, DEC develop and implement an action plan to adopt NRC regulations in accordance with the current NRC policy on adequacy and compatibility. (Section 2.0, Open recommendation from the 2006, 2011, 2014 IMPEP reviews)." That paragraph needs several corrections, and should be reworded to state "The 2014 IMPEP review team recommends that DOH and DEC develop and implement an action plan to adopt NRC regulations in accordance with the current NRC policy on adequacy and compatibility. (Section 2.0, Open recommendation from the 2011 IMPEP review).

From: Dimmick, Lisa
To: Meyer, Karen
Subject: FW: Comments on draft NY IMPEP report
Date: Tuesday, June 03, 2014 4:17:38 PM

DOH's comments

From: Gavitt, Stephen M (HEALTH) [mailto:stephen.gavitt@health.ny.gov]
Sent: Tuesday, June 03, 2014 4:11 PM
To: Dimmick, Lisa
Cc: Dansereau, Robert E (HEALTH); Salame-Alfie, Adela (HEALTH); Christopher Boyd; Sandy Hinkel; White, Duncan
Subject: Comments on draft NY IMPEP report

Lisa,

Here's our comments on the draft report:

- The org charts for both NYS DOH Center for Environmental Health and our Bureau are outdate (not sure how that happened). I'll send you updated charts.

- Introduction, 3rd paragraph. Last paragraph, 3 rd sentence - It is unclear what you intend to convey with the word "utilization". If you delete that word then the sentence will be clear and accurate.

- 3.3 page 8, 3 rd paragraph – instrumentation. We believe the word "adequate" in the first sentence should be replaced with "ample". Adequate conveys have meet a minimum standard. Also the ion chamber should be changed to pressurized ion chamber and the portable multi-channel analyzers should indicate both HPGe as well as NaI types. Also the latter only effective for photons and they are not used to analyze wipes. DOH utilizes the Department's Wadsworth Center, Laboratory of Inorganic and Nuclear Chemistry for analysis of samples, including wipe, for routine inspections as well as for incident response.

- 3.4, page 8, first paragraph, 3rd sentence – "The casework was also reviewed for timeliness…… Please indicate where in SA-104, or elsewhere, where a timeliness standard exists.

- Page 9, 1st paragraph: 7+2+3=12, not 9.

- Second paragraph, 1st sentence – It should be noted in the report that DOH requires original documents before a license action is approved. (n email or fax may certainly start the process.)

- Last sentence is incorrect. The Section Chief, Director and Assistant Director have signature authority and have signed numerous licensing actions for this IMPEP review period.

- 4th sentence. "Routinely staff used electronic mail and phone calls to follow up with deficiency notices." For DOH, follow up requests are fully documented in the license files, and this should be noted.

- Overdue regs. Pages 14-15. The first one listed as overdue for DOH on page 15 should be listed under the prior listing that is on page 14 –Partial Amendments (10 CFR 35 only). Also it is unclear why the 4 (now 5 with the above correction) are listed again on page 15 as well.

Thank you for the opportunity to review and comment. If you have any questions, please contact Robert Dansereau or myself.

Steve.

Stephen Gavitt, Director
Bureau of Environmental Radiation Protection
Empire State Plaza – Corning Tower, 12th Fl
Albany, NY 12237
518-402-7550
stephen.gavitt@health.ny.gov

NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE
Mary T. Bassett, MD, MPH
Commissioner

Christopher Boyd
Assistant Commissioner
Bureau of Environmental Sciences and Engineering

42-09 28th Street
14th Floor, CN #56
Queens, NY 11101
347-396-6001 (tel)
347-396-6089 (fax)

June 4, 2014

Duncan White, Chief
Agreement State Programs Branch
Division of Materials Safety and State Agreements
Office of Federal and State Materials
and Environmental Management Programs
Nuclear Regulatory Commission
Washington, D.C. 2055-0001

Dear Mr. White:

The New York City Department of Health and Mental Hygiene (DOHMH), Bureau of Environmental Sciences & Engineering (ES&E) has reviewed the April 30, 2014 draft Integrated Materials Performance Evaluation Program (IMPEP) of the New York Agreement. ES&E provides the following comments and supporting documents which identify several errors of fact and interpretation that warrant revisions to the conclusions and recommendations to the April 2014 draft IMPEP report.

Comments on Licensing Actions Reviewed:

File No.: 2
Licensee: Daniel Amen, M.D./Amen Clinics Inc. License No: 91-3475-01
Type of Action: Amendment No.: 01
Date Issued: License Reviewer: I. S.
Comment: The reviewer improperly added an individual as an AU and RSO to the license. The
proposed AU and RSO did not meet the qualification requirements in accordance with 175.103(j)(5), and 175.103(j)(1), respectively.

DOHMH Comment: The NRC should remove its deficiency finding regarding the qualification of the authorized user (AU) for License No: 91-3475-01. The AU meets the qualifications of 10 CFR Part 35.200 for the activity performed under the license. The AU submitted NRC form 313A (AUD) presenting the necessary classroom, laboratory and supervised work experience and training, which documented 80 hours of classroom and laboratory training (radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, chemistry of byproduct material for medical use). The AU also presented 620 hours of work experience under the supervision of Dr. Daniel Amen for all aspects of section b. of NRC form 313A (AUD), except for those relating to eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies. DOHMH believes that the credentials and training/work experience presented are sufficient to approve the AU for activities allowed under License No: 91-3475-01 and in accordance with 10 CFR Part 35.200.

Attached are copies of NRC form 313A (AUD) the AU submitted to DOHMH, the

certification of 80 hours of certified training, and License No: 91-3475-01.

File No.: 8
Licensee: Montefiore Medical Center License No.: 75-2885-01
Type of Action: Amendment No.: 38 & 39
Date Issued: in 2012 License Reviewer: D.H.
Comment:
(a)The license did not have an issuance date.
(b)The reviewer improperly added new material to the license. License amendment was not properly supported by information in the file.
(c) The same material was removed in the next with no letter, correspondence, or other supporting documentation that would explain the removal of the material from the license.

DOHMH Comment: The NRC should withdraw the three deficiencies identified from its review of Montefiore Medical Center License No.: 75-2885-0. Each of the three findings is not supported by the information in licensing files for License No.: 75-2885-01. Amendment number 38 and 39 were signed and dated March 5, 2012 and November 20, 2012 respectively. The file contains the correspondence requesting the proposed change and the documentation that was submitted in support of the requested amendments. Attached are the letters and the supporting documentation Montefiore Medical Center submitted for Amendments 38 & 39 for License No.: 75-2885-01 and the signed/dated licenses. In light of the information provided, the NRC should withdraw the deficiencies related to its review of License No.: 75-2885-01.

File No.: 10
Licensee: NY Presbyterian Hospital/Columbia University Med Center License No.: 93-2878-05
Type of Action: Amendment No.: 15
Date Issued: 03/03/14 License Reviewer: I. S.
Comment: The reviewer improperly added an individual as an RSO to the license. There was no supporting documentation to show the individual had received or was going to receive training regarding the radiation safety aspects of the gamma knife.

DOHMH Comment: The NRC should withdraw the deficiency finding that the RSO for NY Presbyterian Hospital/Columbia University Med Center License No.: 93-2878-05 was improperly added to the license without supporting documentation. This statement is incorrect. The file reviewed by NRC included a copy of License No.: 75-2878-05. This license file includes Form 313A (RSO) documenting the RSO's compliance with all aspect of the training and education requirements found at 10 CFR Part 35.600 (remote afterloader, teletherapy, and gamma stereotactic radiosurgery). The RSO had previously submitted the same NRC Preceptor Attestation Form 313A (RSO) to be added to NRC License # 08-30577-01. A copy of the NRC Preceptor Attestation Form 313A (RSO) submitted in support of being added to and the NRC License 08-30577-01 and License No.: 75-2878-05 is attached.

Rather than there being no supporting documentation supporting the decision to add the RSO to NY Presbyterian Hospital/Columbia University Med Center License No.: 93-2878-05, the file contained appropriate reference to the related approvals made by DOHMH documenting the qualifications and education and training of the individual to meet all aspects of 10 CFR Part 35.600. Accordingly, the NRC should withdraw this finding.

File No.: 11
Licensee: Bhumi, Sarat License No.: 91-3342-01Type of Action: Renewal Amendment No.: 3
Date Issued: 07/03/12 License Reviewer: D. H.

Comment: Review did not demonstrate a thorough analysis of the licensee's inspection and enforcement history. The license reviewer did not adhere to the applicable and current guidance for this review.

DOHMH Comment: The NRC should remove its deficiency finding claiming that the review did not demonstrate a thorough analysis of the licensee's inspection and enforcement history. The licensing file includes the relevant inspections and enforcement actions taken regarding License No.: 91-3342-01. Multiple inspection findings and reports are included in the licensing action file. A copy of the last inspection report is attached. The facility was found in full compliance. While the primary contact for License No.: 91-3342-01 changed over time, which may have resulted in some confusion for the NRC review team, all of the regulatory and inspection activity in the file relates to License No.: 91-3342-01.

Comment on Status of Regulatory Actions Coming Due:

- Advance Notification to Native American tribes of Transportation of Certain Types of Nuclear Waste, RATS ID 2012-2, (Due date for State Adoption – 08/06/15) deals with advance notification to governor or Native American tribes of transportation of certain types of nuclear waste and irradiated reactor fuel. This would not apply to DOHMH.

- Technical Corrections - Parts 30, 34, 40, and 71, RATS ID 2012-3, deals with requirements for industrial radiography and uranium mills. This would not apply to DOHMH.

- Requirements for Distribution of Byproduct Material, RATS ID 2012-4, (Due date for State Adoption 10/23/15), deals with manufacture and distribution of commercial and industrial devices containing byproduct material, and is not regulated by DOHMH

- DOHMH is actively evaluating the ability to "cite by reference" to adopt regulatory standards established by the NRC that are not addressed in the New York City Health Code. DOHMH is hopeful that Physical Protection of Byproduct Material, New Part 37 RATS ID 2013, (Due date for State Adoption 03/19/16) will be implemented using "cite by reference"

Comment on NRC Recommendations:

NRC Recommendation One: This recommendation should be removed. As stated on page four of the draft IMPEP report, "the materials inspectors were fully qualified and the license reviewers were fully qualified and have full signatory authority for licensing actions." The NRC has applied compatibility "C" to IMC 1248 and cannot require that an Agreement Program mirror the administrative approach used by the NRC to the meet the performance goals of Technical Staffing and Training. In Section 3.1 the NRC did not identify a specific deficiency or inconsistency in the technical qualifications or training of qualified staff, how non-qualified staff are being trained to perform material inspection and licensing activity or how training is documented. It is important for IMPEP teams to use consistent measures between reviews. The procedures used by DOHMH for training and qualifying staff have not changed since the previous IMPEP, which did not make a recommendation. Further, DOHMH significantly increased its utilization of NRC sponsored training for staff that has been qualified and those being trained to be qualified since the last IMPEP. These efforts are not reflected in the IMPEP report and represent important improvements in the technical training and knowledge of the DOHMH staff since the last IMPEP.

If the NRC believes the IMPEP report is the correct forum to provide DOHMH direction regarding how it administers its program unrelated to a deficiency finding to meet the performance standards for technical staffing

and training, DOHMH recommends that this recommendation be revised as a suggestion in the draft report that DOHMH consider incorporating aspects of IMC 1248 or other best practices it is aware. Specific examples of sections of IMC 1248 or other best practices should be provided. If suggested improvement to program administration unrelated to a deficiency finding is best addressed in another forum, DOHMH would welcome a thoughtful discussion regarding ways it may improve its administration of the program.

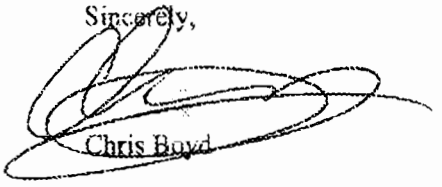
NRC Recommendation 3: The NRC review team found deficiencies with six licensing actions taken by DOHMH. Based on the documentation in licensing files and attached to these comments, the NRC findings were made in error for File 8, File 10 and File 11. A portion of the finding for File 1 was made incorrectly, as the AU met applicable qualifications. The program agrees that the RSO did not fully meet the qualification criteria. File 12 regarding the lack of a letter requesting cancelation of a minor license represents an administrative error rather than an indication of consistent errors in documentation or the technical sufficiency of the reviewer, who has since retired. While DOHMH agrees that File 13 represented a substantive lapse among the files reviewed, as discussed during the IMPEP, no public health risks were associated with improper renewal of this licensing action.

Considering that four of the six files with deficiency findings were made either fully or partially in error, the remaining deficiencies do not indicate that there is a systemic failing in the thoroughness and/or quality of the licensing activity performed by the two staff that is performing this role currently for DOHMH. Nothing in the records reviewed suggests that the NRC has identified systemic deficiencies in program administration that warrants specific corrective actions in administration of the program to be dictated by the NRC and/or the ability of DOHMH to conform to the technical staffing and quality of licensing compatibility requirements. Accordingly, DOHMH requests that recommendation 3 be removed. If the NRC believes it is necessary keep a portion of Recommendation 3, that should be limited to a request that DOHMH document that the errors identified have been addressed.

If the NRC believes that the IMPEP report is the proper forum to provide suggestions for how DOHMH could improve the administration of its program, those suggested improvements should be made in the body of the text and not as part of a formal recommendation requiring the program to present its actions to the NRC for review and acceptance at the next IMPEP.

Recommendation Four: New York City should be removed from this recommendation since its regulatory authorities are compatible with NRC and no regulatory actions are overdue.

Sincerely,



Chris Boyd

Enc.

Cc: Nathan Graber, M.D., MPH, NYSDOH
Mr. Robert Schick, NYSDEC
Steve Gavitt, NYSDOH (w/o Enc.)
Robert E Dansereau, NYSDOH (w/o Enc)

Comment Resolution for the New York
Draft IMPEP Report - REVISED

Comment 1: Page 4

Page 4, last paragraph, first sentence and throughout: change "Radiation Sites Section" to "Radiological Sites Section.

Response 1:

Thank you for the correction. The corresponding edits were made.

Comment 2: Page 4

Page 4, last paragraph: change "Positions are almost always eliminated once they are vacated" to "Positions are often eliminated…

Response 2:
Thank you for the comment. The edit was accepted.

Comment 3: Page 5

Page 5, second sentence, states "New York State employee travel restrictions make it difficult for this employee to travel to Albany for training." These travel restrictions have been eased by that regional employee's administration; the primary difficulty is the long distance (over 8 hours round trip) and overnight hotel costs for this employee to travel to Albany to obtain training with the radiation program staff, all of whom are located in the Albany Central Office.

Response 3:
Thank you for the comment. The comment was resolved by changing report text to read "Travel logistics and State travel restrictions make it difficult for this employee to travel to the Albany central office for training."

Comment 4: Page 12

Page 12, 4.0, second sentence contains a typo: "The NRC's Agreement with New York does not relinquish regulatory authority for a r uranium recovery program…"

Response 4:

Thank you for the correction. The corresponding edit was made.

Comment 5: Page

Page 12, 4.1.1, first paragraph, next to last sentence states "These regulations also cover the transportation and manifestation of LLRW shipments…" Change the word "manifestation" to "manifesting."

Response 5:

Thank you for the correction. The corresponding edit was made.

Comment 6: Page 16

Page 16, 4.1.2: the web link/page name provided appears to include a typo. The stated link is “rss regamendents.html” – was it meant to say “rss regamendments.html”?

Response 6:

Thank you for the comment. A correction was made. The correct link is http://nrc-stp.ornl.gov/rss_regamendents.html

Comment 7: Page 18

Page 18, second paragraph, change “the State-Licensed Disposal Area (SDA)” to “the State-licensed Disposal Area (SDA).” Although this may appear to be a minor correction, it is important to prevent migration of names and terms related to this site.

Response 7:

Thank you for the correction. The corresponding edit was made.

Comment 8: Page 18

Page 18, fourth paragraph, first sentence, insert the words “Part 380” between the words “one” and “permit.” This clarification is necessary because NYSERDA also holds non-radiological DEC permits for the SDA.

Response 8:

Thank you for the clarification. The corresponding edit was made.

Comment 9: Page 18

Page 18, fourth paragraph: change “The NYSERDA also holds a radioactive materials license from DOH for the West Valley Site” to “NYSERDA also holds a radioactive materials license from the DOH for the SDA.” This clarification is needed because NYSERDA does not hold a DOH license for the whole 3,300 acres of the West Valley Site, just for the SDA.

Response 9:

Thank you for the clarification. The corresponding edit was made.

Comment 10: Page 19

Page 19, first paragraph states "…Cornell operates a groundwater treatment system for non-radioactive contaminants." Following "contaminants," add "that collects and discharges minute amounts of radionuclides incidental to the non-radioactive treatment system. Those radioactive discharges are regulated by a substantive Part 380 discharge permit."

Response 10:

Thank you for the comment. The requested edit was made.

Comment 11: Page 19

Page 19, first paragraph also states "DEC plans to issue a substituent Part 380 permit before the remedial activates by the consent order have ended." Reword that sentence to instead state "DEC plans to issue a substantive Part 380 permit for ongoing monitoring and maintenance of the RDS before the Consent Order is terminated. When the Consent Order is terminated, any substantive permits issued under the Order will convert to stand-alone Part 380 permits."

Response 11:

Thank you for the comment. The requested edit was made.

Comment 12: Page 19

Page 19, 4.3.2, second paragraph: change the terms "license" and "licensee" to "permit" and "permittee." This clarification is needed because DEC issues permits, not licenses.

Response 12:

Thank you for your correction. The corresponding edits were made.

Comment 13: Page 19

Page 19, 4.3.2, second paragraph also refers to "pre-operational environmental monitoring." This is not an accurate statement, as the site is in an interim closure status; ongoing environmental sampling would therefore not be considered to be pre-operational.

Response 13:

Thank you for the clarification. "Pre-operational" was removed from the report text.

Comment 14: Page 20

Page 20, 4.3.3, third paragraph, second sentence: refers to a "NYSERDA-SLD Area at West Valley 2011 Annual Report." Correct this reference to refer to the "NYSERDA State-licensed Disposal Area (SDA)."

Response 14:

Thank you for the correction. The requested edit was made.

Comment 15: Page 20

Page 20, fourth paragraph: change the term “licensing” to “permitting.”

Response 15:

Thank you for the correction. The corresponding edit was made.

Comment 16: Page 22

Page 22, recommendation 4 states “The 2006 IMPEP review team recommended that DOH, NYC, DEC develop and implement an action plan to adopt NRC regulations in accordance with the current NRC policy on adequacy and compatibility. (Section 2.0, Open recommendation from the 2006, 2011, 2014 IMPEP reviews).” That paragraph needs several corrections, and should be reworded to state “The 2014 IMPEP review team recommends that DOH and DEC develop and implement an action plan to adopt NRC regulations in accordance with the current NRC policy on adequacy and compatibility. (Section 2.0, Open recommendation from the 2011 IMPEP review).

Response 16:

Thank you for your comment. The IMPEP team re-evaluated its reason for keeping the recommendation open and will recommend closing the recommendation to the Management Review Board. Each NY agency had developed and implemented an action plan as directed by the recommendation. The NYC agency was able to clear its backlog, but due to an arduous rulemaking process for both DOH and DEC, these agencies were not able to clear their backlog of overdue regulations. The IMPEP team determined that each agency is cognizant of the requirements to adopt compatible rules or use legally binding requirement within 3 years of the NRC’s effective date and each agency should address rules coming due proactively. (See also Comment/Response 33)

Comment 17:

The org charts for both NYS DOH Center for Environmental Health and our Bureau are outdate (not sure how that happened). I’ll send you updated charts.

Response 17:

Thank you for your sending current organization charts for DOH. The report will be update for these charts.

Comment 18:

Introduction, 3rd paragraph. Last paragraph, 3 rd sentence - It is unclear what you intend to convey with the word "utilization". If you delete that word then the sentence will be clear and accurate.

Response 18:

Thank you for the comment. "Utilization" was removed from report text.

Comment 19: Page 8

3.3 page 8, 3 rd paragraph – instrumentation. We believe the word "adequate" in the first sentence should be replaced with "ample". Adequate conveys have meet a minimum standard. Also the ion chamber should be changed to pressurized ion chamber and the portable multi-channel analyzers should indicate both HPGe as well as NaI types. Also the latter only effective for photons and they are not used to analyze wipes. DOH utilizes the Department's Wadsworth Center, Laboratory of Inorganic and Nuclear Chemistry for analysis of samples, including wipe, for routine inspections as well as for incident response.

Response 19:

Thank you for your insight. The comment was accepted in part. "Ample" replaced "adequate." This instrumentation discussion section under Technical Quality of Inspection addresses the types of instrumentation available for the New York Agreement State Program (i.e., the Program) as a whole and does not list the specific functionality of the available instrumentation. Therefore, the clarification on specific ion chambers and multi-channel analyzers available to DOH was not added to the report.

Comment 20: Page 8

3.4, page 8, first paragraph, 3rd sentence – "The casework was also reviewed for timeliness Please indicate where in SA-104, or elsewhere, where a timeliness standard exists.

Response 20:

Thank you for the comment. Timeliness is implied in Section III of SA-104, *Reviewing the Common Performance Indicator, Technical Quality of Licensing Actions.* The procedure states that "the evaluation of technical quality includes not only the review of the application and completed actions, but also an examination of any renewals that have been pending for more than a year, because the failure to act on such requests may have health and safety implications." No change was made to the report in response to the comment.

Comment 21: Page 9

Page 9, 1st paragraph: 7+2+3=12, not 9.

Response 21:

Thank you for the comment. A report correction was made.

Comment 22:

Second paragraph, 1st sentence – It should be noted in the report that DOH requires original documents before a license action is approved. (an email or fax may certainly start the process.)

Response 22:

Thank you for the comment. The requested edit was added to the report text.

Comment 23:

Last sentence is incorrect. The Section Chief, Director and Assistant Director have signature authority and have signed numerous licensing actions for this IMPEP review period.

Response 23:

Thank you for the correction. The report was changed to reflect the signature authority of the Director and Assistant Director.

Comment 24:

4th sentence. "Routinely staff used electronic mail and phone calls to follow up with deficiency notices." For DOH, follow up requests are fully documented in the license files, and this should be noted.

Response 24:

Thank you for the comment. The requested edit was added to the report text on page 10 first paragraph.

Comment 25: Page 14-15

Overdue regs. Pages 14-15. The first one listed as overdue for DOH on page 15 should be listed under the prior listing that is on page 14 –Partial Amendments (10 CFR 35 only). Also it is unclear why the 4 (now 5 with the above correction) are listed again on page 15 as well.

Response 25:

Thank you for your comment. The report reflects action taken on rule adoption during the review period. In addition, the Part 35 regulations of the rule (RATS ID 1995–7) referenced in this comment were superseded by RATS IDs 2002-2 and 2005-2 which were submitted by DOH and acknowledged as partial amendments in this report. The Part 20 provisions of

this rule still need to be adopted; hence, the reason it was listed under the overdue amendments. For those RATS IDs listed as both partial and overdue, a note was added in the report to indicate the overdue list includes the four partial amendments because regulations in other Parts still need to be promulgated to complete the rule. The amendments listed as partially complete was added by the IMPEP team to show the progress DOH has made with compatibility requirements since full credit cannot be given for these amendments until the other regulation Parts have been addressed as final rules or legally binding requirements. No other changes were made to the report in regard this comment. The IMPEP report is consistent with DOH's current SRS sheet.

Comment 26:

File No.: 2
Licensee: Daniel Amen, M.D./Amen Clinics Inc. License No: 91-3475-01
Type of Action: Amendment No.: 01
Date Issued: License Reviewer: I. S.
Comment: The reviewer improperly added an individual as an AU and RSO to the license. The proposed AU and RSO did not meet the qualification requirements in accordance with 175.103(j)(5), and 175.103(j)(1), respectively.

DOHMH Comment: The NRC should remove its deficiency finding regarding the qualification of the authorized user (AU) for License No: 91-3475-01. The AU meets the qualifications of 10 CFR Part 35.200 for the activity performed under the license. The AU submitted NRC form 313A (AUD) presenting the necessary classroom, laboratory and supervised work experience and training, which documented 80 hours of classroom and laboratory training (radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, chemistry of byproduct material for medical use). The AU also presented 620 hours of work experience under the supervision of Dr. Daniel Amen for all aspects of section b. of NRC form 313A (AUD), except for those relating to eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies. DOHMH believes that the credentials and training/work experience presented are sufficient to approve the AU for activities allowed under License No: 91-3475-01 and in accordance with 10 CFR Part 35.200. Attached are copies of NRC form 313A (AUD) the AU submitted to DOHMH, the certification of 80 hours of certified training, and License No: 91-3475-01.

Response 26:

Thank you for your insight. The documentation provided to address this comment was the same documents reviewed by the IMPEP team. The individual did not meet the full qualifications under NRC regulation 10 CFR 35.290 or the equivalent New York state regulation 175.103(j)(5) because the individual did not have experience related to eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs. The fact that the individual did not meet the full training and experience as outlined in the regulation and documented in the NRC Form 313 was never addressed by the reviewer. There was no documentation to show that the individual requested an exemption to this regulation, and there was no documentation to show DOHM had decided to exempt the individual from this regulation.

However, during the Management Review Board (MRB) meeting the concerns over the AU's qualifications were resolved. The performance concern was removed from the casework review.

Comment 27:

File No.: 8
Licensee: Montefiore Medical Center License No.: 75-2885-01
Type of Action: Amendment No.: 38 & 39
Date Issued: in 2012 License Reviewer: D.H.
Comment:
(a)The license did not have an issuance date.
(b)The reviewer improperly added new material to the license. License amendment was not properly supported by information in the file.
(c) The same material was removed in the next with no letter, correspondence, or other supporting documentation that would explain the removal of the material from the license.

DOHMH Comment: The NRC should withdraw the three deficiencies identified from its review of Montefiore Medical Center License No.: 75-2885-0. Each of the three findings is not supported by the information in licensing files for License No.: 75-2885-01. Amendment number 38 and 39 were signed and dated March 5, 2012 and November 20, 2012 respectively. The file contains the correspondence requesting the proposed change and the documentation that was submitted in support of the requested amendments. Attached are the letters and the supporting documentation Montefiore Medical Center submitted for Amendments 38 & 39 for License No.: 75-2885-01 and the signed/dated licenses. In light of the information provided, the NRC should withdraw the deficiencies related to its review of License No.: 75-2885-01.

Response 27:

Thank you for your insight. The documentation provided to support this comment is for Technetium-99 which is not the radionuclide the IMPEP team was referencing in items b and c above. The radionuclide added and removed inappropriately to license amendment 38 and 39, respectively was Yttrium-90 (Y-90) Thera-Spheres. The documents reviewed for this finding were in the licensing folder provided to the IMPEP team. The licensee is currently authorized for Y-90 Microspheres; however, the request to add Y-90 Thera-Spheres must be accompanied by additional information regarding training and experience according to guidance from the manufacturer because the delivery process to the patient is significantly different for Y-90 Microspheres and Y-90 Thera-Spheres. In the documents reviewed by the IMPEP team, the Y-90 Thera-Spheres was added based upon a one page request without documentation to outline necessary training and experience. The amendment on file was not dated. The staff was interviewed at the time of the review to try to determine an issuance date and the staff could not find a dated license and could not determine when the amendment was issued. Subsequently, Y-90 Thera-Sphere was removed in amendment 39 and thereafter with no letter, correspondence, or other supporting documentation that would explain the removal of the material from the license. Amendment 39 did not have an issuance date. However, during the MRB, the status of amendments #38 and #39 were resolved. The signed and dated copies of these

amendments did not authorize Y-90 Thera-Shperes. This concern was removed from the casework review.

Comment 28:

File No.: 10
Licensee: NY Presbyterian Hospital/Columbia University Med Center License No.: 93-2878-05
Type of Action: Amendment No.: 15
Date Issued: 03/03/14 License Reviewer: I. S.
Comment: The reviewer improperly added an individual as an RSO to the license. There was no supporting documentation to show the individual had received or was going to receive training regarding the radiation safety aspects of the gamma knife.

DOHMH Comment: The NRC should withdraw the deficiency finding that the RSO for NY Presbyterian Hospital/Columbia University Med Center License No.: 93-2878-05 was improperly added to the license without supporting documentation. This statement is incorrect. The file reviewed by NRC included a copy of License No.: 75-2878-05. This license file includes Form 313A (RSO) documenting the RSO's compliance with all aspect of the training and education requirements found at 10 CFR Part 35.600 (remote afterloader, teletherapy, and gamma stereotactic radiosurgery). The RSO had previously submitted the same NRC Preceptor Attestation Form 313A (RSO) to be added to NRC License # 08-30577-01. A copy of the NRC Preceptor Attestation Form 313A (RSO) submitted in support of being added to and the NRC License 08-30577-01 and License No.: 75-2878-05 is attached.

Rather than there being no supporting documentation supporting the decision to add the RSO to NY Presbyterian Hospital/Columbia University Med Center License No.: 93-2878-05, the file contained appropriate reference to the related approvals made by DOHMH documenting the qualifications and education and training of the individual to meet all aspects of 10 CFR Part 35.600. Accordingly, the NRC should withdraw this finding.

Response 28:

Thank you for your insight. The documents submitted to support the comment was the same set of documents reviewed by the IMPEP team. The documentation submitted to add the RSO to the NY Presbyterian Hospital/Columbia University Medical Center was deficient. The IMPEP review team recognized the proposed RSO was listed on a broad scope license for a facility that has a self-shielded irradiator and High Dose Radiation Unit. However, the NY Presbyterian Hospital/Columbia University Medical Center possesses a gamma knife. There was no supporting documentation to show the individual had received or was going to receive training regarding the radiation safety aspects of the gamma knife. In addition, there was no supporting document (i.e., copy of agreement state license) to show the individuals that served as a preceptor were qualified to do so. Furthermore, there is no documentation to show what type of gamma stereotactic radiosurgery the proposed RSO received his training and experience. In order to be added to the license, the reviewer should have ensured the individual had received training in the radiation safety, regulatory issues, and emergency procedures for the Perfexion™ gamma stereotactic radiosurgery unit. If the individual already has RSO responsibilities for a gamma stereotactic radiosurgery unit, in

accordance with 10 CFR 35.50(e), the training must also include instruction on the differences in the radiation safety, regulatory issues, and emergency procedures of the Perfexion™ unit and other gamma stereotactic radiosurgery units for which the individual has RSO responsibility. This training requirement may be satisfied by completing training that is provided by the Perfexion™ vendor, or supervised by an individual (RSO or AMP or AU) that is authorized for the Perfexion™ unit. The individual should complete or commit to complete supplemental hands-on radiation safety and emergency procedures training on an operational Perfexion™ unit before first use of the unit for patient treatment; AND for an RSO on a license authorized for the 10 CFR 35.600 medical use of a gamma stereotactic radiosurgery unit, documentation that the RSO has satisfactorily completed the above training and completed or provided documentation of a commitment to complete the supplemental hands-on training. No change to the report was made.

Comment 29:

File No.: 11
Licensee: Bhumi, Sarat License No.: 91-3342-01Type of Action: Renewal Amendment No.: 3
Date Issued: 07/03/12 License Reviewer: D. H.
Comment: Review did not demonstrate a thorough analysis of the licensee's inspection and enforcement history. The license reviewer did not adhere to the applicable and current guidance for this review.

DOHMH Comment: The NRC should remove its deficiency finding claiming that the review did not demonstrate a thorough analysis of the licensee's inspection and enforcement history. The licensing file includes the relevant inspections and enforcement actions taken regarding License No.: 91-3342-01. Multiple inspection findings and reports are included in the licensing action file. A copy of the last inspection report is attached. The facility was found in full compliance. While the primary contact for License No.: 91-3342-01 changed over time, which may have resulted in some confusion for the NRC review team, all of the regulatory and inspection activity in the file relates to License No.: 91-3342-01.

Response 29:

Thank you for your insight. The IMPEP team recognizes that documentation regarding the inspection of facilities was thorough and present in the inspection folder. The availability of these files was not the issue of the finding. At the time of the IMPEP review, there was no documentation to show the license reviewer performed a thorough analysis of the licensee's inspection files and the enforcement history. In addition, the same finding was identified in File No. 13 of Appendix D. No change was made to the report.

Comment 30:

Comment on Status of Regulatory Actions Coming Due:

Advance Notification to Native American tribes of Transportation of Certain Types of Nuclear Waste, RATS ID 2012-2, (Due date for State Adoption – 08/06/15) deals with advance notification to governor or Native American tribes of transportation of certain types of nuclear waste and irradiated reactor fuel. This would not apply to DOHMH.

Technical Corrections - Parts 30, 34, 40, and 71, RATS ID 2012-3, deals with requirements for industrial radiography and uranium mills. This would not apply to DOHMH.

Requirements for Distribution of Byproduct Material, RATS ID 2012-4, (Due date for State Adoption 10/23/15), deals with manufacture and distribution of commercial and industrial devices containing byproduct material, and is not regulated by DOHMH

DOHMH is actively evaluating the ability to "cite by reference" to adopt regulatory standards established by the NRC that are not addressed in the New York City Health Code. DOHMH is hopeful that Physical Protection of Byproduct Material, New Part 37 RATS ID 2013, (Due date for State Adoption 03/19/16) will be implemented using "cite by reference"

Response 30:

Thank you for your comment. In response, the State Regulation Status sheet for DOHMH was updated for RATS ID 2012-4 to indicate the rule does not apply to DOHMH. Applicability of RATS ID 2012-2 and 2012-3 require further assessment by DOHMH. Both rules impact transportation requirements (Part 71). In 2009, DOHMH promulgated Part 71 rules. Therefore, the Part 71 rule components may apply to DOHMH. There are no corresponding report changes as a result of this comment.

Comment 31:

NRC Recommendation One: This recommendation should be removed. As stated on page four of the draft IMPEP report, "the materials inspectors were fully qualified and the license reviewers were fully qualified and have full signatory authority for licensing actions." The NRC has applied compatibility "C" to IMC 1248 and cannot require that an Agreement Program mirror the administrative approach used by the NRC to the meet the performance goals of Technical Staffing and Training. In Section 3.1 the NRC did not identify a specific deficiency or inconsistency in the technical qualifications or training of qualified staff, how non-qualified staff are being trained to perform material inspection and licensing activity or how training is documented. It is important for IMPEP teams to use consistent measures between reviews. The procedures used by DOHMH for training and qualifying staff have not changed since the previous IMPEP, which did not make a recommendation. Further, DOHMH significantly increased its utilization of NRC sponsored training for staff that has been qualified and those being trained to be qualified since the last IMPEP. These efforts are not reflected in the IMPEP report and represent important improvements in the technical training and knowledge of the DOHMH staff since the last IMPEP.

If the NRC believes the IMPEP report is the correct forum to provide DOHMH direction regarding how it administers its program unrelated to a deficiency finding to meet the performance standards for technical staffing and training, DOHMH recommends that this recommendation be revised as a suggestion in the draft report that DOHMH consider incorporating aspects of IMC 1248 or other best practices it is aware. Specific examples of sections of IMC 1248 or other best practices should be provided. If suggested improvement to program administration unrelated to a deficiency finding is best addressed in another forum, DOHMH would welcome a thoughtful discussion regarding ways it may improve its administration of the program.

Response 31:

Thank you for your insight. However, the IMPEP team does not agree and stands by its recommendation. Qualification journals are designated as Compatibility Category C. Program elements with a Compatibility Category C designation need to contain the essential objectives of the NRC regulations. The NYC's training document provided to the IMPEP team is not consistent with IMC 1248. NYC has staff going through the qualification process and the qualification process used by NYC should reflect current standards.

Comment 32:

NRC Recommendation 3: The NRC review team found deficiencies with six licensing actions taken by DOHMH. Based on the documentation in licensing files and attached to these comments, the NRC findings were made in error for File 8, File 10 and File 11. A portion of the finding for File 1 was made incorrectly, as the AU met applicable qualifications. The program agrees that the RSO did not fully meet the qualification criteria. File 12 regarding the lack of a letter requesting cancelation of a minor license represents an administrative error rather than an indication of consistent errors in documentation or the technical sufficiency of the reviewer, who has since retired. While DOHMH agrees that File 13 represented a substantive lapse among the files reviewed, as discussed during the IMPEP, no public health risks were associated with improper renewal of this licensing action.

Considering that four of the six files with deficiency findings were made either fully or partially in error, the remaining deficiencies do not indicate that there is a systemic failing in the thoroughness and/or quality of the licensing activity performed by the two staff that is performing this role currently for DOHMH. Nothing in the records reviewed suggests that the NRC has identified systemic deficiencies in program administration that warrants specific corrective actions in administration of the program to be dictated by the NRC and/or the ability of DOHMH to conform to the technical staffing and quality of licensing compatibility requirements. Accordingly, DOHMH requests that recommendation 3 be removed. If the NRC believes it is necessary keep a portion of Recommendation 3, that should be limited to a request that DOHMH document that the errors identified have been addressed.

If the NRC believes that the IMPEP report is the proper forum to provide suggestions for how DOHMH could improve the administration of its program, those suggested improvements should be made in the body of the text and not as part of a formal recommendation requiring the program to present its actions to the NRC for review and acceptance at the next IMPEP.

Response 32:

Thank you for your insight. However, the IMPEP team does not agree and stands by its recommendation. The noted deficiencies were not changed as a result of the submitted documentation. See the response to Comments 26–29. The recommendation focuses on underlying the cause of the licensing quality issues and intends to promote improvement.

Comment 33:

Recommendation Four: New York City should be removed from this recommendation since its regulatory authorities are compatible with NRC and no regulatory actions are overdue.

Response 33

Thank you for your comment. The IMPEP team re-evaluated its reason for keeping the recommendation open and will recommend to the Management Review Board that this performance recommendation be closed. Each NY agency had developed and implemented an action plan as directed by the recommendation. The NYC agency was able to clear its backlog, but due to an arduous rulemaking process for both DOH and DEC, these agencies were not able to clear their backlog of overdue regulations. The IMPEP team determined that each agency is cognizant of the requirements to adopt compatible rules or use legally binding requirement within 3 years of the NRC's effective date and each agency should address rules coming due proactively. (See also Comment/Response 16).