UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
612 E. LAMAR BLVD., SUITE 400
ARLINGTON, TEXAS 76011-4125

July 15, 2011

Christopher Boyd, Assistant Commissioner
Office of Radiological Health
Bureau of Environmental Sciences & Engineering
New York City Department
of Health and Mental Hygiene
22 Courtlandt Sreet, 28th Floor, CN 60
New York, NY 10007

Dear Mr. Boyd:

The United States Nuclear Regulatory Commission (NRC) uses the Integrated Materials Performance Evaluation Program (IMPEP) in the evaluation of Agreement State programs. Enclosed for your review is the draft IMPEP report, which documents the results of the Agreement State review, held in New York on June 6-16, 2011. I was the team leader for the review. The review team's preliminary findings were discussed with you and Gene Miskin on the last day of the review. The review team's proposed recommendations are that the New York Agreement State Program be found adequate to protect public health and safety, but needs improvement, and not compatible with NRC's program.

NRC conducts periodic reviews of Agreement State programs to ensure that public health and safety are adequately protected from the potential hazards associated with the use of radioactive materials and that Agreement State programs are compatible with NRC's program. The process, titled IMPEP, employs a team of NRC and Agreement State staff to assess both Agreement State and NRC Regional Office radioactive materials programs. All reviews use common criteria in the assessment and place primary emphasis on performance. Three additional areas applicable to the New York Agreement State Program have been identified as non-common performance indicators and are also addressed in the assessment. The final determination of adequacy and compatibility of each Agreement State program, based on the review team's report, is made by a Management Review Board (MRB) composed of NRC managers and an Agreement State program manager who serves as a liaison to the MRB.

In accordance with procedures for implementation of IMPEP, we are providing you with a copy of the draft team report for your review and comment prior to submitting the report to the MRB. Comments are requested within four weeks from your receipt of this letter. This schedule will permit the issuance of the final report in a timely manner that will be responsive to your needs.

The team will review your response, make any necessary changes to the report, and issue it to the MRB as a proposed final report. Coordinating with your staff, I scheduled the New York MRB meeting for September 8, 2011, from 10:30 a.m.-12:30 p.m. EST. The NRC will provide invitational travel for you or your designee to attend the MRB meeting at NRC Headquarters in Rockville, Maryland. The NRC has video conferencing capability if it is more convenient for the

State to participate through this medium. Please contact me if you desire to establish a video conference for the meeting.

If you have any questions regarding the enclosed report, please contact me at (817) 860-8143.

Thank you for your cooperation.

Sincerely,

/RA/

Randy Erickson
Team Leader

Enclosure:
As stated

cc w/ encl:

Gene Miskin, Director
Office of Radiological Health
Bureau of Environmental Sciences & Engineering
New York City Department
of Health and Mental Hygiene
22 Courtlandt Sreet, 34th Floor, CN 60
New York, NY 10007

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
612 E. LAMAR BLVD., SUITE 400
ARLINGTON, TEXAS 76011-4125

July 15, 2011

Dale Desnoyers, Director
Division of Environmental Remediation
New York State Department of Environmental Conservation
625 Broadway
Albany NY 12233-7011

Dear Mr. Desnoyers:

The United States Nuclear Regulatory Commission (NRC) uses the Integrated Materials Performance Evaluation Program (IMPEP) in the evaluation of Agreement State programs. Enclosed for your review is the draft IMPEP report, which documents the results of the Agreement State review, held in New York on June 6-16, 2011. I was the team leader for the review. The review team's preliminary findings were discussed with Jim Harrington, Sandra Hinkel, and Timothy Rice on the last day of the review. The review team's proposed recommendations are that the New York Agreement State Program be found adequate to protect public health and safety, but needs improvement, and not compatible with NRC's program.

NRC conducts periodic reviews of Agreement State programs to ensure that public health and safety are adequately protected from the potential hazards associated with the use of radioactive materials and that Agreement State programs are compatible with NRC's program. The process, titled IMPEP, employs a team of NRC and Agreement State staff to assess both Agreement State and NRC Regional Office radioactive materials programs. All reviews use common criteria in the assessment and place primary emphasis on performance. Three additional areas applicable to the New York Agreement State Program have been identified as non-common performance indicators and are also addressed in the assessment. The final determination of adequacy and compatibility of each Agreement State program, based on the review team's report, is made by a Management Review Board (MRB) composed of NRC managers and an Agreement State program manager who serves as a liaison to the MRB.

In accordance with procedures for implementation of IMPEP, we are providing you with a copy of the draft team report for your review and comment prior to submitting the report to the MRB. Comments are requested within four weeks from your receipt of this letter. This schedule will permit the issuance of the final report in a timely manner that will be responsive to your needs.

The team will review your response, make any necessary changes to the report, and issue it to the MRB as a proposed final report. Coordinating with your staff, I scheduled the New York MRB meeting for September 8, 2011, from 10:30 a.m.-12:30 p.m. EST. The NRC will provide invitational travel for you or your designee to attend the MRB meeting at NRC Headquarters in Rockville, Maryland. The NRC has video conferencing capability if it is more convenient for the

State to participate through this medium. Please contact me if you desire to establish a video conference for the meeting.

If you have any questions regarding the enclosed report, please contact me at (817) 860-8143.

Thank you for your cooperation.

Sincerely,

/RA/

Randy Erickson
Team Leader

Enclosure:
As stated

cc w/ encl:

Jim Harrington, Director
Remedial Bureau A
Division of Environmental Remediation
New York State Department of Environmental Conservation
625 Broadway
Albany, NY 12233-7015

Sandra Hinkel, Chief
Radiation Control Permits Section
Remedial Bureau A
Division of Environmental Remediation
New York State Department of Environmental Conservation
625 Broadway
Albany, NY 12233-7255

Timothy Rice, Chief
Radiological Sites Section
Remedial Bureau A
Division of Environmental Remediation
New York State Department of Environmental Conservation
625 Broadway
Albany, NY 12233-7255

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
612 E. LAMAR BLVD., SUITE 400
ARLINGTON, TEXAS 76011-4125

July 15, 2011

Howard Freed, MD, Director
Center for Environmental Health
New York State Health Department
547 River Street, Room 500
Troy, New York 12180-2216

Dear Dr. Freed:

The United States Nuclear Regulatory Commission (NRC) uses the Integrated Materials Performance Evaluation Program (IMPEP) in the evaluation of Agreement State programs. Enclosed for your review is the draft IMPEP report, which documents the results of the Agreement State review, held in New York on June 6-16, 2011. I was the team leader for the review. The review team's preliminary findings were discussed with you, Robert Chinery, Adela Salame-Alfie, Stephen Gavitt, Robert Dansereau and Charles Burns of your staff on the last day of the review. The review team's proposed recommendations are that the New York Agreement State Program be found adequate to protect public health and safety, but needs improvement, and not compatible with NRC's program.

NRC conducts periodic reviews of Agreement State programs to ensure that public health and safety are adequately protected from the potential hazards associated with the use of radioactive materials and that Agreement State programs are compatible with NRC's program. The process, titled IMPEP, employs a team of NRC and Agreement State staff to assess both Agreement State and NRC Regional Office radioactive materials programs. All reviews use common criteria in the assessment and place primary emphasis on performance. Three additional areas applicable to the New York Agreement State Program have been identified as non-common performance indicators and are also addressed in the assessment. The final determination of adequacy and compatibility of each Agreement State program, based on the review team's report, is made by a Management Review Board (MRB) composed of NRC managers and an Agreement State program manager who serves as a liaison to the MRB.

In accordance with procedures for implementation of IMPEP, we are providing you with a copy of the draft team report for your review and comment prior to submitting the report to the MRB. Comments are requested within four weeks from your receipt of this letter. This schedule will permit the issuance of the final report in a timely manner that will be responsive to your needs.

The team will review your response, make any necessary changes to the report, and issue it to the MRB as a proposed final report. Coordinating with your staff, I scheduled the New York MRB meeting for September 8, 2011, from 10:30 a.m.-12:30 p.m. EST. The NRC will provide invitational travel for you or your designee to attend the MRB meeting at NRC Headquarters in Rockville, Maryland. The NRC has video conferencing capability if it is more convenient for the

State to participate through this medium. Please contact me if you desire to establish a video conference for the meeting.

If you have any questions regarding the enclosed report, please contact me at (817) 860-8143.

Thank you for your cooperation.

Sincerely,

/RA/

Randy Erickson
Team Leader

Enclosure:
As stated

cc w/ encl:

Robert Chinery, M.S., P.E., Assistant Director
Center for Environmental Health
New York State Health Department
547 River Street, Room 500
Troy, New York 12180-2216

Adela Salame-Alfie, Ph.D., Acting Director
Division of Environmental Health Investigations
New York State Health Department
547 River Street, Room 500
Troy, New York 12180-2216

Stephen Gavitt, CHP, Director
Bureau of Environmental Radiation Protection
New York State Department of Health
547 River Street, Room 530
Troy, New York 12180-2216

Robert Dansereau, Assistant Director
Bureau of Environmental Radiation Protection
New York State Department of Health
547 River Street, Room 530
Troy, New York 12180-2216

DISTRIBUTION:
Ray Lorson, RI, DNMS
Robert Lewis, FSME
Terry Reis, FSME
James Luehman, FSME
Duncan White, FSME
Lisa Dimmick, FSME
Monica Orendi, RI, SAO
Randy Erickson, RIV, SAO
Sandra Gabriel, RI
Shirley Xu, FSME
Stephen Poy, FSME
Maurice Heath, FSME
James Thompson, RIV
Michelle Beardsley, FSME
Karen Meyer, FSME

Ann Troxler, State of Louisiana
(Ann.Troxler@la.gov)

S:\!dnms\!sao\impeps\2011\New York\2011 NY Draft IMPEP Report.doc ML11196A207

ADAMS	✓ Yes ☐ No	☑ SUNSI Rev Complete	Reviewer Initials:	RRE
Publicly Avail	✓ Yes ☐ No	Non Sensitive		
RIV: RSAO				
RRErickson				
/RA/				
7/15/11				

OFFICIAL RECORD COPY T=Telephone E=E-mail F=Fax

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF THE NEW YORK AGREEMENT STATE PROGRAM

JUNE 6-16, 2011

DRAFT 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 New York Agreement State program is currently administered by three agencies including the New York City Department of Health and Mental Hygiene (NYC), the New York State Department of Health (DOH), and the New York State Department of Environmental Conservation (DEC). The review was conducted during the period of June 6-16, 2011, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Louisiana.

Based on the results of this review, the review team recommends that New York's performance be found unsatisfactory for two performance indicators reviewed; satisfactory, but needs improvement for two performance indicators reviewed; and satisfactory for the four remaining performance indicators reviewed.

The review team made five recommendations regarding the performance of the New York Agreement State Program. These recommendations, which are briefly described below, included areas for improvement to correct identified performance deficiencies and weaknesses in New York Agreement State Program. The review team recommends that for each of the individual Programs within the Agreement State Program that: (1) DOH develop and implement a process to track reciprocity inspections to ensure at least 20 percent of candidate licensees for reciprocity are inspected; (2) NYC respond to each incident received in accordance with their established Incident Response Procedure; (3) NYC modify their Incident Response Procedure to add timely notifications to the NRC Operations Center in accordance with the timelines identified in SA-300; (4) NYC evaluate all incident statistical information received from licensees, both past and future, and follow-up in a manner to ensure that each incident is properly evaluated for health, safety, and security implications; and (5) 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 SA-300.

The review team further recommends that the New York Agreement State Program be found adequate to protect public health and safety, but needs improvement, and not compatible with NRC's program.

Based on the results of the current review, the review team recommends that the period of Heightened Oversight continue and that the current Program Improvement Plan be revised to include those recommendations identified during the 2011 IMPEP review. The review team further recommends that a Periodic Meeting be held in approximately one year and that the next full IMPEP review take place in approximately four 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 June 6-16, 2011, by a review team comprised of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Louisiana. 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 a Final General Statement of Policy" published in the *Federal Register* on October 16, 1997, and the February 26, 2004, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results, which covered the period of November 10, 2006, to June 16, 2011, were discussed with New York management on the last day of the review.

[A paragraph on the results of the Management Review Board (MRB) meeting will be included in the final report]

The New York Agreement State program is currently administered by three agencies: (1) 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; (2) 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; 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 programs are included as Appendix B.

At the time of the review, the combined New York programs regulated approximately 1,500 specific licenses, including all major types of licenses with the exception of uranium mill tailings. The review focused on the radioactive materials program, as implemented 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 non-common performance indicators was sent to each of the three agencies on January 20, 2011 (ML110200486). Each agency provided an electronic response to the questionnaire; DEC on May 9, 2011; NYC on May 20, 2011; and DOH on May 23, 2011. A copy of the respective questionnaire responses can be found in the NRC's Agencywide Document Access and Management System (ADAMS) using the Accession Numbers ML111290549, ML111460424 and ML111460513. An update to the questionnaire response from NYC was received by email on June 9, 2011 and can be found under (ML to be added).

The review team's general approach for conduct of this review consisted of: (1) examination of each agency's response to the questionnaire; (2) review of applicable New York Statutes and regulations; (3) analysis of quantitative information from each agency's licensing and inspection database; (4) technical review of selected licensing and inspection actions; (5) field accompaniments of 11 State inspectors; and (6) interviews with staff and management to answer questions and to clarify issues. The review team evaluated the information gathered

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

On November 3, 2005, the Management Review Board (MRB) met to consider the findings of a Periodic Meeting with the New York Agreement State Program conducted on April 12-13 and 19, 2005. As a result, the MRB determined that the New York Agreement State Program should enter into a period of Heightened Oversight due to a number of overdue NRC amendments required for compatibility by each of the agencies that comprise the Agreement State program (ML053540394).

On February 8, 2007, the MRB again met to consider the findings of a full IMPEP review conducted on November 1-9, 2006. As a result, the MRB determined that the period of Heightened Oversight should be extended due to a lack of progress in eliminating the overdue amendments. As a result, each agency continued to have bimonthly calls to discuss their progress in adopting regulations; and, additional Periodic Meetings were held respectively with each agency on November 27, 28 and 29, 2007; and again on July 16, 28 and 29, 2009. Following each of the Periodic Meetings, the MRB convened and determined that the period of Heightened Oversight should continue.

Section 2.0 of the report discusses the State's actions in response to recommendations made during the previous IMPEP review. Results of the current review for the common performance indicators are presented in Section 3.0. Section 4.0 discusses results of the applicable non-common performance indicators, and Section 5.0 summarizes the review team's findings and recommendations. The recommendations made by the review team are comments that relate directly to performance by the State. A response is requested from the State to all recommendations in the final report.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous review, which concluded on November 9, 2006, two recommendations were left open from the previous (2002) review. No new recommendations were opened during the 2006 review. The review team's evaluation of the status of these recommendations is as follows:

1. The review team recommends that DEC transmit inspection findings to their licensees within thirty days after the close of the inspection. (Held open from Section 3.2.5 of the 2002 IMPEP review)

   Status: Based on the review of inspection casework and discussions with DEC staff, the review team found that DEC is issuing inspection findings in a timely manner. This recommendation is closed.

2. The review team recommends that each New York Agency (NYC, DOH and DEC) develop and implement an action plan to adopt NRC regulations in accordance with the current NRC policy on adequacy and compatibility. (Held open from Section 4.1.3 of the 2002 IMPEP review).

Status: The review team found that the NYC, DOH and DEC have each developed and implemented an action plan to adopt NRC regulations in accordance with the current NRC policy on adequacy and compatibility. Under Heightened Oversight, each Program's overdue regulations as identified on their current Program Improvement Plan (PIP) continue to be tracked and monitored. And while each Program is still working to achieve the ultimate goal of timely adoption of regulations, the action plans are in place and being followed. This recommendation is closed.

3.0 COMMON PERFORMANCE INDICATORS

IMPEP identifies five common performance indicators to be used in reviewing both 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

Evaluation of this performance indicator included a review of each agency's staffing level and staff turnover, as well as the technical qualifications and training histories of the staff. To evaluate these issues, the review team examined the respective program's response to the IMPEP questionnaire relative to this indicator, interviewed management and staff, reviewed job descriptions and training records, and considered any possible workload backlogs.

3.1.1 New York City Department of Health and Mental Hygiene

NYC is staffed by the Office Director, the Unit Chief for the Materials Program and seven technical staff members equaling a total of 4.7 full-time equivalents (FTE). There are currently no vacancies in this program. During the review period, one staff member transferred from the materials program to the Emergency Response Unit (ERU) and another individual was hired as a replacement.

Previously the ERU was responsible for conducting Increased Controls (IC) inspections for the Program. However, when the ERU expanded and became a Bureau, responsibility for IC inspections became the sole responsibility of the NYC program. With the advent of the Lower Manhattan Security Initiative, NYC inspectors in conjunction with the New York City Police Department now conduct joint IC inspections.

NYC requires a Bachelor's degree in engineering, physical or biological sciences for all technical positions. The review team reviewed the job descriptions as presented by the Office Director, for NYC Scientist I-III staff positions. The job descriptions identify the individual categories and described typical tasks required for the position. The review team found that the job descriptions are consistent with requirements for equivalent NRC positions. The review team also reviewed a portion of the NYC Policy and Procedure Manual dated 2004 as presented by the Unit Chief. This document describes in part, the requirements for training for new members of the field staff. New inspectors are required to attend the five week Applied Health Physics course (5 week course) offered by Oak Ridge Associated Universities (ORAU)

or a similar series of courses unless the individual's background is such that they already have similar training and experience.

The Unit Chief provided the team with a table breakdown of training that each inspector has completed. The review team noted that with the exception of attending NRC's S-201, "Material's Control and Security Course" (IC training course) no member of the staff had attended any technical training courses in several years.

During an accompaniment of an NYC inspector in May 2011, a question arose about the availability of NRC technical training courses. The inspector had been with the program for two years and had not been to any technical training outside of the IC training course, even though additional technical training had been requested various times. The inspector was considered fully qualified to perform all types of inspections independently; however, the inspector did not personally feel that NYC's on-the-job training philosophy fully prepared the staff to understand the technical aspects of several of the highly technical modalities the staff was required to inspect. The inspector stated that additional technical training would be of benefit, not only to him but to all the staff.

The inspector's training concerns were conveyed to the NYC Office Director and Unit Chief via email on May 12, 2011 (ML to be Added). Subsequently, on May 25, 2011, NYC filed an application with the NRC Agreement State Training Coordinator to have three NYC inspectors attend three separate basic training courses (ML to be Added). The inspector with the concern was included in this training request.

During the review another inspector was also interviewed. This inspector came to the NYC Program with a non-science degree. The inspector stated that the on-the-job training received had not been easy to complete as only certain inspectors enjoyed training and would readily share information. The inspector had been with the Program for five years and again, outside of the IC training course, had not been to any additional technical training courses, even though additional training had been requested on multiple occasions. The inspector stated that when a request for training was made to management, the response was "we'll see", after which nothing happened.

The review team provided this information to the Assistant Commissioner (AC) via email on June 15, 2011 (ML to be Added). The AC responded forwarding an email to the review team dated January 4, 2011, where training opportunities had been discussed with the Unit Chief (ML to be Added). The AC added in part, that NYC had been discussing training for several months; however, a cross-training initiative coupled with staff availability delayed their taking advantage of recent training opportunities. The review team determined that requests for additional technical training had been ongoing for several years without action. And while NYC managers began to discuss taking advantage of training in recent months, again nothing had been acted upon until a member of the review team documented and forwarded these requests to NYC management in May 2011.

The review team found that in the case of the two newest inspectors who upon their hire dates did not have technical backgrounds sufficient to exempt them from initial technical training, that NYC failed to follow their own training procedures and send the inspectors to the 5 week course as required. Based on the documentation provided to the review team by the Unit Chief, only

two individuals have attended the 5 week course, one with nearly 20 years experience and one with nearly 15 years experience. No other individuals have attended this training.

As noted in Appendix C, in May 2011, two inspectors were accompanied during an inspection at one NYC licensed facility. The most senior inspector reviewed the health and safety portion of the licensee's program, while the primary IC inspector reviewed the security portion of the licensee's program. While no noteworthy performance issues were identified on this one specific accompaniment, it should be noted that each inspector inspected the specific areas they had the most experience.

As noted in Section 3.5.1 of this report, the review team identified additional training concerns, specifically regarding incident reporting requirements. The team noted that in one case NYC staff reviewed a reported incident of an overdose to a fetus that occurred in 2007. NYC staff did not review the event when it was received. On June 13, 2011, during a daily management briefing, the AC stated that NYC had reviewed this event and determined it was not reportable. The review team questioned the AC about the specific date of that review. The AC stated that they had reviewed it the previous week (June 6-10, 2011). When the review team reviewed the incident, they not only determined that the incident was reportable to NRC within 24 hours, but it also met the Abnormal Occurrence (AO) reporting threshold. The review team found that no individual in the Program understood the reporting requirements or how to apply them for this specific event.

On another incident, NYC staff had determined that a medical event involving a therapeutic administration of samarium-153, where an approximate 30 percent under-dose occurred, was not reportable. However, the review team determined that this event met the reporting criteria found in SA-300. Again the review team found that no individual in the Program understood the reporting requirements or how to apply them for this specific event.

Subsequent to the review, on June 24, 2011, NYC reported a medical event that occurred on June 24, 2009 (EN 46981). This event involved a patient being injected with the wrong diagnostic isotope. A review of this event by a review team member found that this was not a reportable event. The Program was contacted by the Region I State Agreements Officer who again discussed reporting requirements with NYC staff.

The review team found that NYC staff has made requests for additional technical training which have, for the most part, not been acted upon until recently. The review team also noted that NYC could benefit from SA-300 training (reporting requirements) as the team had concerns about the ability of NYC to accurately apply the reporting requirements to incidents that occur within their jurisdiction.

3.1.2 New York State Department of Health

DOH is managed by the Director, the Assistant Director and four Section Chiefs. DOH has a total of 11.5 FTE in the materials program. There are currently no vacancies in this program. During the review period, one senior staff member was reassigned to the Laboratory and 10 other staff members left the program. These positions were permanently eliminated and represented an overall reduction of 6.2 FTE for the materials program. The review team noted

that over the course of the review most, if not all, of the deficiencies (timeliness and resources for program improvements) found within the Program were staffing related.

The Program has 36 total staff members who are responsible for licensing and inspection of approximately 1200 materials licensees, registration and inspection of approximately 11,000 X-Ray facilities, licensing and review of continuing education for approximately 20,000 licensed X-Ray technologists, supporting emergency response activities for three power reactor sites, environmental monitoring, and management of the Radon program. The Director and Assistant Director conduct mainly administrative activities. Program managers stated that they have been forced to take staff from the X-Ray program simply to maintain the materials program. They added that this movement of staff has reduced the effectiveness of the X-Ray program and some work remains uncompleted. The strain of the permanent staff losses has begun to erode the overall effectiveness of the Program and has resulted in reduced performance in some areas. While the review team did not note any performance issues where health, safety, and security was directly involved, the review team did note several areas within the Program where staff losses have resulted in deficiencies as noted throughout this report.

DOH staff is required to have a Bachelor's degree in physical and biological sciences. DOH reported that it does have a general training policy but not a formalized training process. While individual qualification type journals are maintained for the staff, they only attend training classes on an "as needed" basis. The Assistant Director stated that not all staff needs to attend all the training classes, especially under the strained staffing environment they operate in today. DOH has opted to train their staff in a mentorship type program where new staff are trained one-on-one directly with senior staff. The review team determined that DOH staff is well-qualified, based on education, experience and civil-service requirements.

DOH also faces the possibility of more staff losses in the future due to retirements, and anticipates that these positions may also be eliminated. To further complicate the situation, DOH is currently operating under a hard hiring freeze. No staff can be added and no exceptions to the freeze are allowed. Additionally, the State recently announced the possibility of another 10,000 statewide layoffs. How these additional reductions in staff might affect the Program is unclear at this time.

3.1.4 New York State Department of Environmental Conservation

DEC is managed by the Bureau Director and two Section Chiefs. DEC has a total of 5.75 FTE. There have been two vacancies in the program since 2008: an Environmental Radiation Specialist 2 position (West Valley Environmental Monitor) and an Environmental Program Specialist 2 position (LLRW Transporter Program). The Department has not yet requested waivers to fill those positions due to budget constraints. During the review period, the Radiological Sites Section Chief and a staff member in charge of low-level radioactive waste and regulatory development left the program. The staff member who previously filled the West Valley Environmental Monitor position was promoted to Section Chief, and that vacated position currently remains open. Also during the review period DEC hired three new staff members. The permitting and inspection activities of the program are performed by six staff members, with the rest of the staff dedicated primarily to contaminated sites as well as other activities not directly covered under the Agreement. All staff is involved in incident and emergency response activities.

DEC technical positions are required to have a Bachelor's degree in science or engineering and at least two years of experience in the environmental radiation field. From the review of the technical qualifications and discussions with current staff, the review team concluded that DEC has been able to hire qualified individuals.

Because of the small number of inspectors and permit reviewers, DEC has not developed a formal qualification program. DEC does have a documented training policy. Staff in the Radiation Control Permit Section must complete, at a minimum, the following courses: Applied Health Physics, Licensing Practices and Procedures, Inspection Procedures, and Air Sampling courses, as well as the 40-hour HAZWOPER course. All permit section staff have completed those minimum required courses. In addition, new Radiation Control Permit Section staff is trained individually by their supervisors in performing inspections and reviewing permit applications. Inspectors in training move through the following stages: (1) accompanying experienced inspectors, as observers; (2) assisting experienced inspectors; (3) taking the lead in inspections, assisted by experienced inspectors; and (4) performing inspections independently. Inspectors move through these stages based on the assessment of the Section Chief. The same staff is trained to review permit applications by first reviewing minor permit modifications and routine renewals, then applications of increasing complexity. All permitting decisions are reviewed by the Section Chief. The review team noted that DEC monitors training of personnel with a spreadsheet that is updated on a regular basis.

Environmental Radiation Specialist staff in the Radiological Sites Section must also complete courses in Applied Health Physics and 40-hour HAZWOPER, and additional courses in Environmental Monitoring, MARSSIM, and RESRAD, as appropriate for assignments.

DEC also faces the possibility of more staff losses in the future due to retirements and anticipates that these positions may also be eliminated. To further complicate the situation, DEC is currently operating under a hard hiring freeze. No staff can be added and no exceptions to the freeze are allowed. Additionally, the State recently announced the possibility of another 10,000 statewide layoffs. How these additional reductions in staff might affect the Program is unclear at this time.

3.1.5 Indicator Summary

The review team determined that the only Program that was fully staffed during the review period was the NYC Program. DOH appears to be under increasing strain due to several permanent staff losses in many key areas, and has begun to see visible signs of those stressors. While DEC is not fully staffed, they have been less affected by the staff losses. Regardless of the number of staff losses noted, the review team found no specific performance issues at this time where health, safety and security are concerned.

NYC has a documented training program; however, the review team determined that this procedure was not being implemented in all cases. Some NYC staff members interviewed have educational backgrounds in fields unrelated to the work they are performing and admit to being deficient in their knowledge of the license types/activities they inspect. Staff requests for training have only recently been approved by management.

Additionally, NYC staff has not demonstrated the ability to apply reporting criteria to incidents they have received. Serious events which were determined by the review team to meet the reporting criteria had been previously evaluated by NYC staff and found to not be reportable. Furthermore, NYC has also recently reported events that did not meet the reporting requirements. The review team believes that NYC staff would benefit from training on NRC reporting requirements.

Based on the IMPEP evaluation criteria, the review team recommends that New York's performance with respect to the 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 in reviewing the status of the material inspection program: inspection frequency, overdue inspections, initial inspections of new licensees, timely dispatch of inspection findings to licensees, and the performance of reciprocity inspections. The review team's evaluation is based on the individual programs' questionnaire responses relative to this indicator, data gathered from each program's licensing and inspection database, the examination of completed licensing and inspection casework, and interviews with management and staff.

3.2.1 New York City Department of Health and Mental Hygiene

The review team's assessment of NYC inspection priorities verified that inspection frequencies for various types of licenses are either the same as, or more restrictive than, those listed in Inspection Manual Chapter (IMC) 2800.

In their response to the questionnaire, NYC indicated that there were no Priority 1, 2, or 3 inspections overdue by more than 25 percent of their respective inspection frequency. The examination of the data and inspection files provided by NYC during the review confirmed that there were no overdue inspections. During the review period no core inspections and no initial inspections were performed overdue by more than 25 percent of their respective inspection frequency.

The timeliness of the issuance of inspection findings to licensees was evaluated during the inspection casework review. The team found that NYC does not actively track the timeliness of its issuance of inspection findings to licensees. Two of the forty inspections files reviewed contained inspection findings letters issued greater than 30 days.

NYC does not grant reciprocity to out-of-State licensees; therefore, this element of the indicator was not reviewed for this program.

3.2.2 New York State Department of Health

The review team's assessment of DOH inspection priorities verified that inspection frequencies for various types of licenses are the same as, or more restrictive than, those listed in IMC 2800.

In their response to the questionnaire, DOH indicated and the review team verified that seven Priority 1, 2, and 3 inspections were overdue at the time of the review. The review team determined that during the review period DOH performed 19 of its 556 Priority 1, 2, and 3 inspections overdue. All 25 initial inspections were performed within one year of license issuance. Overall, the review team calculated that DOH performed 4.3 percent of the Priority 1, 2, and 3, and initial inspections overdue.

The timeliness of the issuance of inspection findings to licensees was evaluated during the inspection casework review. The review team determined that 20 percent of all inspection findings letters to licensees were sent out greater than 30 days. The review team determined through discussions with Program Staff that issuance of inspection findings is not routinely tracked by the Program.

DOH only authorizes reciprocity for 30 days in a calendar year; as a result, many out-of-State licensees obtain a specific license. During the review period, DOH granted 101 out-of-State reciprocity approvals. The review team determined that DOH does not track the reciprocity inspections performed by its staff. When the review team requested reciprocity inspection files for the review period, DOH could only produce files for reciprocity inspections completed in calendar year 2010. Therefore, the review team could not determine the percentage of candidate reciprocity licensees that were inspected in 2007, 2008 and 2009. Upon examining the files for 2010, the review team found that two of seven candidate reciprocity licensees were inspected or 28 percent of candidate reciprocity licensees, which meets the 20 percent required by NRC Inspection Manual Chapter (IMC) 1220. The review team recommends that DOH develop and implement a process to track reciprocity inspections to ensure at least 20 percent of candidate licensees for reciprocity are inspected.

3.2.4 New York State Department of Environmental Conservation

DEC issues permits to facilities licensed by DOH to release radioactive effluents to the environment and inspects only those aspects of each facility's program affecting those releases. Due to the limited scope of DEC's program, they have established a policy of setting inspection frequencies for permittees based on the actual releases to the environment. Since the permittees are required to report their effluent releases to DEC annually, the Program may adjust their inspection frequency accordingly as releases to the environment change. The assigned frequencies for permittees can range from one to four years with most being inspected at three to four year intervals. The review team determined that these frequencies are adequate to protect public health and safety.

The review team confirmed that five of 72 inspections identified in the questionnaire were performed overdue and none of the three initial inspections were conducted overdue. The review team calculated that DEC performed six percent of its inspections overdue.

The timeliness of the issuance of inspection findings to licensees was evaluated during the inspection casework review. The team discussed issuance of inspection findings with Program management and staff and found that the Program was mistakenly informed that inspection findings should be issued within 30 business days. The team clarified that inspection findings should be issued within 30 calendar days. The review team evaluated letters transmitting the inspection findings to the licensees and found that all inspection letters reviewed were

transmitted within 30 business days from the date of the inspection. The Program manager acknowledged the discrepancy and committed to ensuring that inspection findings are issued within 30 calendar days from this point forward.

DEC does not grant reciprocity to out-of-State licensees; therefore, this element of the indicator was not reviewed for this program.

3.2.5 Indicator Summary

Overall, the review team found that the State performed less than 10 percent of Priority 1, 2, and 3, and initial inspections overdue.

The issuance of inspection findings to licensees for NYC was found to be timely. DOH issued approximately 20 percent of its inspection findings letters past 30 days. DEC was found to be timely with issuance of inspection findings; however there was a misconception with regards to 30 business days versus 30 calendar days.

Based on the information provided in the responses to the questionnaires, gathered during the evaluation of casework by the review team, and obtained during discussions with staff, the review team determined that DOH met the criteria in IMC 2800 for calendar year 2010, but was unable to make determinations for calendar years 2007, 2008 and 2009. The review team recommends that DOH develop and implement a process to track reciprocity inspections to ensure that at least 20 percent of candidate licensees for reciprocity are inspected.

Based on the IMPEP evaluation criteria, the review team recommends, 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 48 inspection files, including enforcement documentation and letters to licensees, and interviewed inspectors who were responsible for radioactive material inspections conducted during the review period. The casework reviewed included inspections performed by each of the State's three programs, and covered inspections of various types of licenses including medical institutions-with/without written directives required , high dose-rate remote afterloaders, gamma knife, brachytherapy, gauges, industrial radiography, radiopharmacy, manufacturing and distribution, research and development, academic and medical broad scope institutions, and irradiators. Appendix C lists the inspection casework files reviewed, with case-specific comments, as well as the results of the review team's inspector accompaniments.

The inspection procedures and techniques utilized by all programs were evaluated by the review team and were determined to be generally consistent with the inspection guidance provided in IMC 2800. Specific guidance for the various license types/activities is also included in the respective procedures manuals and/or checklists.

Based on the evaluation of the casework, the review team determined that inspection documentation for each of the three programs was sufficient to ensure that licensees' performance with respect to health and safety and security was acceptable. Documentation adequately supported the cited violations, recommendations made to the licensee, unresolved safety issues, and discussions held with the licensee during exit interviews. Team inspections were performed when appropriate and were also utilized for training purposes.

Review team members accompanied 11 inspectors from all three programs during the period of May 2 through June 3, 2011. The accompaniments included inspections of medical institutions, medical broad scope, industrial radiography, gauges, open air irradiators, effluent monitoring, Increased Controls and an accompaniment of an inspector during a waste site inspection. The facilities inspected are identified in Appendix C. During the accompaniments, each inspector demonstrated appropriate inspection techniques and knowledge of the regulations. The inspectors were prepared for the inspections, and thorough in their reviews of the licensees' radiation safety programs. Each inspector conducted confirmatory measurements and utilized good health physics practices. The inspections adequately assessed radiological health, safety and security at the licensed facilities.

The review team noted that all three programs had an adequate supply of portable radiation detection instruments for use during routine inspections and response to incidents and emergencies. Each program uses an outside vendor for instrument service and calibration, and/or has in-house capability to perform instrument calibrations. The portable instruments used during the inspector accompaniments were operational and calibrated. DOH and DEC have the capability to analyze alpha, beta, and gamma contamination samples and maintain their respective laboratory counting equipment.

3.3.1 New York City Department of Health and Mental Hygiene

The NYC inspection staff consists of four staff members plus a supervisor. Three of these individuals are being cross-trained to perform machine source (X-Ray) inspections. The inspectors are typically in the field Monday through Thursday of each week and in the office on Fridays.

NYC uses a compliance-based inspection approach. The inspection field notes contained adequate, consistent documentation of inspection findings. NYC divides its licenses into seven categories (limited non-human use, broad non-human use, broad human use, limited human use, teletherapy, and gamma knife). There are separate inspection field notes and checklist forms for each category except gamma knife, as well as a form for Increased Controls security inspections. NYC management noted that they are considering a change to performance-based inspections and agreed that inspection field notes forms will be updated, as needed, to correspond to the ongoing regulation revisions.

To ensure consistency of inspection documentation and findings, the inspection supervisor conducts reviews of the staff member's field notes. Although the inspection supervisor independently performed inspections, his work was not consistently reviewed by another supervisor or manager.

NYC has a policy of performing annual supervisory accompaniments of each inspector. Based on a review of records provided by NYC, the review team concluded that each inspector was accompanied by the supervisor at least once a year during the review period. Although the inspection supervisor independently performed inspections, he was not consistently accompanied each year by another supervisor or manager. NYC management agreed that annual accompaniments will be performed for the inspection supervisor.

The review team determined that inspection files for Increased Controls security inspections are stored in a secure location. The review team noted that these file folders are not marked as containing security-related information. In addition, letters to licensees containing security-related inspection information are not marked to indicate this. NYC management agreed to develop a system to distinguish file folders containing security-related inspection information and to begin marking letters to licensees containing security-related information.

3.3.2 New York State Department of Health

The DOH inspection staff is split between the central office and field offices. A field supervisor and 11 staff members are based in the central office, with 50 percent of the field supervisor's time and no more than 25 percent of each staff member's time assigned to radioactive materials compliance. Seven staff members are based in field offices, with four individuals assigned to devote at least 50 percent of their time to radioactive materials.

DOH uses a compliance-based inspection approach. The inspection field notes contained adequate, consistent documentation of inspection findings. DOH uses a series of forms to record field notes for different types of inspections, including medical, laboratory, PET cyclotron, nuclear pharmacy, other unsealed source, irradiator, fixed radioactive material device, portable radioactive material device, and Increased Controls. The review team determined that there are no formal inspection procedures; staff stated that the field note forms serve as inspection procedures and inspectors use NRC inspection procedures as references.

To ensure consistency and quality of inspection documentation and findings, the field supervisor conducts reviews of the staff members' inspection documentation. For central office staff, the field supervisor reviews the inspection field notes. For field office staff, the inspectors call the supervisor to discuss issues identified during inspections. The supervisor reviews a faxed copy of inspection letters sent by field office staff to licensees; however this is somewhat inconsistent for inspections in which no violations are identified. The supervisor agreed to develop a system to review inspection field notes for field office staff.

DOH has a policy of performing annual supervisory accompaniments of inspectors; however, these have been inconsistently performed. In the year preceding the on-site IMPEP review, 10 of 18 active inspectors were accompanied by a supervisor.

3.3.4 New York State Department of Environmental Conservation

The DEC inspection staff is split between two Sections, the Radiological Sites Section and the Radiation Control Permits Section. At the time of the review, the Radiological Sites Section had a Chief and six staff members. The Radiation Control Permits Section had a Chief and four staff members.

DEC uses a compliance-based inspection approach. During the review period, 72 inspections were conducted; 3 of those were initial inspections of new permits. The review team evaluated ten completed inspection reports and found the reports to be very thorough with inspection findings well documented. Inspection findings were consistently compared to the permit and regulatory requirements. Prior to the inspection, a full briefing is held between the inspectors, the Permit Unit Supervisor and the Section Chief to discuss the inspection. The review team found that unresolved issues, recent changes to the permit, and specific concerns of the inspector were well documented in the inspection reports. The completed reports were reviewed by supervisory personnel. Escalated enforcement procedures are in place and followed, as needed.

The review team evaluated the latest version of DEC's permit inspection and enforcement procedures and all current inspection forms. In general, all procedures and forms appear to be consistent with the applicable guidance found in IMC 2800.

The review team determined that supervisory accompaniments of DEC inspectors are conducted on an annual basis.

3.3.5 Indicator Summary

Team accompaniments of inspectors from the three programs demonstrated competent, thorough, safety-oriented inspections. The inspection processes and documentation for all programs were well implemented.

Based on the IMPEP evaluation criteria, the review team recommends that 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 the reviewers for specific licenses for each of the New York programs. A total of 48 licensing actions were examined, including new license issuances, terminations, amendments (including financial assurance and Increased Controls amendments), renewals, and modifications to permits (DEC). The actions reviewed encompassed the work of license reviewers currently with each Program as well as those who have left each Program during the review period. The sample included a variety of license types, including broad scope academic, broad scope medical, broad scope research and development, gamma knife, high dose-rate remote afterloaders, industrial radiography, irradiators, nuclear pharmacy, portable gauge, radioactive waste brokers, and veterinary teletherapy. A listing of the licensing casework reviewed, with case-specific comments, may be found in Appendix D.

Licensing actions were evaluated for completeness, consistency, proper isotopes and quantities used, qualifications of radiation safety officers and authorized users, adequate facilities and equipment, sufficient operating and emergency procedures, consideration of enforcement history on renewals, pre-licensing visits, peer or supervisory review as indicated, proper signature authorities, and overall technical quality. The casework was also checked for retention of necessary documents and supporting data.

3.4.1 New York City Department of Health and Mental Hygiene

The review team examined completed casework and interviewed license reviewers for licensing actions for NYC's 367 specific radioactive materials licenses over the review period. 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, security requirements, operating and emergency procedures, appropriateness of license conditions, and overall technical quality. The casework was also reviewed for use of appropriate correspondence, reference to appropriate regulations, supporting documentation, consideration of enforcement history, pre-licensing visits, peer and supervisory review, and proper signatures.

The review team noted that NYC does not use licensing check-lists designed to ensure consistency in licensing actions, and that licensing guidance documents used by NYC were developed in 1991. The review team discussed the advantages of using the most current guidance including the NUREG 1556 series of licensing guidance. The license reviewer interviewed stated he had never used the NUREG 1556 series when writing, renewing, or amending NYC licenses. He added that he has worked in this position and licensed in the same manner for the past 20 years, and had attended the NRC licensing course as well as one other NRC technical course years ago. Licenses are being amended by using the previous license issued and incorporating the requested changes.

The review team found that noted deficiencies in licensee submissions are often handled by undocumented telephone calls and e-mail. The review team discussed the importance of fully documenting licensee requests in response to license application deficiencies with NYC management and staff, noting that a complete and well documented licensing action assists the inspectors and demonstrates the steps taken by the license writer and the licensee, in order to issue an amended license.

The review team assessed NYC's implementation of NRC's pre-licensing guidance issued on September 22, 2008, and transmitted to the Agreement States via RCPD-08-020, "Requesting Implementation of the Checklist to Provide a Basis for Confidence That Radioactive Material Will Be Used as Specified on a License and the Checklist for Risk-Significant Radioactive Material." States were given 6 months from the date of the letter to incorporate the essential objectives of the revised pre-licensing guidance into their respective licensing programs.

Based on the licensing casework reviewed, the review team found that NYC had not implemented the essential elements of the pre-licensing guidance for any licensing actions initiated during the review period. Furthermore, NYC had not performed any pre-licensing visits. Since NYC failed to apply the guidance as required, NYC had no indication what licensees might require a pre-licensing visit. The review team suggested that NYC audit those licensing actions performed between the implementation dates of the guidance through the last date of the review and apply the guidance to determine if any licensing actions had been inappropriately issued. The review team also discussed the need to apply the pre-licensing guidance to all future licensing actions to determine and document the basis for confidence, that radioactive materials will be used as intended and as described in the application or amendment request, prior to authorizing the material on the license. On June 30, 2011, the review team received email notification from NYC indicating they had retroactively applied the pre-licensing

criteria to all new licenses issued since the November 2006 IMPEP review and found that none had met the threshold requirements requiring a pre-licensing site visit (ML to Be Added). Furthermore, in a follow-up email message dated July 1, 2011, NYC committed to using the pre-licensing guidance in the future (ML to Be Added).

The review team observed that NYC did not typically review the enforcement history during the license renewal process. The license reviewer stated that because he had not seen many enforcement actions in the licensee's files, he did not use them during a review for an amendment or a renewal. The review team expressed to the reviewer that license renewals are opportunities for the staff to review the licensee's history and to evaluate the historical licensing and inspection documentation and perform a quality assurance assessment of the license file.

The review team reviewed the license files for those licensees subject to the ICs. In 2005, in order to meet compatibility requirements, NYC submitted to the NRC, a proposed license condition and letter to implement the ICs. NRC approved the submitted license condition and letter; however, NYC never implemented the change and the license condition was never added to the applicable licenses. Instead, the review team found that NYC issued a Commissioner's Order to their IC licensees requiring them to implement the provisions of the IC Order. This Commissioner's order was never submitted to NRC for compatibility purposes. The team discussed the importance of this matter with management and reviewed the Commissioner's Order against the submitted license condition and letter. Subsequently NRC requested that NYC amend their IC licenses to incorporate the approved IC license condition as soon as possible. In an email dated June 16, 2011, the NYC AC stated that these changes would be completed by June 17, 2011 (ML to Be Added)

3.4.2 New York State Department of Health

The review team found that a random sampling of DOH's 1,094 licensing actions completed during the review period were thorough, complete, consistent, and of high quality with health and safety issues properly addressed. The licensee's compliance history is taken into account when reviewing renewal applications.

The review team noted that license conditions, including tie-down conditions, are stated clearly, backed by information contained in the file, and they appear enforceable. Deficiency letters are well-written, clearly indicate DOH's regulatory position, and are used at the appropriate times. License reviewers appropriately used DOH's licensing guides and standard license conditions. The review team found that the terminated licensing actions were well-documented, showing appropriate transfer and survey records. License reviewers have the proper signature authority for the cases they review. All licensing actions are peer reviewed by license reviewers for content, grammar, and format. Pre-licensing guidance is applied and pre-licensing visits are being performed where necessary.

The team also noted that DOH license amendments are issued as stand-alone documents. It is expected that the licensee keeps a copy of the original license and all subsequent amendments. This was initiated as a cost saving measure some time ago. The review team questioned this policy and asked DOH managers if they had considered this a potential security issue as it may be easier to produce a false amendment than an entire license. DOH managers did not see this as an issue.

The review team examined the licensees that DOH determined met the criteria for the Increased Controls, per COMSECY-05-0028. The review team determined that DOH had correctly identified the licensees that require Increased Controls based on these criteria, and will continue to issue Increased Controls to any additional licensees, as appropriate. Each license was amended to include the Increased Controls requirements as license conditions. DOH issued the Increased Controls in accordance with the timeline established by the NRC in the SRM for COMSECY-05-0028.

The review team noted that DOH currently has a total of 73 licenses that have been under timely renewal for more than one year. One license has been under timely renewal for the past 21 years, and 10 have been under timely renewal for more than 5 years. This issue was discussed with DOH managers who stated they will get the renewals completed. DOH attributed this backlog to a staffing issue. DOH added that this is an area where they have been forced to choose how to apply their limited resources and that they will try to finish them as soon as they can.

3.4.4 New York State Department of Environmental Conservation

The review team found that DEC's permitting actions were thorough, complete, consistent, and of high technical quality with health and safety issues properly addressed. Permit files contain extensive documentation of the permitting process, including memorandum and electronic mail messages between permit reviewers and senior management. Permit reviewers routinely conduct confirmatory inspections and calculations to verify permit holder status, commitments, and findings presented by permit holders during the permitting process. Permits issued by DEC often incorporate references and conditions related to other permits required by DEC. The review team determined that the permit holder's compliance history appeared to always be taken into account when reviewing renewal applications, as determined from documentation in the permit files and discussion with the permit reviewers.

The review team found that permit cancellation actions were well-documented, showing either survey findings or documentation that the permit holder's effluents did not exceed the 10 percent exemption limit. The casework review indicated that permitting staff follow their guides during the review process to ensure that the permit holders submit the information necessary to support a permit. The review team found the checklists and the worksheets for each type of permit to be comprehensive and incorporated excellent notes to reviewers to assist in the review of the applications. Permit tie-down conditions were stated clearly, backed by information contained in the file, and enforceable. Each permitting action receives a supervisory chain review. Letters of deficiency clearly stated regulatory positions, are used at appropriate times, and are signed by upper management.

Once DEC completes the permit review and drafts the permit document, DEC forwards the draft permit to one of nine permit administrators located throughout the State. The actual permit is then signed and issued by the permit administrator. The permit unit supervisor monitors the status of permits sent to the regional permit administrator for issuance, documents the status in monthly reports, and maintains contact with the regional permit administrator until the permit is issued. In the case of an excessive delay, metrics for the outstanding permit are communicated to DEC's Chief Permit Administrator for follow-up action.

3.4.5 Indicator Summary

The review team found several issues related to licensing that were discussed with the individual Programs.

In the case of NYC, they do not use licensing checklists to ensure consistency in licensing actions, the guidance documents they use for licensing are not the most current documents were last revised in 1991, and follow-up questions to licensing actions are often performed via undocumented telephone calls and email. The review team found that NYC had not implemented the pre-licensing guidance to determine if any licensing actions had been issued inappropriately, nor have they performed any pre-licensing visits. The team also noted that NYC did not review past enforcement history during the license renewal process as a means of performing quality assurance on the license file. Lastly, while NYC did issue a Commissioner's Order to implement the Increased Controls, they failed to incorporate an NRC approved IC license condition into the applicable licenses.

In the case of DOH, the review team found that DOH consistently applies the most current guidance, uses checklists to ensure consistency, and has implemented the pre-licensing guidance. However, the review team noted that licensing was another area within the DOH materials program where the lack of staff has begun to erode the efficiency of the Program. At the time of the 2006 review DOH had 33 licenses under timely renewal for more than one year. During the 2011 review, DOH now had 73 licenses under timely renewal for more than one year. Ten licenses have been under timely renewal for more than 5 years with one of those being under timely renewal for 21 years. DOH stated that licensing renewals is one of those areas that they don't believe to be as critical as other areas of the Program, and therefore have redirected their limited resources to areas they believe to be more critical.

In the case of DEC, the review team found them to be producing high quality work with little difficulty. While they are slightly down on staff, they have been able to keep up with the workload.

Based on the IMPEP evaluation criteria, the review team recommends that New York's performance with respect to the indicator, Technical Quality of Licensing Actions, be found satisfactory, but needs improvement.

3.5 Technical Quality of Incident and Allegation Activities

In evaluating the effectiveness of each program's actions in responding to incidents and allegations, the review team examined each program's response to the questionnaire relative to this indicator, evaluated selected incidents reported for New York in the Nuclear Materials Events Database (NMED) against those contained in the respective program's files, and evaluated the casework and supporting documentation for 18 radioactive materials incidents. A listing of the incident casework examined, with case-specific comments, may be found in Appendix E. The review team also assessed the responsible program's response to three allegations involving radioactive materials, including three allegations referred to the responsible program by the NRC during the review period.

The review team discussed incident and allegation procedures, file documentation, each

program's event and allegation tracking system, NMED, and notification of incidents to the NRC's Headquarters Operations Center based on the guidance in NRC's Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-300, "Reporting Materials Incidents", with the Program Managers and selected staff. The incidents included: lost/stolen materials, equipment failures/disconnects, contamination/spills, damaged devices and packages, and medical events.

3.5.1 New York City Department of Health and Mental Hygiene

The review team noted that NYC's questionnaire response indicated that no reportable incidents were received during the review period. Following discussions of this indicator with NYC staff and review of files, the team found that this was not correct.

NYC staff informed the review team that in 2009, NYC Department of Health and Mental Hygiene issued an Information Notice (2009-03) to remind Licensees and Certified Registrants of the requirements specified in Article 175 of the NYC Health Code for reporting medical events involving radiation. The reporting requirements apply to all radiation equipment and radioactive material use. Subsequent to the Information Notice, NYC sent Orders to licensees in 2009 and 2010, requesting information on the total number of treatments performed, and the number of recordable and reportable errors between year 2006 and 2009, as required by Health Code 175. Approximately 90 licensees responded. The review team reviewed the file of responses and identified two incidents that were reportable under NRC regulations: one report of a dose to an embryo/fetus and one medical event. The review team also noted that NYC had not identified these two incidents as being reportable to NRC. NYC staff reported that they had performed follow-up by e-mail to one of the two incidents and no follow-up to the other incident.

The first of the two incidents was originally reported to NYC in a fax letter from the licensee dated January 3, 2007; however, NYC has no record of receiving the 2007 information. The licensee provided this information again in 2009 in response to the NYC Orders. A patient with a negative pregnancy test was administered 95 mCi of iodine-131 on September 22, 2006. It was later determined that the patient was pregnant at the time of the administration. The reported estimated dose to the embryo/fetus was 25 rad. This case met the NRC reporting requirements in 10 CFR 35.3047 for dose to an embryo/fetus as well as the Abnormal Occurrence (AO) reporting requirements. Following discussion with the IMPEP team, NYC reported this incident to the NRC Operations Center on June 15, 2011, during the IMPEP review.

The second of the two incidents was originally reported to NYC in a letter from the licensee dated October 6, 2009. On that date, a patient was administered a therapeutic dosage of samarium-153 that was determined to be approximately 30 percent less than the prescribed dose. This case met the NRC medical event reporting requirements in 10 CFR 35.3045. Following discussion with the IMPEP team, NYC reported this incident to the NRC Operations Center on June 15, 2011, during the IMPEP review.

The review team identified a third incident reported by an NYC licensee that was not required to be reported to the NRC (EN46891). On June 24, 2009, a patient was intended to receive a diagnostic administration of thallium-201, however they were erroneously administered

gallium-67. The dosimetry information provided by the licensee demonstrated that this incident did not meet the medical event reporting requirements in 10 CFR 35.3045; however, on June 24, 2011, NYC reported this event to NRC believing it was a reportable event.

Based on the response to the request for information from their licensees, NYC staff developed a summary document entitled "Summary of Misadministrations for NYC 2006-2009". This document included statistical information from 14 licensees of reportable/recordable incidents between 2006 and 2009 and included both radiation equipment and radioactive materials incidents. While on site, the review team made several requests for documentation to determine how NYC evaluated the statistical information received from licensees, what type of follow-up they performed, and if any follow-up was performed in accordance with their Policy and Procedure Manual for Incident Response. On June 15, 2011, NYC notified the review team that they had not followed up on the statistical information received from their licensees. On June 16, 2011, during the final exit meeting with the State, the AC reversed his position and stated that NYC had followed up on each of the events and did have documentation to demonstrate they had followed up on each of the incidents. NYC stated they would send the information to the team by June 22, 2011.

On June 28, 2011, the review team received documentation from NYC and determined that three follow-up inspections were performed subsequent to the on-site review for the three incidents described above. For the dose to embryo/fetus incident that occurred on September 22, 2006, a follow-up inspection was performed on June 16, 2011. For the medical event that occurred on October 6, 2009, a follow-up inspection was performed on June 20, 2011. For the non-reportable incident that occurred on June 24, 2009, a follow-up inspection was performed on June 24, 2011.

On June 28, 2011, NYC also submitted a summary of "Institutions with Confirmed Incident Reports for NYC 2006-2009." This table showed a total of 14 reported events with 7 of them being subject to reporting. The letter did not contain any information as to whether additional reports will be made to the NRC or if NYC performed any follow-up investigations/inspections in accordance with NYC incident follow-up procedures.

Based on the above noted issues related to incident identification and follow-up, the review team is recommending the following:

The review team recommends that NYC respond to each incident received in accordance with their established Incident Response Procedure.

The review team recommends that NYC modify their Incident Response Procedure to add timely notifications to the NRC Operations Center in accordance with the timelines identified in SA-300.

The review team recommends that NYC evaluate all incident statistical information received from licensees, both past and future, and follow-up in a manner to ensure that each incident is properly evaluated for health, safety, and security implications.

Additionally, the review team assessed NYC's response to one allegation involving radioactive material during the review period. The review team noted that NYC performed a

prompt and appropriate on-site investigation. The alleged radiation safety concerns were not substantiated, and proper follow-up, notification and close-out were made.

3.5.2 New York State Department of Health

During the review period, DOH investigated 279 incidents. The review team evaluated 13 incidents requiring reporting to the NRC and three allegations. DOH utilizes a newly established automated incident/event tracking system called "Incident." This database is tied directly to DOH's licensing/inspection database and prompts the user to investigate the root cause or contributing factors surrounding each incident. There is also a reminder to notify NRC, as appropriate. The "Incident" database permits the staff to identify incidents and to follow trends. Incidents and allegations are posted to the individual licensing and inspection files for follow-up action, as appropriate. DOH's response to incidents and allegations are investigated based on their radiological health and safety significance. On-site investigations are well-documented, prompt, and comprehensive. Initial responses were coordinated and complete, and the level of effort was commensurate with the health and safety significance. Inspectors were promptly dispatched for on-site investigations, when appropriate, and took suitable enforcement action. Corrective actions were appropriately followed up during the course of the incident's investigation and prior to closure.

The review team reviewed the files for approximately half of all incidents (414) that were reported to DOH during the review period. These include both material and non-material incidents. During the review period, DOH reported 26 incidents (not including Wal-Mart Exit Signs) to the NRC Operation Center. Of those 26 reported incidents, only three were reported in accordance with the timeliness requirements found in SA-300. Of approximately 200 incident files reviewed, the review team identified eight incidents that should have been reported but were not. The review team notified DOH of the 8 unreported incidents and before the review was completed, DOH was already working on reporting these incidents. The review team also informed DOH that they needed to perform a review of the additional 200 incident files to determine if additional incidents should be reported to NRC. DOH agreed to begin that review and notify NRC when it was completed. In reviewing incident and allegation response procedures, the team found that DOH does not have a documented incident response procedure, nor does DOH have a comprehensive allegation response procedure. The review team recommends 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 SA-300.

3.5.4 New York State Department of Environmental Conservation

The review team evaluated DEC's response to two radioactive material incidents. DEC's response to incidents was complete and comprehensive. The staff's initial responses were prompt, well-coordinated and at a level commensurate with the health and safety significance of the incident. DEC dispatched inspectors for on-site investigations, as appropriate, and took enforcement and follow-up action, as needed. DEC did not have any incidents that met the criteria for reporting to NMED. The review team assessed DEC's response to one allegation involving radioactive material. Prompt and appropriate investigations were conducted through on-site and telephone contact with the allegers. The

alleged radiation safety concerns were not substantiated and proper follow-up, notification, and close-out were made.

3.5.5 Indicator Summary

The review team found several issues related to incident identification, application of reporting regulations, and timeliness in reporting that were discussed with the individual Programs.

In 2009, NYC issued Information Notice 2009-03 reminding their licensees of the regulatory requirement to report incidents. Subsequently they were forced to issue Orders to their licensees to get them to report statistical incident information. Once the information was received, NYC did not promptly perform a review to determine whether these incidents were reportable. For events they were aware of, staff was unable to accurately apply the reporting criteria as they failed to report events that were reportable. Additionally, subsequent to the review, NYC again demonstrated their inability to apply the reporting criteria by reporting an incident that was not reportable.

While DOH is able to apply the reporting criteria to incidents under their jurisdiction, they have experienced difficulties in timely reporting. During the review period, DOH reported 26 incidents of which 23 were not reported in a timely manner. DOH attributes this issue to the lack of staff. Additionally, DOH has also experienced difficulty in identifying reportable events. Of approximately 200 incident files reviewed by the review team, 8 reportable incidents were found to have not been reported. DOH has another 200 files to review to determine if any additional incidents should have been reported.

While DEC has far fewer incidents to respond to, the manner in which they respond is timely and efficient. The team found no issues with DEC's incident response or allegation processes.

Based on the IMPEP evaluation criteria, the review team recommends that New York's performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, be found unsatisfactory.

4.0 NON-COMMON PERFORMANCE INDICATORS

IMPEP identifies four non-common performance indicators to be used in reviewing 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. New York State does not currently have a Uranium Recovery Program, therefore, only the first three non-common performance indicators were applicable to this review.

4.1 Compatibility Requirements

4.1.1 Legislation

New York became an Agreement State on October 15, 1962. Historically, there have been four separate programs regulating ionizing radiation in the State of New York; NYC, DOH, New York State Department of Labor (DOL), and DEC. Due to the merging of DOH and DOL in 2006

there are now only three programs; NYC, DOH, and DEC. 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). 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. DOH's legislative authority to administer its portion of the Agreement with the NRC is granted in New York Public Health Law, Article 2, Title II, Sections 201 and 225. Effective July 1, 2006, Part B of Chapter 58 of the Laws of 2006 (S6458/A9558-B) merged the radioactive materials program of DOL with DOH. DEC Law Articles 1, 3, 17, 19, 29 and 37 are the basis to create DEC and implement a portion of the Agreement with the NRC.

4.1.2 Program Elements Required for Compatibility

The review team assessed the status of the regulations required for adoption, evaluated each program's response to the questionnaire, 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 NRC's State Regulation Status Data Sheet. Interviews were conducted with the staff and files were reviewed to confirm the use of license conditions when regulations were not adopted within the 3-year time frame.

The review team found that all programs provide the opportunity for public comment during the regulatory adoption process. The regulations for all programs are not subject to sunset provisions.

NYC regulations are found in Article 175 of the New York City Health Code. NYC's regulatory adoption process can take upwards of two years to complete, depending on the complexity of the rule change.

Since the 2006 IMPEP review, NYC has adopted thirteen NRC amendments.

For NYC, the following eight NRC amendments are overdue for adoption:

- "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.

- "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.

- "Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use," 10 CFR Parts 30, 32, and 35 amendments (59 FR 61767; 59 FR 65243; 60 FR 322), that became effective on January 1, 1995 and was due for Agreement State adoption by January 1, 1998.

- "Minor Corrections, Clarifying Changes, and a Minor Policy Change," 10 CFR Parts 20, 35, and 36 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.

- "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.

- "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.

- "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.

- "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.

For NYC, the following NRC amendment will need to be addressed in upcoming rulemakings or by adopting alternate legally binding requirements:

- "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 regulations are found in 10 NYCRR Chapter 1, Part 16 (Ionizing Radiation), Part 76 (Public Health Administrative Tribunal), and Part 405 (Hospitals-Minimum Standards) of the New York State Public Health Code. DOH's regulatory adoption process takes approximately two years, dependent on the complexity of the rule change.

Since the 2006 IMPEP, DOH adopted eleven NRC amendments.

For DOH, the following 16 NRC amendments are overdue for adoption:

- "Quality Management Program and Misadministrations," 10 CFR Part 35 amendment (56 FR 34104), that became effective on January 27, 1992 and was due for Agreement State adoption by January 27, 1995.

- "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.

- "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.

- "Radiological Criteria for License Termination," 10 CFR Parts 20, 30, 40, and 70 amendments (62 FR 39057), that became effective August 20, 1997 and was due for Agreement State adoption on August 20, 2000.

- "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.

- "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.

- "Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material," 10 CFR Parts 30, 31, and 32 amendments (65 FR 79162), that became effective on February 16, 2001 and was due for Agreement State adoption on February 16, 2004.

- "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.

- "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.

- "Financial Assurance for Materials Licensees," 10 CFR Parts 30, 40, and 70 amendments (68 FR 57327), that became effective on December 3, 2003, and was due for Agreement State adoption by December 3, 2006.

- "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 April 24, 2005.

- "Minor Amendments," 10 CFR Parts 20, 30, 32, 35, 40, and 70 amendments (71 FR 15005), that became effective on March 27, 2006, and is due for Agreement State adoption by March 27, 2009.

- "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.

- "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.

- "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.

- "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.

For DOH, the following NRC amendment will need to be addressed in upcoming rulemakings or by adopting alternate legally binding requirements:

- "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.

DEC regulations are found in 6 NYCRR Chapter IV, Subchapter C, Parts 380, 381, 382, 383, and 384 and apply to environmental releases and disposal of radioactive material. 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 LLRW shipments into, within, and through New York State. DEC's regulatory adoption process takes approximately two years to complete if there are no mitigating factors.

Since the 2006 IMPEP, DEC adopted two NRC amendments.

For DEC, the following eight NRC amendments are overdue for adoption:

- "Notification of Incidents," 10 CFR Parts 20, 30, 31, 34, 39, 40, and 70 amendments (58 FR 64980), that became effective on October 15, 1991, and was due for Agreement State adoption by August 15, 1994.

- "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.

- "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.

- "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.

- "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.

- "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.

- "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.
- "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.

4.1.3 Indicator Summary

The review team noted that all programs continue to have an extensive number of overdue NRC amendments. The review team concluded that the delay in the promulgation of regulations was caused in part by the need to address higher priority issues that may affect public health and safety, and the State's lengthy promulgation process. All three Programs currently have in place a performance improvement plan (PIP) that addresses each Program's plan for adopting overdue NRC regulations. The team reviewed these plans and noted that some overdue regulations were not incorporated into the current PIPs. The PIP for each Program should be revised to incorporate any missing overdue NRC amendments and to incorporate each Program's plan for adoption.

Based upon the IMPEP evaluation criteria, the review team recommends that New York's performance with respect to the indicator, Compatibility Requirements, be found unsatisfactory.

4.2 Sealed Source and Device (SS&D) Evaluation Program

The New York State Department of Health has sole responsibility for performing SS&D evaluations in the State of New York. Three sub-indicators were used to evaluate the Department's performance regarding the SS&D Evaluation Program. These sub-indicators are: (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 Department's SS&D Evaluation Program, the review team examined information gathered from data contained in the National Sealed Source and Device Registry. In the IMPEP questionnaire response, the Department indicated that three SS&D evaluations had been performed since the previous IMPEP. However, during the review, the team determined that actually four SS&D evaluations had been performed since the previous IMPEP. The review team assessed the documentation for the four SS&D evaluations performed and interviewed staff and management involved in SS&D evaluations.

4.2.1 Technical Staffing and Training

The team found that DOH currently has two reviewers who are considered qualified by the Program to conduct and sign safety evaluations of SS&D applications. Both have attended training the Program requires for qualification. The team also noted that the current manager responsible for oversight of the SS&D program is not a qualified reviewer and is therefore not qualified to perform secondary reviews. The team noted that for each of the reviews conducted during the review period, secondary reviews had been performed by a former Program Manager who had been qualified to perform the reviews.

The review team interviewed the current SS&D reviewers and found them to be familiar with the SS&D evaluation process, as well as available guidance and reference documents. While the team did not note any performance issues associated with the Program's SS&D reviews, the review team found that DOH does not have a formal qualification program. They also do not have a set number of reviews to be conducted by each individual prior to being considered qualified to independently perform SS&D reviews. This is mainly due to the low number of evaluations performed annually. Program management authorizes signature authority after the individual has completed required training classes.

DOH provided the training policy used by the Program for SS&D reviewers in training. The review team determined, based on Program requirements for qualification, that the reviewers appear qualified to review and sign SS&D evaluations, and that the DOH appears to have a sufficient number of qualified reviewers to adequately handle their workload.

4.2.2 Technical Quality of the Product Evaluation Program

DOH processed four new SS&D applications since the last review and performed no amendments to existing SS&D evaluations. A listing of the SS&D certificates evaluated by the review team, with case specific comments, can be found in Appendix F. The casework review indicated that DOH 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 evaluation-qualified reviewer. The review team found no health and safety issues relative to the SS&D evaluations.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

DOH staff was not aware of any defects or incidents involving sources and devices evaluated by their program. The review team conducted a search of NMED and DOH files which confirmed this.

4.2.4 Indicator Summary

DOH performed four SS&D evaluations since the last IMPEP review. These evaluations adequately addressed health and safety issues and were of sufficient technical quality.

Based on the IMPEP evaluation criteria, the review team recommends 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 (LLRW) Disposal Program

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. 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 permit for the SDA from the DEC, which regulates monitoring and maintenance of the facility. NYSERDA also holds a radioactive materials license from the Industrial Unit for the West Valley Site.

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. Low-level 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. The review team reviewed a substantive permit issued by DEC in April 2002 authorizing discharges of radioactive materials, the presence of which is incidental to discharges of the groundwater treatment system. When remedial activities required by the Consent Order have ended, DEC will issue a permit through the radiation program for monitoring and maintenance activities at the RDS.

4.3.1 Technical Staffing and Training

Currently, one DEC inspector is assigned to conduct inspections and environmental monitoring at the West Valley site, and inspections at Cornell disposal site. At times, the staff from DEC regional offices accompanies the inspector to observe and to assist with inspections and sampling. The review team evaluated the training, experience, and the educational qualifications for this inspector. DEC uses a mentor approach for training inspectors. The Section Chief will accompany the inspector and verify that inspection procedures and protocol are followed on the inspection. The DEC inspectors have the proper education qualifications and experience and take the necessary courses to prepare them for the job. While the review team noted no performance issues, they did note that DEC had no formal training program to document and track staff training. While DEC inspectors were well qualified and well trained, DEC managers determined their program could benefit from formally documenting training within the Program and immediately began developing a process to document and track training for DEC inspectors.

DOH's low-level waste inspectors are also trained in a manner similar to DEC inspectors. While the review team again noted no performance issues, they noted that DOH also had no formal training program to document and track staff training. While DOH inspectors are also well qualified and well trained, DOH management believes that the current manner in which they develop staff is sufficient and did not see a need to make any changes at this time.

4.3.2 Status of Low-Level Radioactive Waste Disposal Inspections

Both DEC and DOH have one year inspection frequencies at West Valley. DEC has a one year frequency for the Cornell site as well. The review team confirmed that DOH inspected the West Valley license annually.

DEC inspected the West Valley site four times during the review period of November 2006 to June 2011. West Valley was inspected October 2006, September 2009, October 2010 and June 2011. DEC did not have a documented inspection of the West Valley site in 2007 or 2008. The DEC staff admitted they did not have an official site inspection for a 25 month period. They explained that most efforts were involved with participating in a DOE, NRC and EPA working group focused on the development of an Environmental Impact Statement for West Valley. In 2007 DEC hired an inspector who has the responsibility of carrying out inspections at the West Valley disposal site and Cornell disposal site. DEC acknowledged that they missed two inspections and has taken actions to correct their program with yearly inspections being performed as required in 2009, 2010 and 2011. Regarding the timeliness of inspection reports, the review team noted that three of the inspection reports were issued greater than 30 days after the completion of the inspection. It was noted that DEC was issuing their inspection reports within 30 business days rather than 30 calendar days as required due to a miscommunication. The review team clarified the requirement and DEC has made the necessary change.

The review team also reviewed DOH's inspections for their Radiological Environmental Monitoring Program at West Valley. The inspections were completed on time throughout the review period. The team found that DOH issued their inspection reports to NYSERDA within 30 business days of completion of the inspection. DOH expressed interest in changing the frequency of their inspection or asking for assistance from DEC however with any change to their program DOH will need to develop a technical justification and update their inspection procedures.

4.3.3 Technical Quality of Inspections

The review team evaluated all DEC and DOH inspection reports and found the scope and quality of the reports to be complete and thorough, and emphasized public health and safety, as well as protection of the environment. Overall, the inspection reports were of high technical quality. DEC inspects the burial sites for fence and trench cover integrity. Drainage basins, storage buildings, surrounding land surfaces, and surface water drainage pathways are also inspected. In addition to the routine inspections, pre-operational and follow-up inspections, as well as site visits in conjunction with various stakeholders, are conducted by DEC staff.

DEC conducts environmental monitoring at the burial sites, which includes gamma radiation measurements using thermoluminescent dosimeters (TLDs), as well as surface water and

sediment sampling. At West Valley, TLDs are placed along the boundary fence line, at each of the three off-site creeks, the nearest residence, Sardinia and Rock Spring Road. Surface water and sediment samples are collected from the three creeks.

The DEC inspector has been accompanied by a supervisor annually during the last three field inspections. The review team found this frequency acceptable given the small number of inspections performed by the DEC staff.

4.3.4 Technical Quality of Licensing

DOH has issued a radioactive material license to NYSERDA authorizing possession of the wastes previously disposed of at West Valley, management and maintenance of West Valley, and possession and treatment of radioactive solids and liquids generated as a result of management and maintenance activities. The license covers the on-site radiation control program, occupational exposure of individuals, and control of radioactive material as it affects occupational exposures. The review team evaluated a Radioactive Materials License renewal issued by the DOH for this license and found all associated licensing actions thorough, complete, and of high technical quality.

DEC has issued one permit to NYSERDA that authorizes the maintenance and monitoring of West Valley and the operation of the West Valley facilities for the purpose of controlling discharges of radionuclides to the environment. The permit was issued in 2009 in accordance with applicable provisions of the Environmental Conservation Law. The review team evaluated the permit and found all associated actions thorough, complete and of high technical quality.

4.3.5 Technical Quality of Incidents and Allegations

DEC had one incident at the West Valley disposal site during the review period. West Valley's trench 5, 6 and 7 suffered a tear in the geomembrane that covers the disposal cells. The review team evaluated the procedures and protocols for reporting incidents as well as the follow-up actions.

The licensee, NYSERDA, notified DEC of the incident shortly after the problem was discovered. DEC followed up with communication to their regional office, DOH, DOE West Valley and all necessary entities that have any authority at West Valley. The review team noted that DEC conducted an inspection of the trenches, met with the licensee to develop a strategic plan and was present during repairs. DEC was very timely with their documentation, communication, and associated inspections and follow-up. The review team found that DEC procedures and protocol in handling incidents to be very thorough, complete and of high quality.

4.3.6 Indicator Summary

The review team found that oversight of the two former radioactive waste disposal sites by DEC and the DOH is suitable and thorough.

Based on the IMPEP evaluation criteria, the review team recommends 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 2.0, 3.0, and 4.0 above, the review team recommends that New York's performance be found unsatisfactory for the performance indicators, Technical Quality of Incident and Allegation Activities and Compatibility Requirements; and satisfactory, but needs improvement for the performance indicators, Technical Staffing and Training and Technical Quality of Licensing Actions. The review team found New York's performance to be satisfactory for the other indicators reviewed. The review team made five recommendations regarding the performance of the State. Overall, the review team recommends that the New York Agreement State Program be found adequate to protect public health and safety, but needs improvement, and not compatible with NRC's program.

Based on the results of the current IMPEP review, and in accordance with the criteria in NRC Management Directive 5.6, the review team recommends that the period of Heightened Oversight continue for the State of New York. The review team further recommends that a Periodic Meeting be held within 1 year to assess the State's progress in addressing the open recommendations and that the next IMPEP review be performed in approximately four years.

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

RECOMMENDATIONS

1. The review team recommends that DOH develop and implement a process to track reciprocity inspections to ensure at least 20 percent of candidate licensees for reciprocity are inspected.

2. The review team recommends that NYC respond to each incident received in accordance with their established Incident Response Procedure.

3. The review team recommends that NYC modify the Incident Response Procedure to add timely notifications to the NRC Operations Center in accordance with the timelines identified in SA-300.

4. The review team recommends that NYC evaluate all incident statistical information received from licensees, both past and future, and follow-up in a manner to ensure that each incident is properly evaluated for health, safety, and security implications.

5. The review team recommends 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 SA-300.

LIST OF APPENDICES

Appendix A	IMPEP Review Team Members
Appendix B	New York Organization Charts
Appendix C	Inspection Casework Reviews
Appendix D	License Casework Reviews
Appendix E	Incident Casework Reviews
Appendix F	Sealed Source and Device Casework Reviews

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	**Area of Responsibility**
Randy Erickson, Region IV	Team Leader Technical Staffing and Training (NYC) Inspector Accompaniments (DOH and NYC)
Monica Orendi, Region I	Status of Materials Inspection Program Compatibility Requirements
Sandra Gabriel, Region I	Technical Quality of Inspections (DOH and NYC)
Shirley, Xu, FSME	Technical Quality of Licensing Actions (DEC) Technical Quality of Inspections (DEC) Technical Quality of Incident and Allegation Activities
Stephen Poy, FSME	Technical Staffing and Training (DOH and DEC) Sealed Source and Device Evaluation Program
Maurice Heath, FSME	Low-Level Radioactive Waste Disposal Program
James Thompson, Region IV	Inspector Accompaniments (DOH and DEC)
Ann Troxler, Louisiana	Technical Quality of Licensing Actions (DOH and NYC)

APPENDIX B

NEW YORK ORGANIZATION CHARTS

ADAMS ACCESSION NOs.:

ML111460433 – New York City Department of Health and Mental Hygiene
ML111460503 – New York State Department of Health
ML111290559 – New York State Department of Environmental Conservation

APPENDIX C

INSPECTION CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT ARE INCLUDED FOR COMPLETENESS ONLY.

New York City Department of Health and Mental Hygiene

File No.: 1
Licensee: Staten Island University Hospital — License No.: 91-2840-01
Inspection Type: Routine, Unannounced — Priority: 2
Inspection Date: 4/13/10 — Inspector: OA

File No.: 2
Licensee: Weill Medical College of Cornell University — License No.: 91-3197-01
Inspection Type: Routine, Unannounced — Priority: 3
Inspection Date: 6/23/08 — Inspector: EC

File No.: 3
Licensee: Columbia-Presbyterian Medical Center — License No.: 52-2878-04
Inspection Type: Routine, Announced — Priority: 3
Inspection Date: 12/14/06 — Inspector: JH

File No.: 4
Licensee: Lenox Hill Hospital — License Nos.: 91-2926-01
Inspection Type: Special, Announced — 92-2926-02
Inspection Date: 5/11/11 — Priority: 2
Inspector: MR

File No.: 5
Licensee: Columbia-Presbyterian Medical Center — License Nos.: 74-2878-03
Inspection Type: Special, Announced — 75-2878-01
Inspection Date: 1/26/10 — 93-2878-05
Priority: 2
Inspector: MR

File No.: 6
Licensee: The Museum of Modern Art — License No.: 52-2851-01
Inspection Type: Routine, Unannounced — Priority: 5
Inspection Date: 5/22/08 — Inspector: JL

Comment:
No supervisory review.

File No.: 7
Licensee: George Varsos, M.D. — License No.: 91-3126-01
Inspection Type: Routine, Announced — Priority: 2
Inspection Date: 6/11/09 — Inspector: JH

File No.: 8
Licensee: Frederick Feuerbach, M.D. — License No.: 91-3231-01
Inspection Type: Routine, Announced — Priority: 5
Inspection Date: 12/12/06 — Inspector: HT

File No.: 9
Licensee: New York City Veterinary Specialists License No.: 52-3334-01
Inspection Type: Routine, Announced Priority: 5
Inspection Date: 5/3/07 Inspector: HT

Comment:
Report states inspection performed on 5/3/07. Letter to licensee refers to inspection performed on 5/10/07.

File No.: 10
Licensee: K. Peter Rentrop, M.D. License No.: 91-3262-01
Inspection Type: Routine, Unannounced Priority: 5
Inspection Date: 6/10/09 Inspector: JH

File No.: 11
Licensee: Long Island Jewish Medical Center License No.: 75-2986-01
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 3/10/09 to 3/23/09 Inspector: JH

File No.: 12
Licensee: Shirish Thanawala, M.D. License No.: 91-2866-01
Inspection Type: Routine, Unannounced Priority: 5
Inspection Date: 11/10/09 Inspector: OA

File No.: 13
Licensee: Memorial Sloan-Kettering Cancer Center License No.: 75-2968-01
Inspection Type: Routine, Announced Priority: 2
Inspection Date: 12/21/06 Inspector: EC

File No.: 14
Licensee: Beth Israel Medical Center License No.: 91-2897-01
Inspection Type: Routine, Announced Priority: 2
Inspection Date: 2/5/08 Inspector: OA

File No.: 15
Licensee: The New York Hospital Medical Center of Queens License No.: 91-2894-01
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 10/24/07 Inspector: JH

File No.: 16
Licensee: Lenox Hill Hospital License No.: 91-2926-01
Inspection Type: Follow-up, Unannounced Priority: 2
Inspection Date: 3/22/07 Inspector: JL

Comment:
No supervisory review.

File No.: 17
Licensee: Lenox Hill Hospital License No.: 92-2926-02
Inspection Type: Routine, Unannounced Priority: 5
Inspection Date: 5/3/10 Inspector: JH

New York State Department of Health

File No.: 18
Licensee: Massena Memorial Hospital License No.: 3248
Inspection Type: Routine, Unannounced Priority: 5
Inspection Date: 10/30/07 Inspector: SG

File No.: 19
Licensee: William Bradley, DVM License No.: 3114
Inspection Type: Routine, Unannounced Priority: 5
Inspection Date: 5/13/08 Inspector: AD

File No.: 20
Licensee: Able Testing & Inspection, Inc. License No.: C2555
Inspection Type: Routine, Special, Announced Priority: 1
Inspection Date: 12/21/09 Inspector: DG

Comment:
Inspection performed 44 days overdue. Inspection documentation issued to licensee 59 days after inspection.

File No.: 21
Licensee: Utica College License No.: 1143
Inspection Type: Routine, Unannounced Priority: 5
Inspection Date: 12/10/09 Inspector: WV

File No.: 22
Licensee: Northern Westchester Hospital Center License No.: 0585
Inspection Type: Routine, Special, Unannounced Priority: 2
Inspection Date: 5/22-5/23/07 Inspector: AB

File No.: 23
Licensee: Buffalo Cancer Center License No.: 5041
Inspection Type: Routine, Special, Unannounced Priority: 2
Inspection Date: 6/11/10 Inspector: CB/SK

File No.: 24
Licensee: SJB Services, Inc. License No.: C2542
Inspection Type: Routine, Announced Priority: 5
Inspection Date: 9/11/08 Inspector: BK

File No.: 25
Licensee: Newburgh SPECT Imaging License No.: 5088
Inspection Type: Routine, Unannounced Priority: 5
Inspection Date: 3/13/07 Inspector: CB

File No.: 26
Licensee: SUNY College at Geneseo License No.: 1042
Inspection Type: Routine, Announced Priority: 5
Inspection Date: 10/8/09 Inspector: MT

Comment:
No supervisory review.

File No.: 27
Licensee: New York Oncology Hematology License No.: 5107
Inspection Type: Routine, Unannounced Priority: 5
Inspection Date: 12/17/10 Inspector: MS

File No.: 28
Licensee: PB Americas, Inc. License No.: C3235
Inspection Type: Routine, Unannounced Priority: 5
Inspection Date: 12/2/09 Inspector: AC

File No.: 29
Licensee: Steris Isomedix Services, Inc. License No.: C2583
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 12/17/10 Inspector: RS,CB

File No.: 30
Licensee: St. Elizabeth Medical Center License No.: 457-1
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 3/8/07 Inspector: OO

File No.: 31
Licensee: Faxton St. Luke's Healthcare License No.: 0462
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 4/4/11 Inspector: VG

Comment:
No supervisory review.

File No.: 32
Licensee: Cornell University License No.: 0005-3A
Inspection Type: Routine, Announced Priority: 3
Inspection Date: 8/11-8/14/09 Inspector: WK

File No.: 33
Licensee: Regenron Pharmaceuticals License No.: 2904
Inspection Type: Routine, Unannounced Priority: 5
Inspection Date: 3/25/11 Inspector: JM

File No.: 34
Licensee: SUNY at Stony Brook License No.: 0455
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 5/14, 5/28, and 6/10/09 Inspector: AB/JM

File No.: 35
Licensee: Saint-Gobain Performance Plastics Corporation License No.: C2889
Inspection Type: Routine, Unannounced Priority: 5
Inspection Date: 5/21/09 Inspector: MH

File No.: 36
Licensee: Pharmalogic Syracuse, LLC License No.: C3231
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 5/26/11 Inspector: AC

File No.: 37
Licensee: W.M. Burke Medical Research Institute License No.: 1859
Inspection Type: Routine, Unannounced Priority: 5
Inspection Date: 2/27/08 Inspector: CB

File No.: 38
Licensee: Eastman Kodak Company License No.: C1347
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 11/3-11/4/09 Inspector: WV

File No.: 39
Licensee: NRD, LLC License No.: C1391, C1429
Inspection Type: Routine, Unannounced Priority: 5
Inspection Date: 1/23-1/24/07 Inspector: WV

Comment:
Inspection documentation issued to licensee 43 days after inspection. No supervisory review.

File No.: 40
Licensee: Reviss Services, Inc. License No.: IL-0205801
Inspection Type: Reciprocity Priority: N/A
Inspection Date: 4/9/10 Inspector: JM

New York State Department of Environmental Conservation

File No.: 41
Permitee: Triad Isotope, Inc. Permit Nos.: 1-2824-00545/00001
Inspection Type: Announced, Special Priority: 4
Inspection Date: 8/30/2010 Inspector: AG

File No.: 42
Licensee: PharmaLogic, Syracuse Permit No.: 4-0126-00642/00002
Inspection Type: Routine, Unannounced Priority: 4
Inspection Date: 2/15/2008 Inspector: AG

File No.: 43
Permitee: IBA Molecular North America, Inc. Permit Nos.: 4-0126-00502/00007 & /00001
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 9/29/2010 Inspectors: TF, MS

File No.: 44
Permitee: PETNET Solutions, Inc. Permit Nos.: 4-0126-00501/00001
Inspection Type: Routine, Announced Priority: 2
Inspection Date: 5/25/2007 Inspectors: MS

File No.: 45
Permitee: North American Philips Lighting Permit Nos.: 8-4624-00022/00018
Inspection Type: Routine, Announced Priority: 3
Inspection Date: 11/17/2010 Inspectors: JF, AG

Comment:
Inspection documentation issued to licensee 6 days late.

File No.: 46
Permitee: University of Rochester Permit Nos.: 8-2699-00059/00003
Inspection Type: Routine, Announced Priority: 4
Inspection Date: 10/07/2009 Inspectors: AG, TF

Comment:
Inspection documentation issued to licensee 14 days late.

File No.: 47
Permitee: Cardinal Health 420, LLC Permit No.: 8-2614-00811/00001
Inspection Type: Announced, Special Priority: 3
Inspection Date: 11/4/2008 Inspectors: AG, MS

Comment:
Inspection documentation issued to licensee 13 days late.

File No.: 48
Permitee: NRD, Inc.
Permit No.: 9-1446-00018/00001
Inspection Type: Special, Announced
Priority: 4
Inspection Date: 4/8/2009
Inspectors: SH, JF

INSPECTOR ACCOMPANIMENTS

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

New York City Department of Health and Mental Hygiene

Accompaniment No.: 1
Licensee: New York University Hospital Center
License No.: 75-2955-01
Inspection Type: Routine, Announced
Priority: 2
Inspection Date: 5/5/11
Inspector: EC

Accompaniment No.: 2
Licensee: New York University Hospital Center
License No.: 75-2955-01
75-2955-02
92-2955-03
93-2955-05
Inspection Type: Special, Announced
Priority: 2
Inspection Date: 5/6/11
Inspector: MR

New York State Department of Health

Accompaniment No.: 3
Licensee: Good Samaritan Hospital
License No.: 0575
Inspection Type: Routine, Unannounced
Priority: 3
Inspection Date: 5/2/11
Inspector: AB

Accompaniment No.: 4
Licensee: Pall Hauppauge
License No.: C1935
Inspection Type: Routine/Special, Unannounced
Priority: 2
Inspection Date: 5/3/11
Inspector: BK

Accompaniment No.: 5
Licensee: Meade Testing Labs
License No.: C2697
Inspection Type: Routine/Special, Unannounced
Priority: 1
Inspection Date: 5/4/11
Inspector: JM

Accompaniment No.: 6
Licensee: Noyes Memorial Hospital
License No.: 1831
Inspection Type: Routine, Unannounced
Priority: 5
Inspection Date: 5/16/11
Inspector: MT

Accompaniment No.: 7
Licensee: Quality Inspection Services License No.: C2700
Inspection Type: Routine, Unannounced Priority: 1
Inspection Date: 5/17/11 Inspector: SK

Accompaniment No.: 8
Licensee: Radiotherapy Associates, LLC License No.: 3111
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 5/18/11 Inspector: VG

Accompaniment No.: 9
Licensee: Clough, Harbor & Associates License No.: C2844
Inspection Type: Routine, Unannounced Priority: 5
Inspection Date: 5/19/11 Inspector: MH

Accompaniment No.: 10
Licensee: Albany Medical Center License No.: 590
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 5/20/11 Inspector: JF

New York State Department of Environmental Conservation

Accompaniment No.: 11
Permitee: NYS Energy Research & Development Authority Permit No.: 9-0422-00011/00011
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 6/1/11 Inspector: DO

APPENDIX D

LICENSE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY.

New York City Department of Health and Mental Hygiene

File No.: 1
Licensee: Centenary Hospital — License No.: 92-2848-01
Type of Action: Termination — Amendment No.: 9
Date Issued: 10/22/08 — License Reviewer: DH

File No.: 2
Licensee: Cabrini Medical Center — License No.: 92-2922-02
Types of Action: Termination — Amendment No.: 9
Date Issued: 4/01/09 — License Reviewer: DH

File No.: 3
Licensee: Lenox Hill Hospital — License No.: 91-2926-01
Type of Action: Amendment — Amendment No.: 25
Date Issued: 6/22/10 — License Reviewer: DH

File No.: 4
Licensee: Albert Einstein College of Medicine. — License No.: 91-2919-01
Type of Action: Amendment — Amendment No.: 3
Dates Issued: 6/4/08 — License Reviewer: DH

File No.: 5
Licensee: Fordham University — License No.: 52-2964-01
Type of Action: Amendment — Amendment No.: 7
Date Issued: 3/02/09 — License Reviewer: DH

File No.: 6
Licensee: Keith Tobin, M D — License No.: 91-2979-01
Type of Action: Amendment — Amendment No.: 8
Date Issued: 3/9/11 — License Reviewer: DH

File No.: 7
Licensee: SUNY Health Service Center — License No.: 74-2934-02
Type of Action: Renewal — Amendment No.: 4
Date Issued: 11/15/10 — License Reviewer: DH

File No.: 8
Licensee: Polytechnic Institute of New York University — License No.: 52-2903-01
Type of Action: Renewal — Amendment No.: 6
Date Issued: 9/24/08 — License Reviewer: DH

File No.: 9
Licensee: New York Presbyterian Hospital License No.: 75-2960-04
Type of Action: New Amendment No.: 0
Date Issued: 2/17/11 License Reviewer: DH

Comments
License issued without the required security license condition.
No pre-licensing determination performed.

File No.: 10
Licensee: New York Eye & Ear Infirmary License No.: 91-2936-01
Type of Action: Amendment Amendment No.: 6
Dates Issued: 11/03/10 License Reviewers: DH

File No.: 11
Licensee: Columbia Presbyterian Medical Center License No.: 93-2878-05
Type of Action: Amendment Amendment No.: 8
Dates Issued: 10/26/10 License Reviewer: DH

File No.: 12
Licensee: Albert Einstein College of Medicine License No.: 74-2919-02
Type of Action: Amendment Amendment No.: 11
Dates Issued: 5/21/08 License Reviewer: DH

Comments:
License issued without the required security license condition.

File No.: 13
Licensee: Memorial Sloan Kettering Cancer Center License No.: 75-2968-01
Type of Action: Amendment Amendment No.: 13
Date Issued: 5/02/11 License Reviewer: DH

Comment:
License issued without the required security license condition.

File No.: 14
Licensee: New York Blood Center License No.: 74-2946-01
Type of Action: Amendment Amendment No.: 10
Date Issued: 3/04/09 License Reviewer: DH

Comment:
License issued without the required security license condition.

New York State Department of Health

File No.: 15
Licensee: Good Samaritan Hospital — License No.: 490
Type of Action: Amendment — Amendment No.: 53
Date Issued: 5/04/06 — License Reviewer: OO

File No.: 16
Licensee: Roswell Park — License No.: 2923
Types of Action: Amendment — Amendment No.: 28
Date Issued: 12/05/07 — License Reviewer: CB

File No.: 17
Licensee: Regeneron Pharmaceuticals — License No.: 2904
Type of Action: Amendment — Amendment No.: 16
Date Issued: 1/17/08 — License Reviewer: CB

File No.: 18
Licensee: Northshore Radiology at Glen Cove — License No.: 5307
Type of Action: New — Amendment Nos.: 0
Dates Issued: 2/13/08 — License Reviewer: CB

File No.: 19
Licensee: Comprehensive Cardiology of Long Island — License No.: 5330
Type of Action: New — Amendment No.: 0
Date Issued: 2/24/09 — License Reviewers: AC

File No.: 20
Licensee: Melville Surgery Center — License No.: 5361
Type of Action: Termination — Amendment No.: 1
Date Issued: 3/19/09 — License Reviewers: CB

File No.: 21
Licensee: Quality Inspection Services — License No.: C2514
Type of Action: Amendment — Amendment No.: 10
Date Issued: 1/21/09 — License Reviewer: VD

File No.: 22
Licensee: Corning Hospital — License No.: 0421
Type of Action: Amendment — Amendment No.: 53
Date Issued: 2/23/10 — License Reviewer: AC

File No.: 23
Licensee: Westchester PET and Medical — License No.: 5081
Type of Action: Amendment — Amendment Nos.: 12
Dates Issued: 3/7/11 — License Reviewers: AC

File No.: 24
Licensee: Arnot Health
Type of Action: Amendment
Dates Issued: 9/28/08
License No.: 5182
Amendment No.: 6
License Reviewer: AD

File No.: 25
Licensee: SUNY College
Type of Action: Amendment
Dates Issued: Pending
License No.: 1064
Amendment No.: NA
License Reviewer: RD/CB

File No.: 26
Licensee: Benedictine Hospital
Type of Action: Amendment
Date Issued: 3/30/07
License No.: 1181
Amendment No.: 42
License Reviewer: RD

File No.: 27
Licensee: Pepsi Cola
Type of Action: Renewal
Date Issued: 12/26/06
License No.: C3078
Amendment No.: 2
License Reviewer: DG

File No.: 28
Licensee: Eastman Kodak
Type of Action: Amendment
Date Issued: 9/9/09
License No.: C1347
Amendment No.: 3
License Reviewer: DG

File No.: 29
Licensee: Warren & Panzer Engineering
Type of Action: Renewal
Date Issued: 8/7/09
License No.: C2631
Amendment No.: 2
License Reviewer: DG

File No.: 30
Licensee: Medical Arts Radiology
Types of Action: New
Date Issued: 6/13/07
License No.: 5291
Amendment No.: 0
License Reviewer: MH

File No.: 31
Licensee: Glen Falls Hospital
Type of Action: Amendment
Date Issued: 12/5/08
License No.: 0481
Amendment No.: 74
License Reviewer: MH

File No.: 32
Licensee: Sheehan Memorial Hospital
Type of Action: Renewal
Dates Issued: Pending
License No.: 1847
Amendment No.: N/A
License Reviewer: MH

File No.: 33
Licensee: Glen Falls Hospital
Type of Action: Amendment
Date Issued: 1/14/08
License No.: 0481
Amendment No.: 72
License Reviewers: JK

File No.: 34
Licensee: Buffalo Medical Group License No.: 2902
Type of Action: Renewal Amendment No.: 18
Date Issued: 7/8/11 License Reviewers: AC

File No.: 35
Licensee: Sky Testing Services License No.:
Type of Action: Amendment Amendment No.: 2
Date Issued: 7/02/10 License Reviewer: WV

File No.: 36
Licensee: Roswell Park Cancer Institute License No.: 2923
Type of Action: Renewal Amendment No.: N/A
Date Issued: Pending License Reviewer: RD/CB

Comments:
Under timely renewal for 6075 days.

File No.: 37
Licensee: Ciba Specialty Chemicals License No.: C2730
Types of Action: Termination Amendment No.: 3
Dates Issued: 7/17/07 License Reviewer: DH

File No.: 38
Licensee: American Red Cross License No.: 1761
Type of Action: Renewal Amendment Nos.: 24
Dates Issued: 3/10/10 License Reviewers: AC

New York State Department of Environmental Conservation

File No.: 39
Permittee: North American Philips Lighting Permit No.: 8-4624-00022/00018
Type of Action: Modification Facility/Program No.:
Date Issued: 7/27/06 License Reviewer: JF

File No.: 40
Permittee: PETNET Solutions, Inc. Permit No.: 4-0126-00501/00001
Type of Action: Modification Facility/Program No.:
Date Issued: 8/6/08 License Reviewer: JF

File No.: 41
Permittee: Mirion Technologies Permit No.: 8-0724-00139/00003
Type of Action: New Facility/Program No.: Not used since 2008
Date Issued: 1/24/07 License Reviewer: TF

File No.: 42
Permittee: University of Rochester Permit No.: 8-2699-00059/00003
Type of Action: Modification Facility/Program No.: 170-3
Date Issued: 1/12/10 License Reviewer: TF

File No.: 43
Permittee: University of Rochester
Type of Action: Renewal
Date Issued: 2/21/08
Permit No.: 8-2699-00059/00003
Facility/Program No.: 170-3
License Reviewer: TF

File No.: 44
Permittee: NRD, LLC
Type of Action: Modification
Date Issued: 11/10/09
Permit No.: 9-1446-00018/00001
Facility/Program No.: 53-3
License Reviewer: JF

File No.: 45
Permittee: Cardinal Health 420
Type of Action: Modification
Date Issued: 2/17/08
Permit No.: 8-2614-00811/00001
Facility/Program No.: 188-3
License Reviewer: PL

File No.: 46
Permittee: IBA Molecular North America, Inc.
Type of Action:
Date Issued: 2/7/10
Permit Nos.: 4-0126-00502 /00001
Facility/Program No.: 182-3
License Reviewer: TF

File No.: 47
Permittee: PharmaLogic Syracuse
Type of Action: New
Date Issued: 12/10/07
Permit No.: 4-0126-00642-00002
Facility/Program No.: 192-3
License Reviewer: AM

File No.: 48
Permittee: Triad Isotopes, Inc.
Type of Action: Modification
Date Issued: 7/23/09
Permit No.: 1-2824-00545/00001
Facility/Program No.: 131-3
License Reviewer: MP

APPENDIX E

INCIDENT CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY.

New York City Department of Health and Mental Hygiene

File No.: 1
Licensee: Redacted
Date of Incident: 12/22/06
Investigation Date: N/A

Comment: This incident was reported to NRC on June 15, 2011, and the follow-up was not done at the time of review.

File No.: 2
Licensee: Redacted
Date of Incident: 10/6/09
Investigation Date: N/A

Comment: This incident was reported to NRC on June 15, 2011, and the follow-up was not done at the time of review.

New York State Department of Health

File No.: 3
Licensee: Redacted — License No.: N/A
Date of Incident: 3/6/07 — Incident Log No.: 520
Investigation Date: 3/9/07 — Type of Investigation: On-Site

File No.: 4
Licensee: Redacted — License No.: N/A
Date of Incident: 6/19/07 — Incident Log No.: 548
Investigation Date: 6/20/07 — Type of Investigation: On-Site

File No.: 5
Licensee: Redacted — License No.: N/A
Date of Incident: 6/21/07 — Incident Log No.: 550
Investigation Date: 6/22/07 — Type of Investigation: On-Site

File No.: 6
Licensee: Redacted — License No.: N/A
Date of Incident: 5/23/07 — Incident Log No.: 522
Investigation Date: 6/8/07 — Type of Investigation: On-Site

File No.: 7
Licensee: Redacted — License No.: N/A
Date of Incident: 7/2/07 — Incident Log No.: 553
Investigation Date: 7/2/07 — Type of Investigation: On-Site

File No.: 8
Licensee: Redacted
License No.: N/A
Date of Incident: 10/2/07
Incident Log No.: 566
Investigation Date: 10/3/07
Type of Investigation: On-Site

File No.: 9
Licensee: SJB Services, Inc.
License No.: C2500
Date of Incident: 11/1/07
Incident Log No.: 572
Investigation Date: 11/2/07
Type of Investigation: Phone

File No.: 10
Licensee: Xerox Corporation
License No.: C3155
Date of Incident: 3/1/08
Incident Log No.: 662
Investigation Date: 11/17/08
Type of Investigation: On-Site

File No.: 11
Licensee: Redacted
License No.: N/A
Date of Incident: 7/31/09
Incident Log No.: 740
Investigation Date: 7/31/09
Type of Investigation: Phone

File No.: 12
Licensee: Redacted
License No.: N/A
Date of Incident: 5/26/10
Incident Log No.: 837
Investigation Date: 5/28/10
Type of Investigation: Phone

File No.: 13
Licensee: Certified Testing Laboratory
License No.: C2639
Date of Incident: 8/30/09
Incident Log No.: 749
Investigation Date: 8/31/09
Type of Investigation: On-Site

File No.: 14
Licensee: Dominion Resources, Inc.
License No.: N/A
Date of Incident: 4/19/10
Incident Log No.: 822
Investigation Date: 4/19/10
Type of Investigation: Phone

File No.: 15
Licensee: Cole Consulting Corporation
License No.: C2937
Date of Incident: 2/25/08
Incident Log No.: 590
Investigation Date: 2/25/08
Type of Investigation: On-Site

New York State Department of Environmental Conservation

File No.: 17
Permittee: Cardinal Health 41
Permit No.: 8-2614-00812/2
Date of Incident: 12/6/06
Incident Log No.: N/A
Investigation Date: 12/7/06
Type of Investigation: Phone

File No.: 18
Permittee: SUNY Buffalo
Permit No.: 9-1402-00680/29
Date of Incident: 12/1/06
Incident Log No.: N/A
Investigation Date: 12/14/06
Type of Investigation: Phone

APPENDIX F

SEALED SOURCE AND DEVICE REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY.

File No.: 1
Registry No.: NY-1271-S-101-S
Manufacturer: mb-microtec ag
Date Issued: 12/14/06
Type of Action: New Registration
SS&D Reviewers: DS, CB
SS&D Type: Gaseous Light Source
Model Nos.: 400/1, 400/2, 400/3, 400/4, 400/5, and 400/6

File No.: 2
Registry No.: NY-1210-D-102-G
Manufacturer: Inficon, Inc.
Date Issued: 03/02/10
Type of Action: New Registration
SS&D Reviewers: DS, CB
SS&D Type: Ion Generators, Chromatography
Model Nos.: CMS5000

Comments:

Information regarding radiation profiles, leak testing, prototype testing, conditions of use, quality control/quality assurance can be found in case file for SSD NY-1210-D-101-B. Model CMS5000 is very similar to Model CMS500 found in SSD NY-1210-D-101-B.

Drawings used in the registration did not specify overall dimensions to describe the overall size of the device.

File No.: 3
Registry No.: NY-0502-D-112-G
Manufacturer: NRD, LLC
Date Issued: 12/30/2009
Type of Action: New Registration
SS&D Reviewers: DS, CB
SS&D Type: Static Eliminator
Model Nos.: Nuclecel Ionizer Model P-2035

Comment:

Drawings used in the registration did not specify overall dimensions to describe the overall size of the device.

File No.: 4
Registry No.: NY-0502-D-111-G
Manufacturer: NRD, Inc.
Date Issued: 11/23/2009
Type of Action: New Registration
SS&D Reviewers: DS, CB
SS&D Type: Static Eliminator
Model Nos.: Nuclecel Ionizer Model P-2060 and Model P-2062

Comment:

Drawings used in the registration did not specify overall dimensions to describe the overall size of the device.