March 2, 2007

Ms. Jeanine Prud'homme, CIH
Assistant Commissioner
Office of Environmental Sciences & Engineering
New York City Department of Health and Mental Hygiene
2 Lafayette Street, 11th Floor, CN-57
New York, NY 10007

Dear Ms. Prud'homme:

On February 8, 2007, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the New York Agreement State Program. The MRB found the New York Agreement State Program adequate to protect public health and safety and not compatible with the U.S. Nuclear Regulatory Commission's (NRC's) program. The MRB determined the period of Heightened Oversight of the New York Program should continue.

I request that your program revise and resubmit their Program Improvement Plan as part of the response to the applicable recommendations in Section 5 of the enclosed final report. The revised plan should be submitted within 30 days of receipt of this letter. If you have any questions regarding the expectations of the Program Improvement Plan, please have your staff contact Janet R. Schlueter, Director, Division of Materials Safety and State Agreements of the NRC's Office of Federal and State Materials and Environmental Management Programs. I request that the bimonthly conference calls between your program and NRC staff continue during the period of Heightened Oversight. The first call should take place approximately two weeks after the submittal of your program's revised Program Improvement Plan. Two weeks prior to each subsequent call, your program should provide a status report of actions associated with the Plan to the NRC.

Based on the results of the current IMPEP review, the next full review of the New York Agreement State Program will take place in approximately four years, with a periodic meeting tentatively scheduled for November 2007.

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

Sincerely,

/RA/

Martin J. Virgilio
Deputy Executive Director for Materials, Waste, Research, State, Tribal, and Compliance Programs
Office of the Executive Director for Operations

Enclosure: New York Final IMPEP Report

cc: See next page

cc: Gene Miskin, Director
Office of Radiological Health, NYC

Jack Spath, Program Manager
Radioactive Waste Policy &
Nuclear Coordinator, NYSERDA

Steve Collins, Illinois
Organization of Agreement States
Liaison to the MRB

March 2, 2007

Mr. Edwin Dassati, Director
Bureau of Hazardous Waste & Radiation Management
New York State Department of Environmental Conservation
625 Broadway
Albany, NY 12233-7258

Dear Mr. Dassati:

On February 8, 2007, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the New York Agreement State Program. The MRB found the New York Agreement State Program adequate to protect public health and safety and not compatible with the U.S. Nuclear Regulatory Commission's (NRC's) program. The MRB determined the period of Heightened Oversight of the New York Program should continue.

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Sincerely,

/RA/

Martin J. Virgilio
Deputy Executive Director for Materials, Waste,
Research, State, Tribal, and Compliance Programs
Office of the Executive Director for Operations

Enclosure: New York Final IMPEP Report

cc: See next page

cc: Barbara Youngberg, Chief
Radiation Section, DEC

Jack Spath, Program Manager
Radioactive Waste Policy &
Nuclear Coordinator, NYSERDA

Steve Collins, Illinois
Organization of Agreement States
Liaison to the MRB

March 2, 2007

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

Dear Dr. Salame-Alfie:

On February 8, 2007, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the New York Agreement State Program. The MRB found the New York Agreement State Program adequate to protect public health and safety and not compatible with the U.S. Nuclear Regulatory Commission's (NRC's) program. The MRB determined the period of Heightened Oversight of the New York Program should continue.

I request that your program revise and resubmit their Program Improvement Plan as part of the response to the applicable recommendations in Section 5 of the enclosed final report. The revised plan should be submitted within 30 days of receipt of this letter and include those Department of Labor (DOL) regulations required for adoption as a result of the merger with DOL's Radiological Health Unit. If you have any questions regarding the expectations of the Program Improvement Plan, please have your staff contact Janet R. Schlueter, Director, Division of Materials Safety and State Agreements of the NRC's Office of Federal and State Materials and Environmental Management Programs. I request that the bimonthly conference calls between your program and NRC staff continue during the period of Heightened Oversight. The first call should take place approximately two weeks after the submittal of your program's revised Program Improvement Plan. Two weeks prior to each subsequent call, your program should provide a status report of actions associated with the Plan to the NRC.

Based on the results of the current IMPEP review, the next full review of the New York Agreement State Program will take place in approximately four years, with a periodic meeting tentatively scheduled for November 2007.

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/RA/

Martin J. Virgilio
Deputy Executive Director for Materials, Waste,
Research, State, Tribal, and Compliance Programs
Office of the Executive Director for Operations

Enclosure: New York Final IMPEP Report

cc: See next page

cc: Stephen Gavitt, Director
Bureau of Environmental Radiation
Protection, DOH

Jack Spath, Program Manager
Radioactive Waste Policy &
Nuclear Coordinator, NYSERDA

Steve Collins, Illinois
Organization of Agreement States
Liaison to the MRB

March 2, 2007

Ms. Jeanine Prud'homme, CIH
Assistant Commissioner
Office of Environmental Sciences & Engineering
New York City Department of Health and Mental Hygiene
2 Lafayette Street, 11th Floor, CN-57
New York, NY 10007

Dear Ms. Prud'homme:

On February 8, 2007, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the New York Agreement State Program. The MRB found the New York Agreement State Program adequate to protect public health and safety and not compatible with the U.S. Nuclear Regulatory Commission's (NRC's) program. The MRB determined the period of Heightened Oversight of the New York Program should continue.

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Sincerely,
/RA/
Martin J. Virgilio
Deputy Executive Director for Materials, Waste,
Research, State, Tribal, and Compliance Programs
Office of the Executive Director for Operations

Enclosure: New York Final IMPEP Report

cc: See next page

Identical letters sent to Jeanine Prud'homme, Edwin Dassati, and Adela Salame-Alfie.

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cc: Gene Miskin, Director
Office of Radiological Health, NYC

Jack Spath, Program Manager
Radioactive Waste Policy &
Nuclear Coordinator, NYSERDA

Steve Collins, Illinois
Organization of Agreement States
Liaison to the MRB

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF NEW YORK AGREEMENT STATE PROGRAM

NOVEMBER 1-9, 2006

FINAL REPORT

U. S. Nuclear Regulatory Commission

ENCLOSURE

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 November 1-9, 2006, by a review team comprised of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the States of Florida and Washington. Team members are identified in Appendix A. The review was conducted in accordance with in 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 July 26, 2002, to November 9, 2006, were discussed with New York management on the last day of the review.

At that time, the review team's preliminary finding was that the State's performance with respect to the Non-Common Performance Indicator, Compatibility Requirements, was satisfactory, but needs improvement. Upon further reflection and consideration of the status of regulations in the State, the review team determined a finding of unsatisfactory for this indicator was more appropriate. The team leader notified State officials of this change by telephone on December 20, 2006, prior to issuance of the draft report.

A draft of this report was issued to New York for factual comment on December 21, 2006. The three agencies that comprise the New York Agreement State program responded separately. The New York City Department of Health and Mental Hygiene (NYC) responded via letter, dated January 16, 2007, from Jeannine Prud'homme, Assistant Commissioner, Environmental Sciences and Engineering. The New York State Department of Health (DOH) responded via letter, dated January 22, 2007, from Stephen M. Gavitt, Director, Bureau of Environmental Radiation Protection. The New York State Department of Environmental Conservation responsed via letter, dated January 24, 2007, from Barbara Youngberg, Chief, Radiation Section. The Management Review Board (MRB) met on February 8, 2007, to consider the proposed final report. The MRB found the New York program adequate to protect public health and safety and not compatible with NRC's program. The review team recommended, and the MRB agreed, that the period of Heightened Oversight of the New York Agreement State Program continue.

During most of the review period, the New York Agreement State Program was divided among four separate programs. In July 2006, the New York State Department of Labor's Radiological Health Unit (DOL) was merged into DOH. The New York Agreement State program is currently administered by three agencies: (1) NYC, which has jurisdiction over medical, academic, and research uses of radioactive materials within the five boroughs of New York City; (2) 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) 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 October 10, 2006. Each agency provided an electronic response to the questionnaire; DEC on October 16, 2006; DOH on October 19, 2006; and, NYC on October 24, 2006. A copy of the questionnaire responses can be found in the NRC's Agencywide Document Access and Management System (ADAMS) using the Accession Numbers ML063530794, ML063530800, and ML063530801.

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 10 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.

During the review period, New York was placed on Heightened Oversight in November 2005 as a result of overdue NRC amendments required for compatibility by all of the agencies that comprise the Agreement State program. The importance of maintaining up-to-date regulations was stressed during periodic meetings held with each agency in April 2005. NRC representatives at the periodic meetings recommended that each agency adopt legally binding requirements to implement the overdue NRC amendments while regulations are being promulgated.

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 program 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 routine review, which concluded on July 26, 2002, eight recommendations were made, and the results were transmitted to the respective upper management of the three New York State Agencies and the New York City Agency on November 12, 2002. The review team's evaluation of the current status of these recommendations is as follows:

1. The review team recommends that NYC, DOL and DEC perform core inspections in a timely manner, and that NYC take appropriate actions to improve the tracking mechanisms necessary to evaluate their own timeliness for initial inspections. (Section 3.1.5)

   Current Status: Based on review of the IMPEP questionnaires, discussions with State staff, and an examination of inspection data, the review team found that all programs were performing core and initial inspections in a timely manner. This recommendation is closed.

2. The review team recommends that NYC and DEC transmit inspection findings to their licensees within thirty days after the close of the inspection. (Section 3.1.5)

   Current Status: Based on the review of inspection casework and discussions with State staff, the review team found that NYC is issuing inspection findings in a timely manner. DEC, however, continues to experience some delays in their issuance of inspection findings. The review team recommends that DEC's actions in response to this recommendation continue to be tracked. This recommendation remains open for DEC.

3. The review team recommends that NYC review and revise their inspection process, including report preparation to ensure that the inspection findings are accurately described in the documentation of the inspection and that cited violations are supported in the inspection field notes. (Section 3.2.5)

   Current Status: The review team noted significant improvement in the quality of NYC's inspection reports with respect to documentation and substantiation of inspection findings. This recommendation is closed.

4. The review team recommends that DOL and DEC perform annual supervisory accompaniments of all material inspectors. (Section 3.2.5)

   Current Status: DEC supervisors have accompanied each inspector annually during the review period. DOL, now the Industrial Unit of DOH, did not accompany each inspector annually during the review period; however, the inspectors were accompanied by supervisors after the on-site review with no performance issues identified. This recommendation is closed.

5. The review team recommends that NYC review all licenses to ascertain if they require financial assurance, and take appropriate action on each affected license to ensure that all licenses meet codified financial assurance requirements. (Section 3.4.5)

   Current Status: The review team noted that all licenses identified as requiring financial assurance, except for two licenses, had financial assurance instruments in place. The remaining two licensees are currently working with NYC to resolve issues and to complete their financial assurance packages. This recommendation is closed.

6. The review team recommends that DOH provide prompt, in-depth, documented reviews of events with the potential for significant health and safety consequences. (Section 3.5.5)

   Current Status: The review of incident casework and discussions with staff verified that DOH, including the Industrial Unit, provides prompt, in-depth, documented reviews of all

events. DOH requires their licensees to submit a root cause analysis of any incidents, which DOH reviews and analyzes to promptly identify any potential generic issues. The review team verified that the licensees' root cause analyses and DOH's reviews are documented in the appropriate files. This recommendation is closed.

7. The review team recommends that NYC, DOL and DOH draft and implement a method to ensure timely submittal of information to NRC and the Nuclear Materials Events Database and implement an effective procedure to identify, track, and review all incident reports. (Section 3.5.5)

   Current Status: The review of incident casework and discussions with State staff verified that NYC and DOH, including former DOL, are making timely reports to NRC and NMED and are utilizing automated systems to identify, track, and review all incident reports. This recommendation is closed.

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

   Current Status: Discussions with NYC revealed that their regulations are up-to-date except for the 10 CFR Part 35 compatible rule that was due for implementation in October 2005. NYC has drafted this rule, but it cannot be implemented until the equivalent rule is adopted by DOH. DOH, including former DOL, and DEC have drafted a number of regulations and legally binding requirements; however, none have been sent to the NRC for a compatibility review. The New York Agreement State Program is currently on Heightened Oversight based on overdue NRC amendments required for compatibility. This recommendation remains open.

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 eight technical staff members. There are currently no vacancies in this program. During the review period, one senior staff member retired and another staff member left the program. These

vacancies were filled with three individuals experienced in radiation safety and environmental health inspections. Two experienced staff members are involved exclusively in radioactive materials licensing. One of these individuals has a doctorate in physics and is a certified health physicist. Five staff members are devoted to compliance, which encompasses inspection and enforcement actions. The Unit Chief is involved in both licensing and compliance activities, including incident response.

NYC recently added an Emergency Response Unit which is staffed by individuals trained specifically to respond to radiological incidents. This Unit does not conduct routine compliance inspections; however, it will augment the routine compliance effort by responding to radiological incidents. This Unit has the responsibility for conducting NYC's Increased Controls inspections.

NYC technical positions require a Bachelor's degree in engineering, physical or biological sciences. The IMPEP team reviewed job descriptions and the procedure used to qualify new staff as independent inspectors. The procedure, "Training for New Inspectors," is comprehensive and equivalent to the NRC's Inspection Manual Chapter (IMC)1246. There is no equivalent procedure for the training and qualification of new license reviewers. The lack of a documented training plan for license reviewers was discussed with NYC management. Currently, no resulting performance issues from the lack of a documented training plan for license reviewers were identified by the review team; however, the review team encouraged NYC management to consider developing such a procedure as a succession planning tool.

The program utilizes an "Employee Training Record" to document and track the training received by individual staff members. This practice is equivalent to a training and qualification journal. NYC management encourages training and supports out-of-State training opportunities as they meet program and staff needs.

3.1.2 New York State Department of Health

DOH is managed by the Director, the Assistant Director and six Section Chiefs. DOH utilizes 2.5 full-time equivalents (FTE) for licensing activities and 3.6 FTE for compliance activities. DOH currently has one vacancy which is authorized to be filled.

DOH has a comprehensive documented training plan and job descriptions for all current positions. The review team examined these documents. DOH's training plan is comparable to IMC 1246. The review team noted that individual staff qualification journals are kept on an automated database. The review team noted that DOH management actively supports staff training through in-house seminars, as well as off-site training.

DOH staff is required to have a Bachelor's degree in physical and biological sciences, at a minimum. The review team noted that DOH management actively supports staff training through in-house seminars, as well as off-site training. The review team determined that DOH staff is well-qualified, based on education and experience. DOH staff includes several Certified Health Physicists, a Certified Medical Physicist, and a number of other staff possessing specialized nuclear training and work experience.

3.1.3 New York State Department of Health - Industrial Unit

The Industrial Unit consists of the Section Chief and seven technical staff members. Approximately 4.0 FTE are dedicated toward licensing activities, and 3.4 FTE are dedicated toward compliance activities. During the review period, the Industrial Unit lost two staff members. One position has been filled and the Industrial Unit is actively recruiting to fill the remaining vacant position.

The Industrial Unit has a written training qualification program. This program details the core training. The review team determined that the Industrial Unit's training qualification program is consistent with IMC 1246. Individual qualification journals are maintained on an automated database. The review team queried the database and noted that it contained training course information, including dates for each course attended by current staff members. The Industrial Unit has documented position descriptions for each of the current job classifications.

New staff are required to have a Bachelor's degree in physical or biological sciences, at a minimum. Most of the staff members have advanced degrees. Two are Certified Health Physicists and other staff have a variety of nuclear related training and work experience.

3.1.4 New York State Department of Environmental Conservation

DEC is staffed by the Bureau Director, the Section Chief, and nine technical staff members. Currently, there are no vacancies in the program. All of the unfilled vacancies noted during the 2002 IMPEP review have been administratively deleted. During the review period, one staff member was hired and three technical staff left the program. One of the individuals that left the program intends to resume employment before the end of 2006. The permitting (licensing) and compliance functions of the program are performed by five members of the staff. The rest of the staff is dedicated mostly to contaminated sites and events that are not directly covered under the Agreement. All staff perform duties in incident and emergency response. In addition to the Section Chief, two individuals have supervisory roles.

All but one of the staff members have a long history with DEC and are thus able to effectively meet the workload requirements. With the upcoming retirement of a number of key individuals and the hiring of new personnel, DEC management anticipates that a learning period will be needed for these potentially inexperienced staff members. To further complicate the situation, DEC is currently experiencing a hiring freeze, so that staff cannot be added until individuals leave the program. The Section Chief expressed concern that this system provides limited opportunity for knowledge transfer to new personnel especially since the general quantity and complexity of the workload is expected to increase.

DEC will continue to regulate the construction, operation and decommissioning of accelerators. In coordination with the other two agencies, the State is intending to continue to regulate certain accelerator-produced byproduct material, identified in the Energy Policy Act of 2005, by providing the NRC with the Governor certification letter.

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; however, the high level of qualification required has

limited the program's ability to recruit potential personnel in anticipation of increased staff turnover and workload increase.

The review team determined that DEC has a minimally acceptable written training policy. Historically, DEC has not had much need to develop and document a training program due to the small number of inspectors and permit reviewers and the low staff turnover. DEC management stated that new staff will be trained in performing inspections and reviewing permit applications individually by the permit/inspection unit supervisor. Inspectors-in-training will 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 will move through these stages based on the assessment of the unit supervisor. The same staff will be trained to review permit applications by reviewing first minor amendments and routine renewals, then applications of increasing complexity. All permitting decisions are reviewed by the permit unit supervisor and the radiation section supervisor. The review team noted that DEC does not have a consistent method to formally document the training of personnel. After the 2002 IMPEP review, DEC began to record individuals' training, but the spreadsheet has not been updated on a regular basis, because only one new staff member was added during the review period.

3.1.5 Indicator Summary

The review team determined that the New York Agreement State Program is adequately staffed with qualified personnel. During the review period, staff from the four programs attended a number of courses sponsored by several organizations, including NRC. Staff from each program attended the NRC's Increased Controls course. Staff turnover is low and when a vacancy does occur it is filled in a timely manner. The review team noted that inspections were being conducted according to IMPEP criteria and there were no other program deficiencies linked to staffing level or quality.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that New York's performance with respect to the indicator, Technical Staffing and Training, was satisfactory.

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 IMC 2800. Inspection frequencies for NYC licensees range from one to three years.

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, approximately 6 core inspections and 13 initial inspections were performed overdue by more than 25 percent of their respective inspection frequency. Overall, the review team calculated 7 percent of all Priority 1, 2, and 3, and initial inspections were completed overdue during the review period. This represents a significant improvement compared to results in the 2002 review where approximately 23 percent of Priority 1, 2, and 3, and initial inspections were performed overdue. The review team also noted that the accuracy of information in the inspection database has significantly improved since the 2002 review, in that newly issued licenses were entered into the database in a timely manner.

The timeliness of the issuance of inspection findings to licensees was evaluated during the inspection casework review. Nearly all letters transmitting inspection findings to licensees were issued within 30 days after the date of the inspection. Again, this represents a significant improvement over results of the 2002 review. Since the 2002 review, NYC changed their process for the preparation and issuance of letters to licensees. The inspector has more responsibility for the preparation of the transmittal letter. This process change seems to be directly attributable to the increase in the efficiency of the issuance of inspection findings.

During the review period, NYC received 94 reciprocity notifications from seven different licensees. NYC performed five inspections during the review period. These five inspections were performed in 2005 and 2006. In these two years, NYC met the criteria in IMC 1220 of inspecting 20 percent of candidate reciprocity licensees. No inspections were performed in 2003 and 2004. This issue was discussed with NYC management and they indicated that more attention has been focused on this area by the new inspector supervisor.

The review team determined that with respect to Commission Staff Requirements Memorandum (SRM) for COMSECY-05-0028, on Increased Controls, at the time of the on-site review, the NYC program had inspected 6 of the 27 subject licensees in accordance with the Increased Controls requirements. The review team evaluated the program's prioritization methodology and found it acceptable.

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. DOH routinely implements their inspection interval extension policy to increase inspection intervals for licensees demonstrating good prior performance. The latest version of IMC 2800 no longer allows for the extension of inspection frequencies based on good performance. DOH management was not aware of this change and indicated that they would revise their inspection procedure to be consistent with IMC 2800.

In their response to the questionnaire, DOH indicated that eight Priority 1, 2, and 3 inspections were performed overdue during the review period. The review team examined the DOH inspection database and identified an additional 16 inspections that were performed overdue. There were two reasons for the discrepancy. The first reason was the previously mentioned inspection interval extension policy, and the second was a miscalculation performed by the program's inspection database. The review team determined that DOH performed 13 of its 380

Priority 1, 2, and 3 inspections overdue, and 1 of the 150 initial inspections was performed overdue. Overall, the review team calculated that DOH performed 2.6 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. DOH has an effective and efficient process, which ensures that inspection findings are communicated to licensees in a timely manner. For all the inspection casework examined, inspection findings were sent to the licensees within 30 days.

During the review period, DOH did not grant any out-of-State licensees reciprocity to work in the State.

The review team determined that with respect to Commission Staff Requirements Memorandum (SRM) for COMSECY-05-0028, on Increased Controls, at the time of the on-site review, DOH had inspected 2 of the 27 subject licensees in accordance with the Increased Controls requirements. The review team evaluated the program's prioritization methodology and found it acceptable.

3.2.3 New York State Department of Health - Industrial Unit

The review team's assessment of the Industrial Unit's inspection priorities verified that inspection frequencies for various types of licenses are the same as, or more restrictive than, those listed in IMC 2800 with one exception. "Storage only pending disposal" licenses are inspected every five years, as opposed to every three years according to IMC 2800.

In their response to the questionnaire, the Industrial Unit indicated that their database only tracked currently due inspections. At the time of the on-site review, the Industrial Unit's inspection database was not available for review. The review team examined information in the inspection files for most Priority 1, 2, and 3 licenses and initial licenses to compile information on the timeliness of inspections. The review team determined that 7 of 112 Priority 1, 2, and 3 inspections were performed overdue and, of the 148 new licenses issued during the review period, 9 were performed overdue, 126 performed in one year or less, and 13 that are currently due. Overall, the review team calculated that the Industrial Unit performed 6.5 percent of its 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 Industrial Unit has an effective and efficient process, which ensures that inspection findings are generally communicated to licensees in a timely manner. For the inspection casework examined by the review team specifically for timeliness of the communication, nearly all letters with inspection findings were transmitted within 30 days after the date of the inspection.

During the review period, the Industrial Unit granted 117 out-of-State reciprocity approvals to work in the State, of which 37 were candidate licensees. The Industrial Unit conducted 29 reciprocity inspections during the review period which met the criteria in IMC 1220. The Industrial Unit only authorizes reciprocity for 30 days in a calendar year, thus many out-of-State licensees obtain a specific license. These out-of-State specific licensees are contacted at least annually to determine whether work in New York State is planned.

The review team determined that with respect to Commission Staff Requirements Memorandum (SRM) for COMSECY-05-0028, on Increased Controls, at the time of the on-site review, The Industrial Unit had inspected 4 of the 21 subject licensees in accordance with the Increased Controls requirements. The review team evaluated the program's prioritization methodology and found it acceptable.

3.2.4 New York State Department of Environmental Conservation

DEC issues permits to facilities licensed by one of the other agencies 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 permitees based on the actual releases to the environment. Since the 35 permitees are required to report their effluents releases to DEC annually, the Program may adjust their inspections frequency accordingly as releases to the environment change. The assigned frequencies for permitees can range from one to four years. Most permitees are inspected at three or four year intervals. The review team determined that these frequencies are adequate to protect public health and safety.

The review team confirmed that one inspection identified in the questionnaire was performed overdue and that one initial inspection is currently overdue. DEC has not performed the initial inspection of this facility since the permitee has not used radioactive materials requiring emissions. The review team calculated that DEC performed 4 percent of its inspections overdue.

The timeliness of the issuance of inspection findings to licensees was evaluated during the inspection casework review. The review team evaluated eight letters transmitting the inspection findings to the licensees. Six of these letters were issued more than 30 days after the date of the inspection with the longest being issued 59 days after the date of the inspection. The DEC attributed the delay to the need to prioritize work and inefficiencies in the process to issue reports. In the 2002 IMPEP report, that review team noted that timely issuance of inspection findings was also an issue and made a recommendation. The current review team recommends that the 2002 review team's recommendation regarding the timely dispatch of inspection findings remain open for DEC. See recommendation in Section 3.2.5.

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, based on the percentage of licenses for which each program is responsible, the State performed approximately 6.8 percent of their Priority 1, 2, and 3, and initial inspections overdue. For individual programs, the range of overdue inspections ranged from approximately 3 to 7 percent.

The issuance of inspection findings to licensees for NYC, DOH, and the Industrial Unit was found to be timely. DEC was generally not timely in this issuance of inspection results, as discussed in Section 3.2.4. The review team recommends that DEC transmit inspection findings to their licensees within 30 days after the close of the inspection. This is a repeat recommendation from the 2002 IMPEP report.

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 from NYC and the Industrial Unit, the review team determined that the State met the criteria in IMC 1220 for reciprocity inspections.

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

3.3 Technical Quality of Inspections

The review team evaluated the inspection reports, enforcement documentation, and inspection field notes and interviewed select members of the inspection staff for 47 radioactive material inspections conducted during the review period. The casework reviewed included 27 inspections, representing each of the State's four programs, and covered inspections of various types of licenses including hospitals, private practices, high dose-rate remote afterloaders, gamma knife, brachytherapy, industrial radiography, radiopharmacy, manufacturing and distribution, academic and medical broad scope institutions, a commercial irradiator, and a waste processor. 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 certain classes of licensees or facilities are also included in the respective procedures manuals. The review team's evaluation of inspection reports identified three of the four programs have comparable inspection reports in regard to the types of information and data collected under IMC 2800. Inspections conducted by the Industrial Unit are generally performed on an announced basis; the remaining programs generally performed unannounced inspections.

Inspection reports were reviewed to determine if the reports adequately documented the scope of the licensed program, licensee organization, personnel protection, posting and labeling, control of material, equipment, use of material, transfer, increased controls and disposal. The reports were also checked to determine if they adequately documented operations observed, interview of workers, independent measurements, status of previous violations, substantiation of violations, and the substance of discussions during exit interviews with management. Based on the casework reviews and inspector interviews, the review team found that routine inspections covered all aspects of licensees' radiation protection programs by all programs. The review team found that for all four programs, the inspection reports were thorough, complete, consistent, and of high quality, with sufficient documentation 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 for training purposes.

A review team member accompanied ten inspectors from all four programs during the period of November 8, 2005, to October 26, 2006. The accompaniments included inspections of medical institutions, medical private practice, research and development, and a waste broker. 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 trained, well-prepared for the inspection, and thorough in their audits of the licensees' radiation safety programs. Each inspector conducted confirmatory measurements and utilized good health physics practices. Their inspections adequately assessed radiological health and safety at the licensed facilities.

The review team noted that all four 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, requires the inspector to perform instrument calibrations, or has a dedicated person who performs the instrument calibrations. The portable instruments used during the inspector accompaniments were operational and calibrated. All programs 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

During the previous IMPEP reviews in 1998 and 2002, the review teams determined that the documentation in the inspection field notes typically did not support the violations transmitted to licensees. Previous review teams also noted that inspection field notes did not review or discuss the relative safety significance or root causes of the violations identified to licensees. The 2002 review team found that the wording in the inspection field notes lacked sufficient detail in the program scope and for the identified violations, which apparently led to misinterpretation by the inspector supervisor as he prepared the compliance letter and the citations. During this review, the review team noted significant improvement in this area. As noted in Section 3.2.1, NYC changed their process for the preparation and issuance of letters to licensees. The inspector has more responsibility for the preparation of the transmittal letter. The review team found that the wording in the inspection field notes had sufficient detail in the program scope and for the identified violations, which lead to accurate compliance letters and the citations.

The review team noted a number of inspection files where the inspector's radiation survey instruments information was not included in field notes. Based on the discussions with NYC staff, the review team determined that the previous inspector supervisor did not require this information, and consequently, the inspectors did not provide it. Under the current inspector supervisor, the review team noted that this information is being provided more consistently.

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.

In addition to implementing Commission Staff Requirements Memorandum (SRM) for COMSECY-05-0028, on Increased Controls, the NYC Program is working with a DOE national laboratory and a contractor to perform individual security assessments of approximately 30 medical facilities. The assessment will make specific recommendations regarding each facility's overall security (not just radiological) and develop a generic security checklist. In a separate initiative, the New York City Police Department (NYPD) is also visiting radioactive materials users in the City. Although NYPD will make recommendations regarding the facility's security and will outline the usefulness of developing a local facility security plan, an important aspect of this initiative is outreach. NYC also indicated that NYPD has supported their Increased Control inspection efforts. A review team member observed a NYPD visit during an inspector accompaniment.

3.3.2 New York State Department of Health

The inspection field notes provided adequate, consistent documentation of inspection findings. DOH uses the same field note format “Inspection of Radionuclide Installations” for different types of inspections covering the areas of academic, research and development, medical, and teletherapy licenses.

To assure consistency and quality of reports, the Field Supervisor and Section Chief provide thorough reviews. Overall, the review team found that the inspection reports showed excellent quality and attention to detail. Reports contained no major discrepancies from standard practices or established DOH procedures.

When a licensee responds to a notice of violation, an inspector evaluates the response and, in all cases, a reply was sent to the licensee within 30 days of receipt. For the casework reviewed, documented inspection findings led to proper regulatory actions and appropriate enforcement. Inspection results showed licensee compliance was acceptable during the review period. For escalated enforcement, a review of select Administrative Tribunals (Hearing Boards) revealed that this process is very effective in obtaining compliance, whether the end result is a fine or other compliance commitment.

DOH has a policy of performing annual supervisory accompaniments of inspectors. In response to the questionnaire, DOH reported, and the review team confirmed, that all inspectors were accompanied by a supervisor annually during the review period.

3.3.3 New York State Department of Health - Industrial Unit

The inspection field notes evaluated by the review team exhibited adequate, consistent documentation of inspection findings. The review team noted that the Industrial Unit’s inspection field notes and inspection correspondence are peer reviewed by one of the senior inspectors to ensure consistency, thoroughness, and quality of reports. Overall, the review team found that peer review of the inspection documentation and correspondence resulted in their consistent high quality.

Routine enforcement letters were drafted and issued to licensees by the inspector. When the licensee responds to a notice of violation, the inspector evaluates the licensee's submittal and prepares a response. Once the inspector determines that the licensee has satisfactorily responded to the violations and has acknowledged their response, the inspection field notes and correspondence are given to another senior inspector for review. The inspectors informed the review team that they discuss any unusual issues regarding the inspection findings with management prior to issuing the inspection findings to the licensee. When significant commitments are made in response to violations, Industrial Unit staff performed a follow-up inspection to confirm that the commitments made in the licensee's correspondence were implemented.

For the casework reviewed, documented inspection findings led to proper regulatory actions and appropriate enforcement. Escalated enforcement action beyond the issuance of Notices of Violation was limited to the issuance of Orders.

Industrial Unit management has performed one supervisory accompaniment of a material inspector since the 2002 review. The manager stated that competing demands on his time and the extensive experience of the inspectors led him to not perform the accompaniments. However, two additional accompaniments were completed after the on-site reviews. In the 2002 report, the review team noted that Industrial Unit inspector accompaniments were an issue and made a recommendation. The review team considers this matter closed based on the inspector accompaniments performed by the review team and the subsequent accompaniments by DOH supervisors after the on-site review.

3.3.4 New York State Department of Environmental Conservation

The review team evaluated nine 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. Unresolved issues, recent changes to the permit, and specific concerns of the inspector are 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.

DEC also regulates the low-level radioactive waste (LLRW) transportation into, within, and through New York State via issuance of permits under the authority of 6 NYCRR 381 "Low-Level Radioactive Waste Transporter Permit and Manifest Regulations." Currently, one DEC technical staff member is specifically assigned to transportation issues. An annual report on LLRW waste transportation is prepared by DEC; the latest dated June 2005. A list of authorized treatment, storage, and disposal facilities was maintained on file. Verification of authorized facilities is done through the NRC or another Agreement State.

Enforcement actions are taken against generators for shipment of regulated medical waste contaminated with radioactive material to the landfills. Warning letters are sent to the waste generators for improper handling and shipment of regulated medical waste to the landfills.

3.3.5 Indicator Summary

Accompaniments of inspectors from all four programs demonstrated competent, thorough, safety-oriented inspections. The inspection processes and inspection documentation for all programs proved to be well designed and implemented.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that New York's performance with respect to the indicator, Technical Quality of Inspections, was 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 59 licensing actions were examined, including 5 new license issuances, 7 terminations, 29 amendments (including financial assurance and Increased Controls amendments), 3 modifications, 14 renewals, and 1 notification, encompassing the work of 18 license reviewers. The licensing casework was selected to provide a representative sample of licensing actions which had been completed 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 found that NYC's licensing actions were thorough, complete, consistent, and of good technical quality with health and safety issues properly addressed. All licensing actions are peer reviewed by license reviewers for content, grammar, and format. License conditions, including tie-down conditions, are usually stated clearly and are enforceable. Because of the experience level of the license reviewers, checklists, review plans, and standard procedures are not used.

The license reviewers have a longstanding working relationship with the licensees; such that license deficiencies are handled by undocumented telephone calls and e-mail. The review team determined that this practice does not lead to any significant health and safety issues, but it could hinder new reviewers' ability to follow and understand the licensing process. The review team discussed the importance of documenting licensee information requests in response to license application deficiencies with NYC management and staff.

The review team discussed with NYC staff the efforts they have made in terms of acquiring financial assurance for decommissioning from those licensees required to provide it. NYC determined that 14 of their licensees require financial assurance. Four of the 14 have actual possession limits below that requiring financial assurance; however, their authorized possession limits on their license may not have been reduced and therefore the licensee may be able to acquire radioactive material in quantities requiring financial assurance without the need to provide for financial assurance. The review team discussed the benefits of limiting possession limits in these cases with NYC. Eight of the 14 provided financial assurance. In cases where a Standby Trust Agreement (STA) was used, the bank revised the standard language and the reviewer accepted the new wording without a legal review. The review team discussed with NYC the necessity to perform a legal review in order to ensure that the STA meets the intent of the financial assurance requirement. The remaining two licensees have not submitted financial assurance even though the reviewers have provided all of the required information. In

discussions with NYC management, they committed to work with the two remaining licensees to obtain the required financial assurance.

The review team noted that financial assurance mechanisms (e.g., bonds) are kept in a filing cabinet in an unlocked room. NYC committed to moving all financial assurance to the license reviewer's office, and the room or the cabinet will be locked.

In discussions with NYC management, the review team noted that there are no major decommissioning efforts underway with regard to byproduct material within the City. NYC indicated that no exemptions were issued during the review period.

The review team examined the licensees that NYC determined met the criteria for the Increased Controls, per COMSECY-05-0028. The review team determined that NYC had correctly identified the licensees that require Increased Controls based on this criteria, and will continue to issue Increased Controls to any additional licensees, as appropriate. Each licensee was issued a NYC Commissioner's Order requiring the Increased Controls in accordance with the timeline established by the NRC in the SRM for COMSECY-05-0028.

3.4.2 New York State Department of Health

The review team found that DOH's licensing actions 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, as determined from documentation in the license files and/or discussions with the license reviewers.

License conditions, including tie-down conditions, are almost always stated clearly, backed by information contained in the file, and 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. No significant health and safety issues were identified.

The review team noted that financial assurance for decommissioning is required for private universities during the initial application or renewal process. Public institutions do not require financial assurance for decommissioning because State institutions are self-insured.

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 this 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.

3.4.3 New York State Department of Health - Industrial Unit

The review team found that the Industrial Unit's licensing actions 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, as determined from discussions with the license reviewers.

The casework review indicated that the Industrial Unit's staff follow their licensing guides during the review process to ensure that licensees submit the information necessary to support the request. License conditions, including tie-down conditions, are usually stated clearly and are enforceable. Deficiency letters clearly stated regulatory positions.

The review team noted that there are 33 licenses that have been in timely renewal for more than one year. They range in age from 1996 to 2005. In speaking with the Industrial Unit manager, he indicated that these licenses were not completed because of the loss of experienced personal and the reorganization. In some cases, licensed operations have not significantly changed and the facilities are inspected periodically. The Industrial Unit has inspected these licensees at intervals shorter than those prescribed for similar license types in IMC 2800. The review team noted that even though the renewals have not been completed, any potential health and safety issues should have been identified during the inspection process. Industrial Unit management is aware of this licensing backlog and will prioritize the oldest renewals. With the recent merger, there is additional qualified personnel to distribute the workload and minimize or eliminate the licensing backlog.

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

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 permit holders 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 issued six exemptions of 6 NYCRR Part 381 mostly to broad-scope academic licensees who transport Class A LLRW between their various complexes, facilities, and buildings, using registered vehicles for consolidation of waste prior to final transport. These exemption permits are renewed every two years.

The review team found that cancellation permitting 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 enure 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. Currently this process at the permit administrator level may take as long as several months. This delay in the issuance of permits could impact permitees. 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 followup action.

3.4.5 Indicator Summary

The review team found that the licensing and/or permitting actions for all New York programs were thorough, complete, consistent, and of good technical quality with health and safety issues properly addressed.

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

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 NMED against those contained in the respective program's files, and evaluated the casework and supporting documentation for 22 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 seven 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 with the Program Managers and selected staff. The incidents included: lost/stolen materials, equipments failures/disconnects, contamination/spills, damaged devices and packages, and medical events.

3.5.1 New York City Department of Health and Mental Hygiene

NYC staff investigated a total of 72 incidents during the review period. The review team evaluated reports and supporting documentation for seven radioactive materials incidents for NYC. The majority of these incidents were not reportable to NRC, based on the guidance in

NRC's Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-300, "Reporting Materials Incidents." NYC's response to incidents was 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 on during the course of the incident's investigation and prior to closure. The licensees' responses were reviewed by Program staff for adequacy. Copies of incident investigations are placed in licensee's license/inspection file. Incident cases were filed according to year and date of occurrence. Any pending actions are considered before new licensing actions are taken and are also followed up on during the next routine inspection. Individual incident files did not always include an incident log number, during the 2002 to 2005 time frame. NYC does not utilize an automated tracking database for incidents and allegations; however, case files are easily retrieved from folders filed in chronological order.

The review team assessed NYC's response to four allegations involving radioactive material, including two allegations referred to NYC by the NRC. In both NRC cases 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 followup, notification, and close-out were made. The review team identified two additional allegations, which were properly handled including appropriate notification.

3.5.2 New York State Department of Health

During the review period, DOH investigated 37 incidents. The review team evaluated all seven incidents requiring reporting to the NRC and one allegation. DOH utilizes a newly established automated incident/event tracking systems 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 and NMED, 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 followup action, as appropriate.

Incidents and allegations are investigated based on their radiological health and safety significance. On-site investigations are prompt, thorough and well-documented. Significant improvement was noted in DOH's reporting of incidents to NRC and NMED in accordance with FSME Procedure SA-300. A comparison of reportable incidents on file in NMED to those contained in the "Incident" database proved that the required incidents were captured.

3.5.3 New York State Department of Health - Industrial Unit

During the review period the Industrial Unit investigated 41 incidents. The review team evaluated all six incidents requiring reporting to the NRC and three allegations, one of which was referred to the Industrial Unit by NRC. The review team found the Industrial Unit's response to incidents and allegations to be comprehensive and complete. Initial responses were prompt and well-coordinated. The level of investigative effort was commensurate with the health and safety significance. Inspectors dispatched to conduct on-site investigations employed appropriate enforcement tools to achieve regulatory compliance. Allegers' identities are protected from disclosure and feedback to allegers was made as appropriate.

Licensees are required to review each incident from a root cause analysis perspective and to develop measures to prevent recurrence. The Industrial Unit's staff reviews the adequacy of the licensees' responses and provides feedback to the respective licensee.

3.5.4 New York State Department of Environmental Conservation

The review team evaluated DEC's response to two radioactive materials 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 followup action, as needed. DEC did not have any incidents that met the criteria for reporting to NMED. DEC received no allegations during the review period.

3.5.5 Indicator Summary

New York's performance for this indicator was adequate and prompt. The review team noted an improvement in NYC's cataloging of incidents since 2005. DOH's automated "Incident" database is a significant improvement in identifying, tracking, and trending incident and allegation information.

The New York programs have procedures in-place and are, when appropriate, reporting incidents to the NRC and to NMED.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that New York's performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, was satisfactory.

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, DOL, and DEC. Now, there are only three; 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.

Accommodations were made to transfer authority in a manner that minimizes the impact on licensee activities. All rules, regulations, and acts in effect at the time of the transfer will remain in effect until duly modified or abrogated by the Commissioner of Health. Due to the short amount of time between the merge and the IMPEP review, DOH has kept the programs separate (functionally operating as units) until plans can be made to fully integrate personnel, responsibilities, and regulations of the two units. New York State Environmental Conservation Law Articles 1, 3, 17, 19, 27 and 29 are the bases 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, particularly in the case of the Increased Controls license condition. On licenses in which Increased Controls apply, DOH and the Industrial Unit implement the Order in different fashions; DOH listed all six Increased Controls conditions on the licenses, whereas the Industrial Unit used tie-down conditions. These methods will be aligned as the programs become fully integrated.

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. The regulatory adoption processes for the State-wide programs (DOH, including the Industrial Unit, and DEC) include a review of proposed regulations by the Governor's Office for Regulatory Reform (GORR). This Office evaluates proposed regulations for impact on the State's small business community.

NYC regulations are found in Article 175 of the New York City Health Code and apply to all ionizing radiation, whether emitted from radionuclides or devices. NYC requires a license for possession and use of all radioactive material, including naturally occurring and accelerator-produced radioactive material (NARM). NYC also requires registration of all equipment designed to produce x-rays or other ionizing radiation. NYC's regulatory adoption process is a six-step process that takes between six months and one year to complete, depending on the complexity of the rule change.

Since the 2002 IMPEP review, NYC has adopted the Increased Controls license condition and ten NRC amendments. Some of the amendments cannot be implemented until DOH has adopted similar requirements to ensure consistent regulation of licensees throughout the State and to prevent transboundary issues when licensees cross jurisdictions.

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

- "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.

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

- "Compatibility with IAEA Transportation Safety Standards and other Transportation Safety Amendments," 10 CFR Part 71 amendment (69 FR 3697), that became effective on October 1, 2004, and is due for Agreement State adoption by October 1, 2007.

- "Medical Use of Byproduct Material - Recognition of Specialty Boards," 10 CFR 35 Part amendment (70 FR 16336; 71 FR 1926), that became effective on April 29, 2005, and is due for Agreement State adoption by April 29, 2008.

- "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.

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 and apply to all ionizing radiation, whether emitted from radionuclides or devices used for medical, academic, or research and development. DOH requires a license for possession and use of all radioactive material, including NARM. DOH also requires registration of all equipment designed to produce x-rays or other ionizing radiation. DOH's regulatory adoption process is a ten-step process that takes approximately 12 to 18 months, depending on the complexity of the action.

During the review period, DOH adopted the Increased Controls license condition and one NRC amendment. DOH submitted three final regulations to the NRC for a compatibility review. NRC staff identified comments on the regulations that will need to be addressed in order for the regulations to be compatible with Federal requirements. DOH has drafted a number of legally binding requirements to address NRC amendments while regulations are being promulgated. The review team informed DOH management and staff of the process, as detailed in FSME Procedure SA-201, "Review of State Regulatory Requirements," for submitting legally binding requirements, such as license conditions, to the NRC for a compatibility review.

DOH has drafted legally binding requirements for the following NRC amendments; however, none of them have been submitted to the NRC for a compatibility review:

- "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.

- "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.

- "Frequency of Medical Examinations for Use of Respiratory Protection Equipment," 10 CFR Part 20 amendment (60 FR 7900), that became effective on March 13, 1995, and was due for Agreement State adoption by March 13, 1998.

- "Clarification of Decommissioning Funding Requirements," 10 CFR Parts 30, 40, and 70 amendments (60 FR 38235), that became effective on November 24, 1995, and was due for Agreement State adoption by November 24, 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 on August 20, 1997, and was due for Agreement State adoption by August 20, 2000.

- "Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14 Urea," 10 CFR Part 30 amendment (62 FR 63634), that became effective on January 2, 1998, and was due for Agreement State adoption by January 2, 2001.

- "Respiratory Protection and Controls to Restrict Internal Exposure," 10 CFR Part 20 amendment (64 FR 54543, 64 FR 55524), that became effective on February 2, 2000, and was due for Agreement State adoption by February 2, 2003.

- "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 - Recognition of Specialty Boards," 10 CFR 35 Part amendment (70 FR 16336; 71 FR 1926), that became effective on April 29, 2005, and is due for Agreement State adoption by April 29, 2008.

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

- "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.

- "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.

- "Compatibility with the International Atomic Energy Agency," 10 CFR Part 71 amendment (60 FR 50248 and 61 FR 28724), that became effective on April 1, 1996, and was due for Agreement State adoption on April 1, 1999.

- "Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction With an Agreement State," 10 CFR Part 150 amendment (62 FR 1662), that became effective on February 27, 1997, and was due for Agreement State adoption by February 27, 2000.

- "Criteria for the Release of Individuals Administered Radioactive Material," 10 CFR Parts 20 and 35 amendments (62 FR 4120), that became effective on May 29, 1997, and was due for Agreement State adoption by May 29, 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.

- "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.

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

- "Compatibility with IAEA Transportation Safety Standards and other Transportation Safety Amendments," 10 CFR Part 71 amendment (69 FR 3697), that became effective on October 1, 2004, and is due for Agreement State adoption by October 1, 2007.

- "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.

The Industrial Unit's regulations are found in Part 38 of Title 12 of the Official Compilation of Codes, Rules and Regulations of the State of New York (12 NYCRR Part 38) and apply to all commercial and industrial uses of radioactive material. The Industrial Unit requires a license for possession and use of all radioactive material for commercial and industrial purposes, including NARM. The Industrial Unit's regulatory adoption process used to be a seven-step process that took at least 12 months to complete. Since the merger with DOH, the Industrial Unit's regulatory adoption process is now consistent with DOH's regulatory adoption process.

Since the previous IMPEP review, the Industrial Unit adopted the Increased Controls license condition and a legally binding requirement for one overdue amendment. The review team discussed with Industrial Unit staff the use of legally binding requirements to use in interim while GORR considers proposed regulations. Industrial Unit staff started meeting weekly to promulgate legally binding requirements to address outstanding NRC amendments and to discuss necessary accommodations to the regulations for the DOH/DOL merge. Industrial Unit regulations shall be amended to include the new NRC amendments in conjunction with the incorporation of these requirements into DOH regulations. DOH Industrial Unit staff are exploring the legality of adopting regulations by reference to Federal regulations, which may shorten the adoption period.

For the Industrial Unit, the following NRC amendments are overdue for adoption:

- "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.

- "Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction With an Agreement State," 10 CFR Part 150 amendment (62 FR 1662), that became effective on February 27, 1997, and was due for Agreement State adoption by February 27, 2000.

- "Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations," 10 CFR Parts 30, 34, 71, and 150 amendments (62 FR 28947), that became effective on June 27, 1997, and was due for Agreement State adoption by June 27, 2000.

- "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.

- "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.

- "Energy Compensation Sources for Well Logging and Other Regulatory Clarifications," 10 CFR Part 39 amendment (65 FR 20337), that became effective on May 17, 2000, and was due for Agreement State adoption by May 17, 2003.

- "New Dosimetry Technology," 10 CFR Parts 34, 36, and 39 amendments (65 FR 63749), that became effective on January 8, 2001, and was due for Agreement State adoption by January 8, 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 April 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.

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

- "Compatibility with IAEA Transportation Safety Standards and other Transportation Safety Amendments," 10 CFR Part 71 amendment (69 FR 3697), that became effective on October 1, 2004, and is due for Agreement State adoption by October 1, 2007.

- "Security Requirements for Portable Gauges Containing Byproduct Material," 10 CFR Part 30 amendment (70 FR 2001), that became effective on July 11, 2005, and is due for Agreement State adoption by July 11, 2008.

- "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.

DEC regulations are found in Title 6, Parts 380, 381, 382, and 383 of the New York Codes, Rule, and Regulations 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 is a ten-step process that takes approximately 18 to 24 months to complete.

Since the previous review, DEC has drafted regulations to address seven NRC amendments and is in the process of writing the supporting documentation (e.g. Regulatory Analysis, Environmental Assessment, etc.) for submission to GORR. The rulemaking package is estimated to be completed in early 2009. DEC is currently addressing parts of the NRC amendment, "Radiological Criteria for License Termination," through legally binding requirements.

For DEC, the following 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.

- "Decommissioning Record keeping 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.

- "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.

- "Termination or Transfer of Licensed Activities: Record keeping 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 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.

The State-wide programs (DOH, including the Industrial Unit, and DEC) are not able to completely adopt the NRC's "Deliberate Misconduct by Unlicensed Persons" amendment due to legal constraints. The Industrial Unit's legal counsel's review of this amendment determined that it is beyond the scope of the State's regulatory authority. New York's regulatory authority is limited to licensees and registrants. Industrial Unit management indicated that, in the case of a subcontractor or other third party whose deliberate misconduct resulted in a licensee violating DOL regulations, the program's recourse would be the pursuit of enforcement action against the licensee. Despite this limitation of regulatory authority, the New York programs still must include the other requirements of the deliberate misconduct amendment in the State's regulations and implement those requirements effectively.

The review team noted that since the last IMPEP review, DEC adopted the following amendments:

- "Transfer for Disposal and Manifests: Minor Technical Conforming Amendment," 10 CFR Part 20 Amendment (63 FR 50127) that became effective November 20, 1998, and was due for Agreement State adoption by November 20, 2001.

- "Compatibility with IAEA Transportation Safety Standards and other Transportation Safety Amendments," 10 CFR Part 71 amendment (69 FR 3697), that became effective on October 1, 2004, and is due for Agreement State adoption by October 1, 2007.

In response to the requirements of 651(e) of the Energy Policy Act of 2005 (EPAct), the State of New York intends to submit a letter to the NRC to indicate that the State intends to continue to regulate all radioactive materials which includes naturally occurring radioactive material, such as radium, and accelerator-produced radionuclides. Rather than officially amending the New York's Agreement with the NRC, the Governor-appointed State Liaison Officer expects to coordinate with all the programs and obtain the Governor's certification, defined in the EPAct, to continue regulatory authority for the newly-defined byproduct material (NARM).

4.1.3 Indicator Summary

The review team noted that all programs continue have a number of overdue NRC amendments. The review team concluded that the delay in the promulgation of regulations in a timely matter was caused in part by the need to address higher priority issues that may affect public health and safety and in part due to the state's lengthy promulgation process. The review team recommends that the three State Agencies (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.

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

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

The Industrial Unit has sole responsibility for performing SS&D evaluations in the State of New York. Three sub-indicators were used to evaluate the Industrial Unit'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 Industrial Unit'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 Industrial Unit indicated that two SS&D evaluations had been performed since the previous IMPEP. During the on-site review, the review team did not identify any additional SS&D evaluations completed since the previous IMPEP. The review team assessed the documentation for the two SS&D evaluations performed and interviewed staff and management involved in SS&D evaluations.

4.2.1 Technical Staffing and Training

The Program Manager and two radiophysicists are the reviewers qualified to conduct and sign safety evaluations of SS&D applications. The Program Manager documented specific training courses required and taken by all reviewers. The two radiophysicists have taken all required training. The Program Manager has taken all required training, except NRC's Inspection Procedures course; however, the Program Manager's years of experience in inspections reasonably satisfies qualification requirements. Only the Program Manager and one of the radiophysicists performed SS&D evaluations since the previous IMPEP. The review team interviewed these individuals and found them familiar with the SS&D evaluation process. They are also familiar with and have access to applicable guidance and reference documents. Due to the very low number of evaluations performed over the years, the Industrial Unit does not have a formal qualification board, nor a minimum number of evaluations needed to become a qualified SS&D reviewer. Signature authority is granted after successfully completing required training classes. The review team determined that the reviewers are qualified to review and sign SS&D evaluations and that the Industrial Unit has a sufficient staffing level of qualified reviewers to adequately handle their workload.

4.2.2 Technical Quality of the Product Evaluation Program

The Industrial Unit processed two 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 Industrial Unit staff follow 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

Industrial Unit staff were not aware of any defects or incidents involving sources and devices evaluated by their program. The review team conducted a search of NMED and Industrial Unit files to determine whether incidents outside of the knowledge of Industrial Unit staff existed. The review team did not identify any incidents involving sources or devices evaluated by the Industrial Unit.

4.2.4 Indicator Summary

The Industrial Unit performed two 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 recommended, and the MRB agreed, that New York's performance with respect to the indicator, Sealed Source and Device Evaluation Program, was 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. The wastes, approximately 2.4 million cubic feet, that were 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 West Valley and inspections at Cornell. At times, staff from DEC regional offices accompany the inspector to observe and to assist with sampling. As indicated in Section 3.1.4, the training, experience, and the educational qualifications for this inspector were evaluated and were found to be adequate. Qualifications of the three Industrial Unit inspectors that may inspect the facility were reviewed by the team and found to be adequate. See Section 3.1.2 for additional details.

4.3.2 Status of Low-Level Radioactive Waste Disposal Inspections

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

DEC inspected the West Valley site three times during the review period in November 2002, August 2004, and April 2005. The Cornell site was inspected by DEC in October 2002, June 2003, and July 2004. DEC management attributed the delay in conducting the annual inspections to a lack of sufficient staff and higher priority work. The Program Manager indicated that DEC staff has been to both sites a number of times since the last inspections in 2004 and 2005 for site tours and meetings. During these visits, staff has had the opportunity to observe the condition of the sites. The review team concluded that despite the lack of a formal inspection by DEC of these closed sites for the last two to three years, the on-site visits are adequate to ensure that the sites have not changed significantly and that health and safety continues to be adequately protected. The Program completed inspections of both sites following the on-site review.

Regarding the timeliness of inspection reports, the review team noted that six of the seven DEC inspection reports issued were greater than 30 days after the completion of the inspection. This matter is discussed in detail in Section 3.2.4 and the recommendation made in Section 3.2.5 also applies for inspection reports for LLRW facilities. The team found that the Industrial Unit issued their inspection findings to NYSERDA within 30 days of completion of the inspection.

4.3.3 Technical Quality of Inspections

The review team evaluated all the DEC reports and the latest Industrial Unit inspection report 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 inspections 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. The listing of inspection casework reviewed in Appendix C includes the casework reviewed in evaluating this indicator.

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, at the nearest residence, at Sardinia, and at Rock Spring Road. Surface water and sediment samples are collected from the three creeks.

The DEC inspector is accompanied by his supervisor every two years. The review team found this frequency acceptable given the small number of inspections performed by the DEC staff member assigned to these sites.

4.3.4 Technical Quality of Licensing Actions

The Industrial Unit 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 renewal and a subsequent amendment issued by the Industrial Unit for this license and found the licensing actions thorough, complete, and of high technical quality. These casework reviews are included in Appendix D.

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 expired on October 1, 2002; however, it was extended under the State's Administrative Procedures Act. NYSERDA submitted a sufficient application before the expiration date, and DEC staff had initiated reviewing the application and discussing revisions with NYSERDA. NYSERDA and DEC staff were also committed to working with US Department of Energy on the Environmental Impact Statement for the entire West Valley site. This activity took priority over the permit renewal. Renewal of the maintenance and monitoring permit is currently in process. The renewal will include updating or replacing all of the tie-down documents.

An air permit issued to NYSERDA was terminated early in the review period, and relevant provisions were combined with the maintenance and monitoring permit. The review team evaluated licensing actions completed by DEC and found them to be thorough, complete, and of high technical quality.

4.3.5 Technical Quality of Incident and Allegation Activities

There were no incidents, allegations, operational errors, damage, or accidents related to the West Valley or the Cornell sites since the last review.

4.3.6 Indicator Summary

Oversight of the two former radioactive waste disposal sites by DEC and the Industrial Unit is suitable and thorough.

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

5.0 SUMMARY

New York's performance was found satisfactory for all performance indicators with the exception of Compatibility Requirements, which was found unsatisfactory. Accordingly, the review team recommended, and the MRB agreed, that the New York Agreement State Program is adequate to protect public health and safety and not compatible with NRC's program. The compatibility determination was based on significant delays in the adoption of required regulations. The review team recommended, and the MRB agreed, that the period of Heightened Oversight of the New York Agreement State Program continue until required regulations or legally binding requirements are adopted by New York and reviewed and determined to be compatible by the NRC. The review team recommended, and the MRB agreed, that a periodic meeting will be conducted in approximately one year and that the next full IMPEP review of the New York Agreement State Program will take place in approximately four years.

Below is a summary list of recommendations, as mentioned in earlier sections of the report, for evaluation and implementation, as appropriate, by the State.

RECOMMENDATIONS:

1. The review team recommends that DEC transmit inspection findings to their licensees within 30 days after the close of the inspection. (Section 3.2.5) (Open recommendation from the 2002 IMPEP Review)

2. The review team recommends that the three State Agencies (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. (Section 4.1.3) (Open recommendation from the 2002 IMPEP Report)

LIST OF APPENDIXES AND ATTACHMENT

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
Lloyd Bolling, FSME	Team Leader Technical Staffing and Training Technical Quality of Incident and Allegation Activities Compatibility Requirements
Duncan White, Region I	Status of Materials Inspection Program Technical Quality of Inspections Inspector Accompaniments
Kathy Modes, Region I	Technical Quality of Licensing Actions
Deborah Gilley, Florida	Technical Quality of Licensing Actions
Jennifer Tobin, FSME	Technical Staffing and Training Technical Quality of Incident and Allegation Activities Compatibility Requirements
Jonathan Rivera, FSME	Sealed Source and Device Evaluation Program
Stephen Matthews, Washington	Status of Materials Inspection Program Technical Quality of Inspections Low-Level Radioactive Waste Disposal Program

APPENDIX B

NEW YORK ORGANIZATION CHARTS

ADAMS ASSESSION NOS.
ML063530794, ML063530800, ML063530801

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: MDS Nordion — License No.: 2087-0793
Inspection Type: Reciprocity — Priority: N/A
Inspection Date: 6/29/06 — Inspector: HT

File No.: 2
Licensee: Our Lady of Mercy — License No.: 91-2900-01
Inspection Type: Routine, Announced — Priority: 5
Inspection Date: 7/25/06 — Inspector: JH

Comment:
Inspection file contained personnel information.

File No.: 3
Licensee: Our Lady of Mercy — License No.: 91-2900-01
Inspection Type: Increased Controls — Priority: N/A
Inspection Date: 7/25/06 — Inspectors: JD/TL

File No.: 4
Licensee: Columbia Presbyterian Medical Center — License No.: 93-2878-05
Inspection Type: Initial, Unannounced — Priority: 2
Inspection Date: 8/15/06 — Inspector: JH

File No.: 5
Licensee: Columbia Presbyterian Medical Center — License No.: 93-2878-05
Inspection Type: Increased Controls — Priority: N/A
Inspection Date: 8/15/06 — Inspector: JD

File No.: 6
Licensee: Memorial Sloan Kettering — License No.: 75-2968-01
Inspection Type: Routine, Announced — Priority: 2
Inspection Date: 1/25/06 — Inspector: EC

Comments
a) Violation was issued identifying the incorrect procedure number.
b) Inspector's radiation survey instruments information not included in field notes.

File No.: 7
Licensee: Herry Gunarta — License No.: 91-3294-01
Inspection Type: Routine, Announced — Priority: 5
Inspection Date: 9/7/06 — Inspector: OC

File No.: 8
Licensee: Columbia Unversity License No.: 74-3030-01
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 4/6/06 Inspector: JH

Comment:
Inspector's radiation survey instruments information not included in field notes.

File No.: 9
Licensee: New York University Medical Center License No.: 93-2955-05
Inspection Type: Routine, Announced Priority: 2
Inspection Date: 11/6/05 Inspector: EC

File No.: 10
Licensee: New York Community Hospital License No.: 91-2991-01
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 3/30/06 Inspector: HT

Comment:
Inspector's radiation survey instruments information not included in field notes.

File No.: 11
Licensee: Coney Island Hospital License No.: 91-2902-01
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 6/15/06 Inspector: OC

New York State Department of Health

File No.: 12
Licensee: Community General Hospital License No.: 1099
Inspection Type: Routine, Announced Priority: 3
Inspection Date: 11/10/05 Inspector: WK

File No.: 13
Licensee: Canton-Potsdam Hospital License No.: 1097-2
Inspection Type: Routine, Announced Priority: 5
Inspection Date: 10/17/05 Inspector: VG

File No.: 14
Licensee: SUNY Upstate Medical University License No.: 0047
Inspection Type: Routine, Announced Priority: 2
Inspection Dates: 12/8-19/03 Inspectors: GB, JC, HS

Comment:
Inspectors reviewed licensee's gamma knife program but did not document due to lack of specific inspection field notes for this modality.

File No.: 15
Licensee: Geneva General Hospital License No.: 1766
Inspection Type: Routine, Announced Priority: 5
Inspection Date: 8/24/04 Inspector: WK

File No.: 16
Licensee: SUNY Albany License No.: 0459-01
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 11/2/04 Inspectors: AD, JC

File No.: 17
Licensee: New York United Hospital Medical Center License No.: 1005
Inspection Type: Routine, Unannounced Priority: 2
Inspection Dates: 3/9/03 and 7/25/03 Inspector: OO

File No.: 18
Licensee: Kaleida Health- DeGraff Memorial Hospital License No.: 0548
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 9/21/05 Inspector: BI

Comment:
Inspector's radiation survey instruments information not complete.

File No.: 19
Licensee: Columbia University License No.: 0537-3
Inspection Type: Routine, Unannounced Priority: 3
Inspection Dates: 5/13-14/05 Inspector: GB

Comment:
Inspector's radiation survey instrument information not complete.

File No.: 20
Licensee: Good Samaritan Hospital License No.: 0575
Inspection Type: Routine, Unannounced Priority: 2
Inspection Dates: 8/17-18/06 Inspector: CB

File No.: 21
Licensee: Amsterdam Associates in Cardiology License No.: 5051
Inspection Type: Routine, Unannounced Priority: 5
Inspection Date: 3/6/06 Inspector: JC

Comment:
Inspection file contained personnel information.

File No.: 22
Licensee: John T. Mather Memorial Hospital License No.: 0495
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 12/15/05 Inspector: AB

File No.: 23
Licensee: Cold Spring Harbor Laboratory License No.: 0574
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 12/12/03 Inspector: AB

Comment:
Inspector's radiation survey instrument information not complete.

File No.: 24
Licensee: Good Samaritan Hospital License No.: 0490
Inspection Type: Routine, Unannounced Priority: 2
Inspection Dates: 6/13/06 and 6/21/06 Inspector: JK

File No.: 25
Licensee: Cornell University License No.: 0005-3A
Inspection Type: Routine, Announced Priority: 2
Inspection Dates: 5/20-23/03 Inspectors: SK, OO, GB

File No.: 26
Licensee: Orange Regional Medical Center License No.: 0563
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 7/11/06 Inspector: JK

Comment:
Inspector's radiation survey instrument information not complete.

File No.: 27
Licensee: Inter-Community License No.: 3191
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 6/22/06 Inspector: SK

File No.: 28
Licensee: Mount Vernon Hospital License No.: 1006
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 4/21/06 Inspector: OO

Comment:
Inspector's radiation survey instrument information not complete.

File No.: 29
Licensee: Sisters of Charity Hospital License No.: 2911
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 5/31/06 Inspector: SK

New York State Department of Health - Industrial Unit

File No.: 30
Licensee: Buffalo X-Ray Company — License No.: 0286-0511
Inspection Type: Increased Controls — Priority: N/A
Inspection Dates: 9/7/06 and 10/20/06 — Inspector: BK

File No.: 31
Licensee: Cardinal Health — License No.: 2449-3500
Inspection Type: Routine, Unannounced — Priority: 2
Inspection Dates: 6/28-29/05 — Inspector: RP

File No.: 32
Licensee: CoPhysics Corporation — License No.: 2691-3949
Inspection Type: Routine, Announced — Priority: 3
Inspection Date: 12/21/05 — Inspector: RP

File No.: 33
Licensee: General Electric Company — License No.: 0794-0220
Inspection Type: Routine, Announced — Priority: 2
Inspection Date: 1/10/05 — Inspector: RP

File No.: 34
Licensee: General Electric Company — License No.: 0794-0220
Inspection Type: Routine, Announced — Priority: 2
Inspection Dates: 1/5-6/05 — Inspector: JM

File No.: 35
Licensee: Municipal Testing Laboratory, Inc. — License No.: 2072-1988
Inspection Type: Routine, Unannounced and Increased Controls — Priority: 1
Inspection Dates: 9/1/06 and 9/28/06 — Inspector: BK

File No.: 36
Licensee: NYSERDA — License No.: 0382-1139
Inspection Type: Routine, Unannounced — Priority: 1
Inspection Date: 12/1/04 — Inspector: JM

File No.: 37
Licensee: Radiac Research Corporation — License No.: 1944-1879
Inspection Type: Routine, Announced — Priority: 2
Inspection Date: 12/19/05 — Inspector: RP

File No.: 38
Licensee: Pall RAI Manufacturing Company — License No.: 1935-1921
Inspection Type: Routine, Unannounced — Priority: 2
Inspection Date: 2/7/06 — Inspector: BK

Comment:
Inspection file contained personnel information.

New York State Department of Environmental Conservation

File No.: 39
Permitee: Eastman Kodak Company Permit Nos.: 8-2614-00205/01177 & /01826
Inspection Type: Routine, Unannounced Priority: 4
Inspection Date: 10/2/06 Inspector: SH

Comment:
Letter to permitee issued 47 days after completion of inspection.

File No.: 40
Permitee: Proctor & Gamble Pharmaceuticals Permit Nos.: 7-0842-00013/00007 & /00009
Inspection Type: Routine, Announced Priority: 4
Inspection Date: 7/18/06 Inspectors: AG, JF

Comment:
Letter to permitee issued 44 days after completion of inspection.

File No.: 41
Permitee: Cardinal Health Permit No.: 9-1430-00175/00001
Inspection Type: Routine, Unannounced Priority: 4
Inspection Date: 8/27/03 Inspectors: AG, MS

Comments:
Letter to permitee issued 39 days after completion of inspection.

File No.: 42
Permitee: NRD, Inc. Permit No.: 9-1446-00018/00001
Inspection Type: Special, Announced Priority: 3
Inspection Date: 7/14/05 Inspectors: BY, JF

Comment:
Letter to permitee issued 59 days after completion of inspection.

File No.: 43
Permitee: NYS Health Department - Wadsworth Center Permit No.: 4-0130-00034/0001
Inspection Type: Routine, Announced Priority: 4
Inspection Date: 1/11/06 Inspectors: JF, AG

Comment:
Letter to permitee issued 42 days after completion of inspection.

File No.: 44
Permitee: MP Biomedicals East, Inc. Permit No.: 3-3924-00003/00002
Inspection Type: Termination Priority: 4
Inspection Date: 10/20/05 Inspector: SH

File No.: 45
Permitee: MP Biomedicals East, Inc. Permit No.: 3-3924-00003/00002
Inspection Type: Routine, Announced Priority: 4
Inspection Date: 8/3/04 Inspector: MS

File No.: 46
Permitee: Wyeth Research Permit No.: 3-3924-00025/386-0
Inspection Type: Routine, Unannounced Priority: 4
Inspection Date: 6/6/06 Inspector: SH

File No.: 47
Permitee: Nuclear Diagnostics Products Permit No.: 1-2824-02390/2
Inspection Type: Initial, Announced Priority: 4
Inspection Date: 7/26/05 Inspectors: AG, SH

Comment:
Letter to permitee issued 51 days after completion of inspection.

File No.: 48
Permitee: Cornell University Permit No.: 7-5032-00102/00001
Inspection Type: Routine, Announced Priority: 1
Inspection Dates: 10/22/02, 6/12/03, 12/4/03, 7/28/04 Inspector: TR

Comment:
Letters to permitee issued at 40, 145, 46 and 20 days after completion of inspections.

File No.: 49
Permitee: NYSERDA - West Valley State Disposal Area Permit No.: 9-0422-00011/00011
Inspection Type: Routine, Announced Priority: 1
Inspection Dates: 11/12-13/02, 8/18-19/04, 4/25-27/05 Inspector: TR

Comment:
Letters to permitee issued at 35, 149 and 54 days after completion of inspections.

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: Long Island College Hospital License No.: 91-2843-01
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 10/24/06 Inspector: EC

Accompaniment No.: 2
Licensee: St. Vincent's Midtown Hospital License No.: 91-2882-01
Inspection Type: Routine, Unannounced Priority: 5
Inspection Date: 10/26/06 Inspector: JH

New York State Department of Health

Accompaniment No.: 3
Licensee: Hudson Valley Heart Center — License No.: 3036
Inspection Type: Routine, Unannounced — Priority: 5
Inspection Date: 11/8/05 — Inspector: JC

Accompaniment No.: 4
Licensee: Glen Falls Hospital — License No.: 0481
Inspection Type: Routine, Unannounced — Priority: 2
Inspection Date: 11/9/05 — Inspector: AD

Accompaniment No.: 5
Licensee: Community General Hospital — License No.: 1099
Inspection Type: Routine, Unannounced — Priority: 2
Inspection Date: 11/10/05 — Inspector: WK

Accompaniment No.: 6
Licensee: Southside Hospital — License No.: 0405-2
Inspection Type: Routine, Unannounced — Priority: 3
Inspection Date: 6/8/06 — Inspector: CB

Accompaniment No.: 7
Licensee: Good Samaritan Hospital — License No.: 0490
Inspection Type: Routine, Unannounced — Priority: 2
Inspection Date: 6/13/06 — Inspector: JK

Accompaniment No.: 8
Licensee: White Plains Medical Center — License No.: 1059
Inspection Type: Routine, Unannounced — Priority: 3
Inspection Date: 6/14/06 — Inspector: OO

New York State Department of Health - Industrial Unit

Accompaniment No.: 9
Licensee: Radiac Research Corporation — License No.: 1944-1879
Inspection Type: Routine, Announced — Priority: 2
Inspection Date: 12/19/05 — Inspector: RP

New York State Department of Environmental Conservation

Accompaniment No.: 10
Permitee: Wyeth Ayerst Research — Permit No.: 3-3924-00025/386-0
Inspection Type: Routine, Unannounced — Priority: 3
Inspection Date: 6/6/06 — Inspector: SH

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: Herry Gunarta, M.D. License No.: 91-3294-01
Type of Action: Termination Amendment No.: 2
Date Issued: 10/10/06 License Reviewer: DH

File No.: 2
Licensee: Mt. Sinai School of Medicine License No.: 74-2909-05
Type of Action: Financial Assurance Amendment No.: 3
Date Issued: 9/20/06 License Reviewer: DH

Comment:
Upon review, by NYC, it was determined that financial assurance is required. Discussions with the licensee over an extended period of time have not resolved several issues. NYC staff is referring this case to upper management for resolution.

File No.: 3
Licensee: NYU Hospitals Center License Nos.: 75-2955-01, 92-2955-03, 93-2955-05
Type of Action: Financial Assurance Amendment No.: N/A
Date Issued: N/A License Reviewer: DH

Comment:
A revised Standby Trust Agreement was accepted without a legal review.

File No.: 4
Licensee: NYU School of Medicine License No.: 74-2955-02
Type of Action: Financial Assurance Amendment No.: N/A
Date Issued: N/A License Reviewer: DH

Comment:
Upon review, by NYC, it was determined that financial assurance is required. Discussions with the licensee over an extended period of time have not resolved several issues. NYC staff is referring this case to upper management for resolution.

File No.: 5
Licensee: SUNY Health Sciences Center License No.: 74-2934-02
Type of Action: Financial Assurance Amendment No.: 2
Date Issued: 10/24/06 License Reviewer: DH

File No.: 6
Licensee: St Vincent's Hospital License No.: 75-3009-01
Type of Action: Notification Amendment No.: 11
Date Issued: 2/13/03 License Reviewer: DH

Comment:
Licensee is currently in Chapter 11 bankruptcy. NYC is receiving copies of the court documents and is monitoring the situation. The licensee is still in operation.

File No.: 7
Licensee: City College (CUNY) License No.: 74-3042-01
Type of Action: Renewal Amendment No.: 5
Date Issued: 3/28/06 License Reviewer: DH

File No.: 8
Licensee: New York Blood Center License No.: 74-2946-01
Type of Action: Amendment Amendment No.: 7
Date Issued: 9/26/06 License Reviewer: DH

File No.: 9
Licensee: Columbia University License No.: 74-3030-01
Type of Action: Amendment Amendment No.: 8
Date Issued: 2/9/05 License Reviewer: RF

File No.: 10
Licensee: NYU Medical Center License No.: 74-2955-02
Type of Action: Renewal Amendment No.: 6
Date Issued: 9/20/06 License Reviewer: RF

File No.: 11
Licensee: Manhattan College License No.: 52-2974-01
Type of Action: Renewal Amendment No.: 4
Date Issued: 10/12/06 License Reviewer: RF

Comment:
Radiation Safety Officer approved with no prior, hands-on experience.

File No.: 12
Licensee: NYCHHC-Kings County Hospital Center License No.: 91-3310-01
Type of Action: New Amendment No.: 0
Date Issued: 5/25/06 License Reviewer: RF

Comments:
a) Complex review encompassed the separation of Kings County from SUNY. A review of the file did not show the many communications that took place between NYC and the licensee. Telephone calls were made, but not documented.
b) Social security numbers were visible on the Landauer exposure reports which were included in the file.

File No.: 13
Licensee: NYCHHC-Kings County Hospital Center License No.: 92-3287-02
Type of Action: New Amendment No.: 0
Date Issued: 9/15/06 License Reviewer: RF

Comment:

Complex review encompassed the separation of Kings County from SUNY. A review of the file did not show the many communications that took place between NYC and the licensee. Telephone calls were made, but not documented. It appears that the experienced license reviewers were very familiar with the license activities of Kings County.

File No.: 14
Licensee: Columbia Presbyterian License No.: 93-2878-05
Type of Action: Renewal Amendment No.: 3
Date Issued: 1/14/03 License Reviewer: DH

File No.: 15
Licensee: Long Island Jewish Medical Center License No.: 75-2986-01
Type of Action: Amendment Amendment No.: 16
Date Issued: 5/26/06 License Reviewer: RF

Comments:

a) Financial assurance was based on actual inventory rather than license possession limits. License was not amended, nor was a limiting license condition.
b) An amendment request dated December 29, 2005 was reviewed. An invoice was sent on February 23, 2006. The licensee has not paid the fee and therefore the amendment has not been issued. No documentation in the file to indicate that the licensee has been contacted since the invoice was issued.

File No.: 16
Licensee: St. Luke's Roosevelt Medical Center License No.: 75-2898-01
Type of Action: Amendment Amendment No.: 18
Date Issued: 8/4/06 License Reviewer: DH

Comment:

Financial Assurance evaluation was based on actual inventory and not possession limits. NYC will amend the license to reduce possession limits to a level in which Financial Assurance is not required.

File No.: 17
Licensee: Memorial Sloan Kettering License No.: 75-2968-02
Type of Action: Financial Assurance Amendment No.: 6
Date Issued: 7/29/05 License Reviewer: RF

File No.: 18
Licensee: Beth Israel Medical Center/Kings Highway Division License No.: 91-3022-01
Type of Action: Amendment Amendment No.: 7
Date Issued: 5/17/05 License Reviewer: DH

New York State Department of Health

File No.: 19
Licensee: AVC Services License No.: 5074
Type of Action: Amendment Amendment No.: 4
Date Issued: 11/25/05 License Reviewers: CC, CB

File No.: 20
Licensee: Bertrand-Chaffee Memorial Hospital License No.: 5084
Type of Action: Amendment Amendment No.: 3
Date Issued: 4/27/05 License Reviewer: RD

File No.: 21
Licensee: Cold Springs Harbor Laboratory License No.: 574
Type of Action: Amendments Amendment No.: 39
Dates Issued: 10/23/05, 10/3/06, 10/21/06 License Reviewer: CB

File No.: 22
Licensee: Good Samaritan Hospital License No.: 490
Type of Action: Amendment Amendment No.: 49
Date Issued: 7/21/03 License Reviewer: WV

File No.: 23
Licensee: Good Samaritan Hospital Medical Center License No.: 575
Type of Action: Renewal Amendment No.: 58
Date Issued: 4/27/05 License Reviewer: CC

Comments:
a) Facility diagram for HDR and brachytherapy source location was not in license file. DOH sent letter on November 8, 2006, to acquire facility diagram.
b) Specific procedures give an orderly authority to perform contamination control procedures.
c) License file did not contain a checklist of the evaluation of HDR devices.

File No.: 24
Licensee: North Westchester Hospital Center License No.: 585
Type of Action: Amendment Amendment No.: 53
Date Issued: 9/8/06 License Reviewer: CB

File No.: 25
Licensee: University of Albany License No.: 459-1
Type of Action: Amendment Amendment No.: 57
Date Issued: 4/27/05 License Reviewer: CB

File No.: 26
Licensee: John T. Mather Memorial Hospital License No.: 495
Type of Action: Amendment Amendment No.: 21
Date Issued: 11/23/05 License Reviewer: RD

File No.: 27

Licensee: Kaleida Health
Type of Action: Amendment
Date Issued: 7/13/04
License No.: 548
Amendment No.: 24
License Reviewer: JC

Comment:
Review was of limited scope.

File No.: 28
Licensee: Charles H. Albrecht Radiation Oncology, P.C.
Type of Action: Amendment
Date Issued: 4/27/05
License No.: 2823
Amendment No.: 7
License Reviewer: OAO

Comment:
Review was of limited scope.

File No.: 29
Licensee: Good Samaritan Hospital
Type of Action: Amendment
Date Issued: 10/3/06
License No.: 575
Amendment No.: 68
License Reviewer: JK

File No.: 30
Licensee: New York United Hospital Medical Center
Type of Action: Termination
Date Issued: 4/10/06
License No.: 1005
Amendment No.: 40
License Reviewer: CJB

File No.: 31
Licensee: Inter-Community Memorial Hospital
Type of Action: Renewal
Date Issued: 11/29/02
License No.: 3191
Amendment No.: 4
License Reviewer: CC

File No.: 32
Licensee: Orange Regional Medical Center
Type of Action: Renewal
Date Issued: 10/3/06
License No.: 563
Amendment No.: 82
License Reviewer: AD

File No.: 33
Licensee: Institute for Cancer Prevention
Type of Action: Termination
Date Issued: 9/16/05
License No.: 1799
Amendment No.: 32
License Reviewer: CB

File No.: 34
Licensee: NYSERDA - West Valley Site Management Program
Type of Action: Amendment
Date Issued: 9/22/06
License No.: C-0382
Amendment No.: 1
License Reviewer: WV

<u>New York State Department of Health - Industrial Unit</u>

File No.: 35
Licensee: Imaging and Sensing Technology Corporation
License No.: 0387-0058

Type of Action: Amendment Amendment No.: 2
Date Issued: 4/27/05 License Reviewer: WV

File No.: 36
Licensee: Imaging and Sensing Technology Corporation License No.: 0754-0058
Type of Action: Amendment Amendment No.: 3
Date Issued: 11/21/05 License Reviewer: WV

File No.: 37
Licensee: Cardinal Health License No.: 2593-3842
Type of Action: Amendment Amendment No.: 6
Date Issued: 1/12/06 License Reviewer: DS

Comment:
Amendment completed on an expired license. License expired January 31, 2003. Renewal application and timely filed letter issued December 20, 2002 and January 12, 2006, respectively.

File No.: 38
Licensee: Mallinckrodt Medical Inc. License No.: 2312-3141
Type of Action: Amendment Amendment No.: 5
Date Issued: 7/31/97 License Reviewer: DS

Comment:
License has not been renewed since July 31, 1997. Renewal and timely filed letters available for October 20, 2000 and August 27, 2003.

File No.: 39
Licensee: Cardinal Health License No.: 2364-3250
Type of Action: Amendment Amendment No.: 13
Date Issued: N/A License Reviewers: DS, CB

Comment:
License expired October 31, 2002. Five amendments were issued since expiration date and prior to renewal. Industrial Unit employees could not locate the 2002 renewal application and timely filed letter.

File No.: 40
Licensee: Able Testing Inspection, Inc. License No.: 2555-3760
Type of Action: Amendment Amendment No.: 2
Date Issued: 11/21/05 License Reviewer: CB

File No.: 41
Licensee: Meade Testing Laboratories License No.: 2697-3954
Type of Action: Renewal Amendment No.: 0
Date Issued: 4/15/03 License Reviewer: WV

File No.: 42
Licensee: Meade Testing Laboratories License No.: 2697-3954

Type of Action: Amendment Amendment No.: 1
Date Issued: 2/13/06 License Reviewer: CB

File No.: 43
Licensee: VITS America Inc. License No.: 3188-4421
Type of Action: New Amendment No.: N/A
Date Issued: 6/16/06 License Reviewer: DS

File No.: 44
Licensee: INFICON License No.: 3113-4348
Type of Action: New Amendment No.: N/A
Date Issued: 6/4/04 License Reviewer: CB

File No.: 45
Licensee: Eustance & Horowitz, P.C. License No.: 2338-3186
Type of Action: Termination Amendment No.: 1
Date Issued: 7/21/04 License Reviewer: AC

File No.: 46
Licensee: Integrated Technologies License No.: 3051-4286
Type of Action: Termination Amendment No.: 1
Date Issued: 4/18/05 License Reviewer: DG

Comment:
Reviewer did not obtain leak test, but did verify that gauge was transferred to authorized recipient.

File No.: 47
Licensee: Bristol-Myers Squibb Company License No.: 0931-0311
Type of Action: Amendment Amendment No.: 3
Date Issued: 4/20/06 License Reviewer: WV

File No.: 48
Licensee: General Electric Company License No.: 0794-0220
Type of Action: Renewal Amendment No.: 2
Date Issued: 5/13/04 License Reviewer: DS

Comment:
Licensee submitted a surety bond for more money than previously submitted. Reviewer accepted bond for the licensee's financial assurance without obtaining a revised cost estimate. The revised cost estimate would have described how the new cost figure was calculated.

File No.: 49
Licensee: Radiac Environmental Services License No.: 1944-1879
Type of Action: Renewal Amendment No.: 1
Date Issued: 9/13/05 License Reviewer: DS

Comment:

Limited renewal review completed.

File No.: 50
Licensee: Pall Corporation License No.: 1935-1921
Type of Action: Renewal Reference/Amendment No.: N/A
Date Issued: N/A License Reviewers: CB, WV

Comment:
This license was last renewed in 1993 and expired in 1996. In the last 10 years, the license was amended twice. This renewal application has been re-assigned and is estimated for completion by June 2007.

New York State Department of Environmental Conservation

File No.: 51
Licensee: University of Rochester Permit No.: 8-2699-00059/00003
Type of Action: Modification Facility/Program No.: 170-3
Date Issued: 7/27/06 License Reviewer: JF

File No.: 52
Licensee: University of Rochester Permit No.: 8-2699-00059/00003
Type of Action: Renewal Facility/Program No.: 170-3
Date Issued: 1/21/03 License Reviewer: SH

File No.: 53
Licensee: NRD, LLC Permit No.: 9-1446-00018/00001
Type of Action: Modification Facility/Program No.: 53-3
Date Issued: 12/6/05 License Reviewer: BY

File No.: 54
Licensee: SP Lighting Corp. Permit No.: 3-3920-00277/00003
Type of Action: Termination Facility/Program No.: 164-3
Date Issued: 3/4/05 License Reviewer: SH

File No.: 55
Licensee: Phillips Lighting Co. Permit No.: 8-4624-00022/00018
Type of Action: Renewal Facility/Program No.: 172-3
Date Issued: 10/16/03 License Reviewer: AG

File No.: 56
Licensee: Cornell University Permit No.: 7-5007-00037/00001
Type of Action: Renewal Facility/Program No.: 155-3
Date Issued: 12/2/03 License Reviewer: AG

Comment:
The renewal application was received on January 28, 2003. There was a delay in the review due to staffing shortage - additional information received October 21, 2003; permit drafted November 17, 2003 and issued December 2, 2003.

File No.: 57
Licensee: Trudeau Institute
Type of Action: Termination
Date Issued: 3/24/05
Permit No.: 5-1646-00014/00002
Facility/Program No.: 96-1
License Reviewer: SH

File No.: 58
Licensee: Cardinal Health 414
Type of Action: Modification
Date Issued: 7/27/05
Permit No.: 8-2614-00812/00002
Facility/Program No.: 191-3
License Reviewer: SH

File No.: 59
Licensee: Nuclear Diagnostic Products
Type of Action: New
Date Issued: 7/27/06
Permit No.: 1-2824-02390/00002
Facility/Program No.: 190-3
License Reviewer: AG, SH

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: U. S. Customs — License No.: N/A
Date of Incident: 6/3/04 — Incident Log No.: 040498
Investigation Date: 7/2/04 — Type of Investigation: On-Site

File No.: 2
Licensee: Redacted — License No.: N/A
Date of Incident: 4/13/05 — Incident Log No.: 050276
Investigation Date: 4/19/05 — Type of Investigation: Phone

File No.: 3
Licensee: Redacted — License No.: N/A
Date of Incident: 4/18/05 — Incident Log No.: 050398
Investigation Date: 4/18/05 — Type of Investigation: Phone

File No.: 4
Licensee: Non-Licensee — License No.: N/A
Date of Incident: 4/30/04 — Incident Log No.: N/A
Investigation Date: 4/30/04 — Type of Investigation: On-Site

Comment:
File lacks incident log number.

File No.: 5
Licensee: U. S. Customs — License No.: N/A
Date of Incident: 4/21/04 — Incident Log No.: 040356
Investigation Date: 4/21/04 — Type of Investigation: On-Site

File No.: 6
Licensee: Material Testing Labs — License No.: N/A
Date of Incident: 11/27/02 — Incident Log No.: 9
Investigation Date: 11/27/02 — Type of Investigation: On-Site

File No.: 7
Licensee: U. S. Post Office — License No.: N/A
Date of Incident: 8/30/04 — Incident Log No.: 2004-8-29
Investigation Date: 8/30/04 — Type of Investigation: On-Site

New York State Department of Health

File No.: 8
Licensee: Redacted
License No.: N/A
Date of Incident: 4/16/03
Incident Log No.: 86
Investigation Date: 4/17/03
Type of Investigation: Phone

Comment:
Date of patient followup call not recorded.

File No.: 9
Licensee: Redacted
License No.: N/A
Date of Incident: 5/12/03
Incident Log No.: 13
Investigation Date: 5/27/03
Type of Investigation: Phone

File No.: 10
Licensee: Redacted
License No.: N/A
Date of Incident: 5/19/05
Incident Log No.: 9
Investigation Date: 5/20/05
Type of Investigation: Phone

File No.: 11
Licensee: Redacted
License No.: N/A
Date of Incident: 5/17/06
Incident Log No.: 455
Investigation Date: 7/21/06
Type of Investigation: On-Site

File No.: 12
Licensee: Redacted
License No.: N/A
Date of Incident: 10/21/03
Incident Log No.: 131
Investigation Date: 10/22/03
Type of Investigation: Phone

File No.: 13
Licensee: Redacted
License No.: N/A
Date of Incident: 4/13/05
Incident Log No.: 344
Investigation Date: 4/19/05
Type of Investigation: On-Site

Comment:
Written response from non-licensed transport company received 5-months late.

File No.: 14
Licensee: Vassar College
License No.: RML-410
Date of Incident: 12/13/04
Incident Log No.: NY-06-004
Investigation Date: 12/13/04
Type of Investigation: Phone

New York State Department of Health - Industrial Unit

File No.: 15
Licensee: Materials Testing — License No.: 2274-3075
Date of Incident: 11/22/02 — Incident Log No.: 3-10
Investigation Date: 11/27/02 — Type of Investigation: On-Site

File No.: 16
Licensee: Testwell Laboratories — License No.: 2406-3328
Date of Incident: 10/30/03 — Incident Log No.: 3-20
Investigation Date: 10/31/03 — Type of Investigation: Phone

Comment:
Lost gauging device, case remains open.

File No.: 17
Licensee: SJB Services, Inc. — License No.: 2574-3792
Date of Incident: 7/26/04 — Incident Log No.: 4-25
Investigation Date: 7/26/04 — Type of Investigation: Phone

File No.: 18
Licensee: Testwell Laboratories — License No.: 2930
Date of Incident: 8/29/04 — Incident Log No.: 4-34
Investigation Date: 8/29/04 — Type of Investigation: On-Site

File No.: 19
Licensee: Pall Corp. — License No.: 1935-1921
Date of Incident: 8/31/05 — Incident Log No.: 5-23
Investigation Date: 8/31/05 — Type of Investigation: Phone

File No.: 20
Licensee: Steris Isomedix Services, Inc. — License No.: 2583-3814
Date of Incident: 5/26/06 — Incident Log No.: 6-14
Investigation Date: 7/10/06 — Type of Investigation: On-Site

New York State Department of Environmental Conservation

File No.: 21
Licensee: QIS, Inc. — License No.: N/A
Date of Incident: 4/10/06 — Incident Log No.: C09-20060804-13
Investigation Date: 4/10/06 — Type of Investigation: On-Site

File No.: 22
Licensee: Syncor - Rochester — Permit No.: 8-2646-00001/00001
Date of Incident: 6/25/03 — Incident Log No.: N/A
Investigation Date: 6/25/03 — 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-1210-D-101-B
Manufacturer: Inficon, Inc.
Date Issued: 6/4/04

SS&D Type: Ion generators, Chromatography
Model Nos.: Scanex ESD-450, Scanex I, Scentograph Series, Aquaprobe
SS&D Reviewers: DS, CB

Comments:

a) The drawings and operator's manual submitted by the applicant were marked "preliminary." The SS&D reviewer indicated that these documents were tied-down in the References section of the certificate, requiring the applicant to submit an amendment request if changes are made to them.
b) A letter from the applicant, dated May 5, 2004, was not included as a tie-down condition under the References section of the certificate. This letter requested minor typographical corrections to the certificate and a minor request to change the color of the device label for better clarity. The SS&D reviewer indicated that, because of no health and safety significance, these minor corrections and request would not normally be tied down to the certificate. The requested change in the device label did not affect the information present on the certificate.
c) The file did not specify overall dimensions in the drawings/illustrations in the attachments to certificates, nor in the text of the certificates, to describe the overall size of the device.

File No.: 2
Registry No.: NY-1260-D-101-G
Manufacturer: VITS America, Inc.
Date Issued: 6/16/06

SS&D Type: Beta Gauge
Model Nos.: 721X Series (7210, 7211, 7212, 7213)
SS&D Reviewers: DS, CB

Comments:

a) The radiation profiles had essentially the same reading for the shutter in both the open and closed positions. The SS&D reviewer indicated that due to the small size of the air gap between the detector and source housing, there would not be much change in the readings between the shutter in the open and closed positions.
b) The file did not specify overall dimensions in the drawings/illustrations in the attachments to certificates, nor in the text of the certificates, to describe the overall size of the device.

ATTACHMENT

Letters from Jeannine Prud'homme,Stephen Gavitt,
and Barbara Youngberg
New York's Response to Draft IMPEP Report

ADAMS: ML070300584