UNITED STATES
NUCLEAR REGULATORY COMMISSION
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Dear Sirs and Madam:

On November 5, 2002, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the New York Agreement State Program. The MRB found the New York program adequate to protect public health and safety and compatible with the Nuclear Regulatory Commission's program. .

Section 5.0, page 38, of the enclosed final report presents the IMPEP team's recommendations for the State of New York. We request your evaluation and response to recommendations within 30 days from receipt of this letter.

Based on the results of the current IMPEP review, the next full review will be in approximately four years.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review and your support of the Radiation Control Program. I look forward to our agencies continuing to work cooperatively in the future.

Sincerely,

Carl J. Paperiello

Carl J. Paperiello
Deputy Executive Director
for Materials, Research and State Programs

Enclosure:
As stated

cc: Gene Miskin, Director
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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF NEW YORK AGREEMENT STATE PROGRAM

July 15-26, 2002

FINAL REPORT

U.S. Nuclear Regulatory Commission

1.0 INTRODUCTION

This report presents the results of the review of the New York radiation control program. The review was conducted during the period July 15-26, 2002, by a review team comprised of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement States of Texas and California. Team members are identified in Appendix A. The review was conducted in accordance with the "Implementation of the Integrated Materials Performance Evaluation Program and Rescission of a Final General Statement of Policy," published in the Federal Register on October 16, 1997, and the November 5, 1999, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period of April 25, 1998 to July 14, 2002, were discussed with New York management on July 26, 2002.

The team issued a draft report to New York on September 12, 2002 for factual comment. New York responded to the findings and conclusions of the review by letter dated October 4, 2002 from Stephen Hammond, P.E., Director, Division of Solid & Hazardous Materials, for the State Department of Environmental Conservation; by letter dated October 21, 2002 from Adela Salame-Alfie, Ph.D., Director, Bureau of Environmental Radiation Protection, for New York State Department of Health (DOH); by electronic mail dated October 24, 2002 from Clayton J. Bradt, CHP, Principal Radiophysicist, for New York State Department of Labor; and by electronic mail dated October 28, 2002 from Gene Miskin, Director, Bureau of Radiological Health, for the City Department of Health (Attachments 1-A to 1-D). The review team has prepared a resolution of comments document to accompany DOH's comments (Attachment 2). The Management Review Board (MRB) met on November 5, 2002 to consider the proposed final report. The MRB found the New York radiation control program was adequate to protect public health and safety and compatible with NRC's program.

The New York Agreement State program is administered by: (1) the New York City Department of Health and Mental Hygiene, Office of Radiological Health (NYC), which has jurisdiction over medical, academic, and research uses within the five boroughs of New York City; (2) the New York State Department of Labor, Radiological Health Unit (DOL), which has jurisdiction over commercial and industrial uses of radioactive material, including the possession of radioactive material to be disposed of at a commercial disposal site; (3) the New York State Department of Health, Bureau of Environmental Radiation Protection (DOH), which has jurisdiction over medical, academic, and research uses of radioactive material except in New York City; and (4) the New York State Department of Environmental Conservation, Bureau of Radiation (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 four programs are included as Appendix B. At the time of the review, the combined New York programs regulated approximately 1,400 specific licenses, including all types of major licensees except for uranium mill tailings.

The review focused on the material program as it is carried out under the Section 274b (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the State of New York.

In preparation for the review, a questionnaire addressing the common and non-common performance indicators was sent to each of the four Agencies on April 29, 2002. Each Agency provided an electronic response to the questionnaire; NYC, DOL and DEC on July 3, 2002 and DOH on July 5, 2002. A copy of the questionnaire responses can be found on NRC's Agencywide Document Access and Management Systems using the Accession Number ML022470209.

During previous reviews of the New York Agreement State program, each New York Agency was reviewed and evaluated separately for each performance indicator. The on-site review for each Agency took approximately one week with the entire New York review taking approximately three months to complete. Each program received ratings for each indicator, and the overall determination of adequacy and compatibility for the State was based on the weight of the numerous ratings for each performance indicator. NRC's rationale for treating the four New York Agencies separately in the past was that each of the New York Agency's radiation control programs is administered independently of each other. Consequently, the level of review for New York was four times greater than the State of California, which has more material licensees than New York. For this review, NRC attempted to treat the State more like a single program, including giving only one rating for the State as a whole for each indicator.

This review was conducted over two consecutive weeks, more in line with other States having complex organizations. The approach reduced the resources expended on the review by both the NRC and New York, but still provided sufficient opportunity for the IMPEP review team to assess New York's performance and provide more timely feedback. This revised approach was discussed with management from each of the four New York Agencies and the State Coordinator, New York State Energy Research and Development Authority (NYSERDA), in a teleconference on November 29, 2001.

The review team's general approach for conduct of this review consisted of: (1) examination of New York's responses to the questionnaire; (2) review of applicable New York statutes and regulations; (3) analysis of quantitative information from the radiation control program licensing and inspection data base; (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 or clarify issues. The review team evaluated the information that it gathered against the IMPEP performance criteria for each common and applicable non-common performance indicator and made a preliminary assessment of the New York Agreement State program's performance.

Section 2 below discusses the State's actions in response to recommendations made following the previous IMPEP review. Results of the current review for the IMPEP common performance indicators are presented in Section 3. Section 4 discusses results of the applicable non-common performance indicators, and Section 5 summarizes the review team's findings. Recommendations made by the review team are comments that relate directly to performance by the State. A response is requested from the State to all recommendations in the final report.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous routine review, which concluded on April 24, 1998, 21 recommendations were made and the results were transmitted to the respective Commissioners of the three New York State Agencies and the New York City Agency on November 30, 1998. During the April 1999 follow-up review of the New York City program, five of the eight recommendations for that Agency were closed. Results of the follow-up review were sent to the New York City Department of Health Commissioner on July 29, 1999.

The review team's evaluation of the current status of the remaining 16 open recommendations is as follows:

NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE (NYC)

1. The review team recommends that NYC inspectors follow the guidance in the NYC inspection procedures manual which includes the information necessary for properly documenting violations. (Recommendation 3, Section 3.2.1 of the 1998 report and Section 3.2 of the 1999 report)

   Current Status: Based on casework and interviews with inspectors, the review team determined that most routine inspection reports neither adequately describe the scope of the licensees' activities/radiation protection programs nor indicate observed licensee activities. This issue is further discussed in Section 3.2.1. This recommendation remains open.

2. The review team recommends that NYC document its training program to include overall policy and minimum training requirements to be qualified to conduct the responsibilities of the program for both the licensing and compliance staff. (Recommendation 5, Section 3.3.1 of the 1998 report and Section 3.3 of the 1999 report)

   Current Status: NYC updated their Procedures Manual and documented their training program for licensing and compliance staff. This recommendation is closed.

3. The review team recommends that NYC review the staff's training against their training requirements, clearly document how the training was achieved, and acquire the necessary training, as appropriate. (Recommendation 6, Section 3.3.1 of the 1998 report and Section 3.3 of the 1999 report)

   Current Status: NYC performed an appropriate review of the staff's training. This recommendation is closed.

NEW YORK STATE DEPARTMENT OF LABOR (DOL)

4. The review team recommends that DOL perform initial inspections of licensees within six months of the licensees' receipt of licensed material, or commencement of licensed activities. (Section 3.1.2 of the 1998 report)

Current Status: It is DOL's policy to conduct initial inspections within six months of license issuance, or commencement of licensed activities. During this review period most initial inspections were conducted within these time constraints. The overall timeliness of DOL's core inspections was impacted more significantly by the conduct of Priority 1 inspections on an overdue basis than by the conduct of initial inspections on an overdue basis. Thus, this recommendation is closed, but a new recommendation regarding the timely performance of all core inspections is made in Section 3.1.2 of this report.

5. The review team recommends that DOL document its training program to include overall policy and minimum training requirements for both the licensing and compliance staff. (Section 3.3.2 of the 1998 report)

   Current Status: DOL created a written procedure documenting their training program for licensing and compliance staff. This recommendation is closed.

6. The review team recommends that DOL notify NRC of significant reportable events and provide documentation for all reportable events both in accordance with SA-300 "Reporting Material Events." (Section 3.5.2 of the 1998 report)

   Current Status: During the review period, the team noted that DOL did not notify the NRC of reportable events and provide documentation in accordance with STP Procedure SA-300. As discussed in Section 3.5 of this report, this recommendation remains open.

7. The review team recommends that DOL management take appropriate action to move the rule package through the rule promulgation process. (Section 4.1.2.2 of the 1998 report)

   Current Status: DOL adopted 13 NRC amendments by rulemaking that became effective on April 15, 1999. This recommendation is closed.

8. The review team recommends that DOL establish and use customized procedures for conducting sealed source and device (SS&D) reviews based on the guidelines presented in the SS&D Workshop and tailored to DOL's types of SS&Ds, specific policies, requirements, and regulations. (Section 4.2.1 of the 1998 report)

   Current Status: DOL developed checklists for conducting SS&D evaluations in congruence with guidelines presented in NUREG 1556, Volume 3 and the SS&D Workshop. This recommendation is closed.

9. The review team recommends that DOL establish a clear policy for what constitutes a concurrence review in accordance with guidelines in Management Directive 5.6 (Section 4.2.1 of the 1998 report)

   Current Status: DOL established a clear policy for conducting concurrence reviews including the documentation of those reviews. This recommendation is closed.

10. The review team recommends that DOL develop a written formal SS&D training and qualification program including minimum qualifications for signature authority. (Section 4.2.2 of the 1998 report)

    Current Status: DOL established an acceptable written formal SS&D training qualification program. This recommendation is closed.

11. The review team recommends that DOL explore one of the following options to meet the qualifications for an SS&D program for New York: (a) immediately before performing another review, provide additional structured training for the SS&D reviewers or (b) if DOL determines that maintaining SS&D evaluation authority with a staff that has sufficient qualifications and training to conduct adequate reviews is not viable, return the SS&D program to NRC. (Section 4.2.2 of the 1998 report)

    Current Status: DOL management verified that if DOL received an SS&D evaluation request that was beyond the scope of staff training, capabilities or experience, DOL would contact the NRC for technical assistance or for training. This recommendation is closed.

NEW YORK STATE DEPARTMENT OF HEALTH (DOH)

12. The review team recommends that DOH modify it's inspection program to ensure that initial inspections are performed within six months of the licensee's receipt of licensed material, within six months after commencement of licensed activities, or within one year of license issuance, whichever comes first, consistent with NRC Inspection Manual Chapter (IMC) 2800. (Section 3.1.3 of the 1998 report)

    Current Status: The DOH Inspection Procedures Manual was revised consistent with NRC IMC 2800 for only Priority 1 licenses. However, the vast majority of new licensees are inspected within six months after license issuance, and extensions are granted on a case-by-case basis when the licensee has not received material, or, for mobile nuclear medicine licensees, when the licensee is inspected in conjunction with another licensee's activities. Overall, the program is adequately meeting the goals of NRC IMC 2800 with respect to inspection timeliness. This recommendation is closed.

13. The review team recommends that DOH notify NRC of significant reportable events and provide documentation for all reportable events both in accordance with SA-300. (Section 3.5.3 of the 1998 report)

    Current Status: It is not DOH's policy to report events in accordance with STP Procedure SA-300. DOH management indicated they would review their reporting obligations and consider reporting to the extent authorized by New York State law. This issue is discussed further in Section 3.5.3. This recommendation remains open.

NEW YORK STATE DEPARTMENT OF ENVIRONMENTAL CONSERVATION (DEC)

14. The review team recommends that DEC document its training program to include overall policy and minimum training requirements for both the permitting and compliance staff. (Section 3.3.4 of the 1998 report)

    Current Status: DEC provided the review team with a document titled "Recommended Training for Staff in the Bureau of Radiation," this document is acceptable to close this item. This recommendation is closed.

15. The review team recommends that DEC incorporate the handling of incidents and allegations into their inspection procedures. (Section 3.5.4 of the 1998 report)

    Current Status: DEC has drafted changes to their inspection procedures to incorporate the handling of incidents and allegations, but has not completed the task due to higher priorities. The team did not note any performance issues related to the handling of incidents and allegations. This recommendation is closed.

16. The review team recommends that DEC coordinate with the appropriate New York licensing Agency, the notification to the NRC of significant reportable events and provide documentation for all reportable events both in accordance with SA-300. (Section 3.5.4 of the 1998 report)

    Current Status: During a review of incidents over the review period, the team noted that DEC coordinated with the appropriate New York licensing Agencies with respect to the incidents. None of the events that DEC responded to required reporting to the NRC. This recommendation is closed.

During the 1998 review, 13 suggestions were also made for the State to consider. The team determined that the State considered the suggestions and took appropriate actions.

3.0 COMMON PERFORMANCE INDICATORS

The IMPEP identifies five common performance indicators to be used in reviewing both NRC Regional and Agreement State programs. These indicators are: (1) Status of Materials Inspection Program; (2) Technical Quality of Inspections; (3) Technical Staffing and Training; (4) Technical Quality of Licensing Actions; and (5) Response to Incidents and Allegations.

3.1 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 independently from each program's licensing and inspection data tracking system, the examination of completed licensing and inspection casework, and interviews with management and staff.

In order to compare the performance of the four New York programs with respect to this indicator, the team limited their review of completed and overdue inspections to the period beginning after the follow-up review in New York City in April 1999. With this limitation, each program's performance could be weighted in accordance with the percentage of core licensee inspections for which each was responsible during the same period of time. The review team believes that this approach was sufficient to complete this portion of the review.

3.1.1 New York City Department of Health and Mental Hygiene

The review team's review of the NYC inspection priorities verified that inspection frequencies for various types of NYC material licenses are generally the same as, or more restrictive than, those listed in the NRC IMC 2800, "Materials Inspection Program." However, due to the manner in which NYC categorizes licensees, those that are licensed for possession and use of a high dose-rate remote afterloader (HDR) were inadvertently assigned a Priority 2 as opposed to a Priority 1. Despite this administrative discrepancy, NYC inspected most HDRs on an annual basis during the review period. The team discussed the issue with NYC staff, and was told that they are in the process of compiling a list of licensees possessing and using HDRs, so that they can adjust the priority to be consistent with NRC IMC 2800.

In their response to the questionnaire, NYC indicated that there was only one currently overdue core licensee inspection. The examination of the data and inspection files provided by NYC during the review revealed twelve initial inspections that were currently overdue, as well as the one Priority 1 inspection currently overdue that was identified by NYC. In addition, during this review period approximately 16 core inspections were performed on an overdue basis (i.e., more than 25% of the inspection frequency beyond the due date for Priority 1, 2, and 3 licensees; or, more than six months after license issuance for new licensees). Overall, for this review period, the team calculated the percentage of core inspections performed on an overdue basis, or currently overdue, to be 23%, based on a review of all initial inspections performed or currently overdue, and approximately 32% of the Priority 1, 2, and 3 inspection files.

Two main factors have contributed significantly to the number of overdue inspections. The first is, as discussed earlier, HDRs were inadvertently assigned a Priority 2, instead of a Priority 1. These licenses are in the NYC database as "limited medical" facilities, which includes all non-broad human-use licensees, except those possessing a gamma knife or teletherapy machine. NYC staff is in the process of identifying all of their licensees authorized to possess and use an HDR, so that they can re-evaluate and revise the inspection frequency, as appropriate. The second contributing factor is the inability of NYC to accurately and completely identify new licensees in the inspection database. During the review, NYC provided the review team with what was intended to be a list of licenses that had recently been issued, however a review of the list and comparison with the license and inspection files revealed that the list contained a high proportion of licenses that were in fact, renewed licenses, or re-issued licenses, and not newly issued licenses. In addition, the list did not contain a significant number of newly issued licenses that were identified by reviewing hard copies of licensing actions taken during the review period, copies of which are maintained by the NYC licensing staff. See recommendation in Section 3.1.5.

The timeliness of the issuance of inspection findings was evaluated during the inspection file review. The team reviewed 87 letters transmitting inspection findings to licensees. Thirty two of these letters were issued more than 30 days after the date of the inspection, and in one case the findings were issued 253 days after the date of the inspection. The responsibility for the transmission of all inspection findings to the licensee rests with the Materials Inspection Senior Scientist. The field inspection staff visits the office at least one time per week to deliver raw field notes to the Senior Scientist, who then prepares the letter transmitting the inspection findings and the notice of violation, if any. In discussions with the NYC staff, it could not be clearly ascertained where the delay in the transmission of the findings is occurring. See recommendation in Section 3.1.5.

During the review period, NYC received 320 reciprocity notifications from six different licensees. Two hundred and six of these notifications pertained to HDR source changes or servicing, and 98 involved teletherapy source changes, removals, or servicing. NYC performed two inspections, one involving a teletherapy source removal, and another involving a teletherapy source exchange, during the review period. The number of reciprocity inspections performed by NYC was minimally adequate to meet the revised criteria in NRC IMC 1220, published June 6, 2002. To determine whether a reciprocity licensee requires an inspection, NYC staff indicated that they review their file on a licensee, but do not review the Nuclear Materials Events Database (NMED) for events involving the licensee as required by NRC IMC 1220. The team noted that the files contain only minimal information about the last inspection. The team discussed the benefits of conducting reciprocity inspections and reviewing the events in the Nuclear Materials Events Database and the enforcement histories of licensees requesting reciprocity in New York City in their management of reciprocity inspections.

3.1.2 New York State Department of Labor

The team's review of the DOL inspection priorities verified that inspection frequencies for various types of DOL material licenses are the same as, or more restrictive than, those listed in NRC IMC 2800. DOL has approximately 500 active licenses, but only about 140 are Priority 1, 2 or 3 licensees in accordance with NRC IMC 2800. During the review period, DOL issued 394 new licenses, but the vast majority of these were for devices that are generally licensed by the NRC. Only about 80 of the new licenses issued were for Atomic Energy Act (AEA) material requiring specific licensure. The team limited its review to 10-15% of the approximately 220 licensees that were Priority 1, 2 or 3, or that were newly issued during the review period, and required specific licensure for AEA material pursuant to NRC's IMC 2800.

The inspection interval extension/reduction policy has not been used by DOL since 1999. The team focused on examining the timeliness of DOL's core inspections relative to the NRC's priorities except where DOL had extended a routine inspection interval based on the licensee's good performance.

In their response to the questionnaire, DOL indicated that there were currently no overdue inspections of core licensees. This information was verified during the inspection casework reviews and the review of a listing of all licensees and the date of their last inspection provided to the team. The review team noted that out of 46 core inspections examined, 6 were

conducted overdue during the review period; five Priority 1 licensees were inspected four to nine months past their inspection due dates; and one initial inspection was conducted nine months after the date of issuance. See recommendation in Section 3.1.5.

The timeliness of the issuance of inspection findings was evaluated during the inspection file review. DOL has an effective and efficient process, which ensures that inspection findings are generally communicated to licensees in a timely manner. For the 28 inspection files examined specifically for timeliness of the communication, only three letters transmitting the inspection findings were issued more than 30 days after the date of the inspection, and none more than 60 days.

During the review period, DOL granted 50 out-of-state licensees reciprocity to work in New York State. DOL does not keep a record of the priorities of reciprocity applicants, so the team was unable to determine how many core licensees had requested reciprocity. DOL conducted 14 reciprocity inspections during the review period. DOL staff stated that they place a priority on inspecting radiographers versus non-core licensees. In addition, DOL only authorizes reciprocity for 30 days in a calendar year, thus many out-of-state licensees obtain an DOL license, and are included in the inspection database. These licensees are contacted at least annually to determine whether work in New York State is planned, so that an inspection can be scheduled. It could not be determined whether DOL met the criteria in NRC IMC 1220, as that document stood during the review period. Based on discussions with DOL staff, and given DOL's requirement for specific licensure after 30 days of reciprocity work in a calendar year, DOL met the revised criteria in NRC IMC 1220, published June 6, 2002.

3.1.3 New York State Department of Health

The team's review of the DOH inspection priorities verified that inspection frequencies for various types of DOH material licenses are generally the same as, or more restrictive than, those listed in NRC IMC 2800, with two exceptions. These exceptions include the fact that DOH assigns a Priority 2 to gamma knives (they currently license two facilities with gamma knives). DOH staff stated that they assigned a Priority 2 to be consistent with their treatment of teletherapy machines, which they believe pose potential hazards comparable to those associated with gamma knives. This is consistent with NRC's Temporary Instruction 2800/033, and the review team agrees that this approach is adequate to protect public health and safety.

DOH stated in response to the questionnaire that they assign all special nuclear material (SNM) licensees a Priority 4, rather than use the NRC's Priorities of 1, 2, 3, or 5, based on quantity and use of the material. DOH stated that they do not license any facilities solely or primarily for the use of SNM, and that licensees possessing SNM are actually broad scope licenses, which are Priority 2. The review team confirmed that SNM licensees were inspected at frequencies consistent with NRC licensees.

DOH routinely implements their inspection interval extension policy to increase inspection intervals for licensees demonstrating good prior performance. The team focused on examining the timeliness of DOH's core inspections relative to the NRC's priorities, except in the cases discussed in the paragraphs above, or when DOH had extended a routine inspection interval based on the licensee's good performance.

DOH has approximately 560 active licenses, but only about 90 are Priority 1, 2, or 3 licensees based on the priorities defined in the NRC's IMC 2800. During the review period, DOH issued approximately 95 new licenses authorizing the possession and use of AEA material. The team limited its review to 20-25% of the approximately 185 licensees that were Priority 1, 2, or 3, or that were newly issued during the review period, and authorized the possession and use of AEA material.

In their response to the questionnaire, DOH indicated that there were currently six core inspections overdue. These inspections were still overdue during the on-site review, but were scheduled for inspection before the end of the year. The review team noted that out of 48 inspections examined in a random sample, four were performed on an overdue basis, including two of the inspections reported by the Agency as overdue at the time of the review. Thus, on average, approximately 4 out of 48 of the DOH inspections were conducted overdue during the review period or were currently overdue for inspection at the time of the review.

The timeliness of the issuance of inspection findings was evaluated during the inspection file review. DOH has an effective and efficient process, which ensures that inspection findings are communicated to licensees in a timely manner. For the 22 inspection files examined, all inspection findings were sent to the licensees within 30 days.

During the review period, DOH granted only one out-of-state licensee reciprocity to work in New York State. They did not inspect this licensee. Based on the fact that DOH only received and granted one request for reciprocity, DOH met both the criteria in NRC IMC 1220, as that document stood during the review period, and as revised June 6, 2002.

3.1.4 New York State Department of Environmental Conservation

DEC issues permits to facilities licensed by one of the other three Agencies to release radioactive effluents to the environment, and inspects only those aspects of each facility's program affecting those releases. DEC does not grant reciprocity to out-of-state licensees, so this element of the indicator was not reviewed for this program. Due to the limited scope of DEC's program, they have established a policy of reduced inspection frequency based on actual and potential releases. For example, nuclear pharmacies are inspected every three years, rather than annually; and incinerators are inspected every two years, rather than annually. These reduced frequencies were assessed during the 1998 IMPEP review, and found to be adequate to protect public health and safety. The assigned frequencies remain the same as those reviewed during 1998, and the review team finds they are still adequate to protect public health and safety with respect to DEC's limited-scope inspection program.

DEC staff stated they have extended inspection intervals due to insufficient staff, but that the permittee's inspection history is reviewed before deciding which inspections may be postponed. The team focused on examining the timeliness of DEC's core inspections relative to their reduced inspection frequencies, and included all those inspections performed on an overdue basis, irrespective of the review of the permittees' performance, because: 1) DEC has already substantially extended the frequency of their inspections based on their limited scope of inspection, and 2) DEC stated the primary cause of the inspection delay was due to staffing issues, and not a result of a routinely implemented policy of extension of inspection intervals for good prior performance.

DEC has 37 active permits, 23 of which are core AEA material. During the review period, DEC issued four new permits authorizing the release of AEA material to the environment. The team reviewed inspections for all 23 AEA permittees that were Priority 1, 2 or 3, or that were issued during the review period.

In their response to the questionnaire, DEC indicated that there were currently two core inspections of AEA permittees that were overdue. Of these, one involved a permittee that had only restarted operations in May 2002 after a three-year hiatus, and the team did not consider this inspection to be overdue. The second inspection reported as overdue by DEC is a Priority 2 permittee pursuant to DEC's assigned inspection frequencies, and is currently 10 months overdue for inspection. DEC has committed to performing this inspection before the end of the calendar year. The review team noted that 4 out of the 23 inspections examined were performed on an overdue basis or were overdue at the time of the review, based on DEC's assigned inspection frequencies. See recommendation in Section 3.1.5.

The timeliness of the issuance of inspection findings was evaluated during the inspection file review. The team reviewed six letters transmitting the inspection findings to the licensees. Four of these letters were issued more than 30 days after the date of the inspection, and in one case the findings were issued 90 days after the date of the inspection. DEC staff attributed the delay to a lack of sufficient staff. See recommendation in Section 3.1.5.

3.1.5 Indicator Summary

Overall, based on the percentage of core licensees for which each program is responsible, New York State performed approximately 13% of their core inspections on an overdue basis. 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.

The timeliness of the issuance of inspection findings varied significantly from program to program. Overall, New York State issued approximately 24% of their inspection findings to licensees more than 30 days after the date of the inspection. The review team recommends that NYC and DEC transmit inspection findings to their licensees within thirty days after the close of the inspection.

Based on the information provided in response to the questionnaires and discussions with staff from each of the New York State programs, New York State met the current criteria in NRC IMC 1220, as published June 6, 2002.

Based on the IMPEP evaluation criteria, the review team recommends that New York State's performance with respect to the indicator, Status of Materials Inspection Program, be found satisfactory with recommendations for improvement.

3.2 Technical Quality of Inspections

The team evaluated the inspection reports, enforcement documentation, and inspection field notes and interviewed select members of the inspection staff. The evaluation included 39 radioactive material inspections conducted during the review period. The casework included

23 inspectors (including one former inspector), representing each of the State's four Agency Offices, and covered inspections of various types of licensees including hospitals, gamma knife, industrial radiography, well logging, radiopharmacy, manufacturing and distribution, academic and medical broad scope institutions, a commercial irradiator, a waste processor, and an inactive waste burial site. Appendix C lists the inspection casework files reviewed for completeness and adequacy, with case-specific comments.

The inspection procedures and techniques utilized by all four Agencies were reviewed and determined to be generally consistent with the inspection guidance provided in NRC 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 Agencies to be comparable with the types of information and data collected under NRC IMC 2800. Inspections conducted by DOL are generally performed on an announced basis; the remaining Agencies 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, 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 file reviews and inspector interviews, the team found that routine inspections covered all aspects of licensee radiation protection programs by all Agencies. The review team found that for three of the four Agencies, the inspection reports were thorough, complete, consistent, and of high quality, with sufficient documentation to ensure that licensee's performance with respect to health and safety was acceptable. Except as noted below for NYC, the 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.

Review team members accompanied ten inspectors from all four New York Agencies during the period of February 26 to June 20, 2002. The accompaniments included inspections of an industrial radiographer, medical institutions, medical private practice, research and development, incinerator and burial site. 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 were adequate to assess radiological health and safety at the licensed facilities.

The review team noted that all four New York Agencies had adequate numbers of portable radiation detection instruments for use during routine inspections and response to incidents and emergencies. Each Agency either 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 Agencies have the capability to analyze alpha, beta and gamma contamination samples and maintain their respective laboratory counting equipment.

3.2.1 New York City Department of Health and Mental Hygiene

For NYC, the team reviewed the inspection reports, enforcement documentation, and inspection field notes and interviewed inspectors for 12 material inspections conducted during the review period. The 12 inspections selected for review included at least one inspection for each of NYC's inspectors, including one former inspector, and one team inspection of a broad scope licensee. NYC's inspection procedures are consistent with the inspection guidance outlined in NRC's IMC 2800. Inspection reports are in checklist format with space for limited narrative input that would adequately cover all inspection areas. The NYC has specific inspection forms for the various types of licensees.

Of the 12 inspections reviewed, six resulted in no violations being identified. For the remaining six, violations were identified in transmittal letters to licensees. Of those violations, two were not described in the field notes documenting the results of the inspections. Based on casework and interviews with select inspectors, the review team determined that the documentation in the inspection field notes typically did not support the violations transmitted to licensees. None of the inspection field notes reviewed discussed the relative safety significance or root causes of the violations identified to licensees. The team found that the wording in the inspection field notes lacked sufficient detail in the program scope and for the identified violations which may lead to misinterpretation by the supervisor as he prepares the compliance letter and the citations. Based on interviews with the NYC staff it appears that the inspections are performance-based and risk-informed, however, the staff does not document these inspection efforts, licensee interviews, or observed licensee activities.

The review team noted that five inspection field notes did not include any documentation of observation of licensed activities or interviews of licensee personnel who performed those activities. In addition, the documentation in the inspection field notes typically did not support the violations transmitted to licensees. The team found that violations identified in the casework were not supported, and in one case contradicted, by information in the inspection report. None of the inspection field notes discussed the relative safety significance or root causes of the violations identified to licensees.

The NYC inspectors typically conduct inspections Monday-Thursday. The inspectors return to the office on Fridays and document the week's inspections and prepare for the following week's inspections. Upon return from the field, the inspector debriefs the supervisor and provides the inspection field notes for review and approval. The supervisor prepares the compliance letter and writes up the citations. Based on the findings described above, there appears to be a "disconnect" between the staff and the supervision of the inspection program. Specifically, the team found that the wording in the inspection field notes lacks sufficient detail in the program scope and for the identified violations which may lead to misinterpretation by the supervisor as he prepares the compliance letter and the citations. See recommendation in Section 3.2.5.

NYC has a policy of performing annual supervisory accompaniments of inspectors. In response to the questionnaire, NYC reported, and the team confirmed, that each inspector was accompanied by the supervisor at least once a year during the review period. Following those inspections, the supervisor provided feedback to the inspector.

3.2.2 New York State Department of Labor

The review team evaluated the inspection reports, enforcement documentation, and the database information for 11 material inspections conducted during the review period. The casework included five material inspectors.

The inspection procedures and techniques utilized by DOL are generally consistent with the inspection guidance provided in NRC IMC 2800. Specific guidance for certain classes of licensees or facilities are also included in the procedures manual. The team reviewed inspection reports and found them to be comparable with the types of information and data collected under NRC IMC 2800. The inspection field notes provided adequate, consistent documentation of inspection findings.

The review team noted that DOL'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 team found that peer review of the inspection documentation and correspondence resulted in their consistent excellent 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 the Program Manager prior to issuing the inspection findings to the licensee. When significant commitments are made in response to violations, DOL 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 typically limited to the issuance of Orders. The review team noted a considerable coordination effort between DOL and DOH on an escalated enforcement case involving a teletherapy service vendor who failed to file for reciprocity and was not licensed to perform the proposed licensed activities. DOL issued an order to the company, prohibited the firm from conducting licensed activities within the State of New York for a period of one year.

The DOL Program Manager has not performed annual supervisory accompaniments of the material inspectors since 2000. The manager stated that competing demands on his time and the fact that most inspectors are located in the Manhattan office have not allowed him to perform the accompaniments. See the review team recommendation in Section 3.2.5.

3.2.3 New York State Department of Health

The inspection procedures and techniques utilized by DOH were reviewed and determined to be generally consistent with the inspection guidance provided in NRC IMC 2800. The review team evaluated inspection reports and found them to be comparable with the types of information and data collected under NRC IMC 2800 and DOH procedures.

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. Both individuals sign a memo-sized paper documenting their review. This form is maintained in the inspection file folder. Overall, the 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 thorough review of all Administrative Tribunals (Hearing Boards) revealed that this process is very effective in obtaining eventual compliance whether the end result is a fine, an American College of Radiology audit commitment, or other compliance commitment.

DOH has a policy of performing annual supervisory accompaniments of inspectors. In response to the questionnaire, DOH reported, and the team confirmed, that all inspectors had accompaniments in 2001.

3.2.4 New York State Department of Environmental Conservation

A representative cross-section of completed inspection reports was reviewed and found 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 in a very prompt time frame. Escalated enforcement procedures are in place and followed, as needed. The escalated actions include referral to the General Counsel in preparation for an enforcement conference which may result in a fine and/or a Consent Order. This process is used approximately once a year.

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 NRC IMC 2800.

With one exception, supervisory accompaniments of DEC inspectors are conducted at least once a year. The inspector responsible for inspecting the activities at an inactive radioactive waste site, has not been accompanied by a supervisor since 1998. See the team's recommendation in Section 3.2.5.

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 October 2001. 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. Since the last review, warning letters were sent to 40 generators who shipped regulated medical waste contaminated with radioactive material to the landfills.

3.2.5 Indicator Summary

Accompaniments of inspectors from all four Agencies identified competent, thorough, safety-oriented inspections. The inspection processes for DOL, DOH and DEC proved to be well designed and implemented. The NYC inspection process, however, is in need of revision. A disconnect exists between the inspectors and the supervision of the inspection program. Inspection reports and notices of violation are incomplete, inconsistent and of marginal quality. 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.

DOL inspectors have not been accompanied by a supervisor since 2000. As indicated in Section 4.3.2, a DEC inspector has not been accompanied since 1998. The review team recommends that DOL and DEC perform annual supervisory accompaniments of all material inspectors.

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

3.3 Technical Staffing and Training

Issues central to the evaluation of this indicator include the radioactive material program staffing level, technical qualifications of the staff, training, and staff turnover. To evaluate these issues, the team examined each program's questionnaire responses relative to this indicator, interviewed program management and staff, and considered any possible workload backlogs in licensing or compliance actions, as well as the status of regulation development and other program activities.

3.3.1 New York City Department of Health and Mental Hygiene

NYC's radioactive material program is staffed by the Director and a Chief of Radioactive Materials Division who supervise a licensing section with two staff and an inspection section with a supervisor and five staff. The program currently has two vacancies in the compliance section. The Director indicated that they currently do not have the approval to fill either vacancy due to a hiring freeze.

During 2000 and 2001, the program lost six experienced individuals due to a City staff reduction buyout. Four new technical staff where hired, leaving two vacancies in the inspection section and reducing the number of license reviewers from four to two. There is currently a new buyout available to four technical staff, and the backfilling of those vacancies may be curtailed if those staff choose to accept the buyout.

The review team determined that NYC staffing is currently adequate. However, if any of the current staff that are eligible for the buyouts leave and their vacancies are not filled, this could adversely effect the program.

NYC technical staff are required to have a Bachelor's degree in science and at least one year of experience. From the review of the technical qualifications of the current staff, the review team concluded that NYC has been able to hire qualified individuals. NYC has one Certified Health Physicist on staff.

The review team's evaluation of NYC's training records and interviews with the staff indicated that new and current staff had appropriate training. In discussions with senior management, they pointed out that getting approval for out-of-city travel was difficult and that they would seek as much training as they could from institutions within New York City. They have been utilizing several one-day seminars in the appropriate training areas. In response to a recommendation from the previous IMPEP review, NYC updated their procedure manual that documents the licensing and inspection training program.

3.3.2 New York State Department of Labor

DOL's radioactive material program is staffed by the Program Manager and eight associate radiophysicists. All six of the inspection staff, and two of the licensing staff were with the program for the entire review period. During the review period, two staff members, an associate radiophysicist and a principal radiophysicist retired from State employment. The principal radiophysicist position was filled by promoting an associate radiophysicist leaving two associate vacancies. These vacancies were filled during this review period by hiring three new associate radiophysicists. The review team found that the current staffing level is adequate for the workload.

The licensing and inspection functions of the program are segregated with all of the licensing conducted in Albany and nearly all of the inspections conducted out of the Manhattan office. Licensing duties are performed by the Program Manager and four associate radiophysicists (one of the associate radiophysicist also conducts some inspections). Inspection duties are performed by four associate radiophysicists. All staff perform duties in incident and emergency response.

Associate radiophysicist staff are required to have a Bachelor's degree in science and at least three years of experience. Twenty-four graduate credit hours in radiological science may be substituted for up to one year of experience. To be considered for a position, an individual must successfully complete a technical examination to be placed on the registry from which individuals are selected. From the review of the technical qualifications of the current staff, the team concluded that the State has been able to hire qualified individuals. DOL has three Certified Health Physicists on staff.

The team determined that there was an appropriate written training policy. All formal training is documented in a computer database. On-the-job training is documented in signature cards signed by the mentoring staff person. A review of training records and interviews with the staff hired since the last review identified that they met the training requirements for licensing and inspection staff.

3.3.3 New York State Department of Health

The DOH radioactive material program is staffed by the Director, the Section Chief, the Field Supervisor, and ten staff. There are currently two vacancies for Radiological Health Specialists, however, there is a freeze on new hires. The Director indicated that waiver requests have been submitted to fill these vacancies. The review team found the current staffing level to be adequate.

The staff of the material program is positioned in four field offices and the main office in Albany. The field staff perform only compliance activities including compliance work for the x-ray and other radiation programs. The Albany staff conduct all of the licensing and a portion of the compliance activities. Licensing duties are performed by the supervisors and three staff. All staff perform duties in incident and emergency response.

All but two DOH technical staff were with the program for the entire review period. One individual is a license reviewer in the Albany office and the other is a compliance inspector in the Buffalo office. Both of the staff attended required training courses and had appropriate on-the-job training. The license reviewer is not yet fully qualified, so all of his work is reviewed by qualified staff prior to issuance. The inspector is considered by the field supervisor to be fully qualified to perform independent inspections. This inspector was accompanied by the review team. Details of this accompaniment can be found in Section 3.2.3.

DOH Radiological Health Specialists are required to have a Bachelor's degree in science and at least two years of experience. A Masters or Doctorate degree in health physics can be substituted for one or two years experience, respectively. To be considered for a position, an individual must successfully complete a technical examination to be placed on the registry from which individuals are selected. From the review of the technical qualifications of the current staff, the review team concluded that the State has been able to hire qualified individuals. There are four certified health physicists in the DOH program.

The review team evaluated the DOH written training policy and requirements and found them acceptable. Previously, DOH successfully used a training matrix to track training courses required for technical staff. Due to other priorities and personnel changes, the matrix has not been maintained over the last several years. The use of a training matrix is considered to be a

beneficial tool in helping to keep track of required training and DOH management indicated that it would be instituted again. Monthly video conferences are held between regional and Albany staff. These sessions cover current health physics topics and other programmatic matters, as needed.

3.3.4 New York State Department of Environmental Conservation

DEC's radioactive material program is staffed by the Bureau Director, Section Chief, and ten staff. There are currently two vacancies in the radiation section. One position is in the contaminated sites section and the other is in the permits and inspections section. The permitting (licensing) and compliance functions of the program are performed by three staff members. The rest of the staff is dedicated mostly to contaminated sites and events that are not directly covered under the Agreement with the NRC. All staff perform duties in incident and emergency response.

At the time of the review, the three staff members who performed permitting and compliance functions had been with the program for the entire review period. The team noted that there was an upswing in cyclotron inspection and permitting during this review period that has effectively reduced the staff available for the program from three to two. This was recognized and a vacancy is currently shown on the permitting and inspection section organization chart. The Bureau Director indicated that the State currently has a freeze on hiring and that the vacant position could not be filled unless a waiver is granted for need.

DEC recently received two new applications for accelerators and have had numerous inquiries regarding possible accelerator construction. Thus, the staff needed for inspection and permitting of accelerators will most likely increase over time, further reducing the staffing available for the Agreement State program inspection and permitting. During the review period, the staffing was adequate, however, with the increased workload due to accelerators and the current vacancy, the program could be adversely effected.

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 of the current staff, the team concluded that DEC has been able to hire qualified individuals.

The review team determined that there was a minimally acceptable written training policy. DEC has not completed the training policy due to the small number of inspectors and permit reviewers, as well as low turnover. DEC management stated that new staff will be trained in performing inspections and reviewing permit applications individually by the Permit 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.

3.3.5 Indicator Summary

Technical staffing and training for all four Agencies is adequate for the Agreement State program workload. As indicated above, hiring freezes and increased responsibilities in other program areas have stretched some program staffs.

Based on the IMPEP evaluation criteria, the review team recommends that New York's performance with respect to the indicator, Technical Staffing and Training, be found satisfactory.

3.4 Technical Quality of Licensing Actions

The review team examined completed licensing casework and interviewed the reviewers for specific licenses as specified for each of the four New York programs. A total of 33 licensing actions were examined, including five new license issuances, five terminations, 10 amendments, and 15 renewals, encompassing the work of 12 license reviewers. Licensing actions were evaluated for completeness, consistency, proper isotopes and quantities used, qualifications of 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 files were checked for retention of necessary documents and supporting data.

3.4.1 New York City Department of Health and Mental Hygiene

The licensing casework was selected to provide a representative sample of licensing actions which had been completed in the review period and to include work by three reviewers. The cross-section sampling included all but three of NYC's major licenses as defined by NYC in the questionnaire, and included the following types: broad scope medical; broad scope academic; gamma knife; hospital nuclear medicine; private practice physicians; teletherapy; HDR remote afterloaders; and intravascular brachytherapy. Twelve license files were evaluated by the review team. Licensing actions included one new license, five renewals, five amendments, and one termination. A list of these licenses with case-specific comments may be found in Appendix D.

The review team found that the licensing actions were thorough, complete, consistent, of good technical quality, and with health and safety issues properly addressed. The licensee's compliance history appeared to be taken into account when reviewing renewal applications as determined from discussion with license reviewers.

All licensing actions are peer reviewed by license reviewers for grammar and format. The Director does a second complete review prior to signing license documents. Individual license reviewers sign letters of deficiency that are mostly well written and used at the proper time. Because of the experience level of license reviewers, checklists are not used. The team found that termination licensing actions were adequately documented. No potentially significant health and safety issues were identified.

NYC defines backlog as licensing actions not addressed, either by letter of deficiency or completed license document, within 100 days of receipt. At the time of the review, NYC had

no actions on backlog. License conditions, including tie-down conditions, are usually stated clearly and are inspectable/enforceable. Applicable guidance documents are available to license reviewers and are generally followed. All team members experienced numerous delays in casework reviews due to the condition of files, missing documentation subsequently discovered in staff offices, and misfiled documents.

The review team discussed with NYC staff the process for obtaining financial assurance for decommissioning from those licensees required to provide it. Four of the 12 licenses evaluated were authorized for quantities of radioactive material which met the NYC criteria for financial assurance. The review team discussed with NYC staff how they addressed the financial assurance requirements contained within their rule. License reviewers indicated that determinations of financial assurance were not being conducted when renewing licenses or writing new licenses. NYC management indicated that due to the long existence and financial ties to government of many of the licensees that would require financial assurance for decommissioning, it was decided to no longer make financial assurance determinations or require licensees and applicants to submit either a decommissioning funding plan or certification of financial assurance. Further, during evaluations of affected licensees, the team discovered that the table used to assess the need for financial assurance contained in the NYC regulations is inaccurate (see Section 4.1.2). See recommendation in Section 3.4.5.

In discussions with NYC management, it was noted that there are no major decommissioning efforts underway with regard to byproduct material in New York City. NYC indicated that no exemptions were issued during the report period.

3.4.2 New York State Department of Labor

The team examined completed licenses and casework for six license actions, representing the work of three license reviewers. The license reviewers and program manager were interviewed to supply additional information regarding licensing decisions or file contents. The license casework was selected to provide a representative sample of licensing actions which had been completed in the review period. The sampling included most of DOL's major byproduct material licenses as defined by DOL in the questionnaire including the following types: broad scope research and development; panoramic irradiator; industrial radiography; portable gauge; and nuclear pharmacy. Licensing actions reviewed included two new licenses, two renewals, and two amendments (one including a use area/building decommissioning). A list of these six licenses with case specific comments may be found in Appendix D.

The review team found that the licensing actions were very thorough, complete, consistent, of high technical quality, and 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 DOL staff follows their, or NRC, licensing guides during the review process to ensure that licensees submit the information necessary to support the request. The team found that termination licensing actions were adequately documented. No

potentially significant health and safety issues were identified. License conditions, including tie-down conditions, are usually stated clearly and are inspectable/enforceable. Deficiency letters clearly state regulatory positions and are used at the proper time.

During the assessment of appropriate financial assurance for decommissioning for one licensee, an error was found in the table in the regulations used to determine the amount of financial assurance. The result is that instead of accepting financial assurance in the amount of $750,000, the licensee should be required to submit a decommissioning funding plan. See Section 4.1.2 for additional information.

DOL indicated that one exemption to their regulations, pertaining to a variance from filing an application for a DOL license for manufacturers of generally licensed devices operating in the State, was issued during the report period. The variance allowed these manufacturers to work under existing NRC or Agreement State radioactive material licenses in the State under reciprocity. The DOL regulation requiring a specific license for generally licensed device manufacturers is more restrictive than NRC regulation. The granting of this variance brings the State into congruence with NRC and other Agreement State policies.

3.4.3 New York State Department of Health

The cross-section sampling of licensing casework included DOH's major licenses as defined by DOH in the questionnaire, including the following types: broad scope medical; broad scope academic; gamma knife; hospital nuclear medicine; brachytherapy; HDR remote afterloaders; research and development, and self-shielded irradiator. The licensing casework was selected to provide a representative sample of licensing actions which had been completed in the review period and to include work by five reviewers. Nine license files were reviewed. Licensing actions included five renewals, three amendments, and one termination. A list of these licenses with case-specific comments may be found in Appendix D.

The review team found that the licensing actions were very thorough, complete, consistent, of high quality, and 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 inspectable. Deficiency letters are well written, clearly indicating regulatory position and used at the appropriate times. The licensee's compliance history was taken into account when reviewing renewal applications. License reviewers appropriately used the Department's licensing guides and standard license conditions. The team found that the terminated licensing action was well documented, showing appropriate transfer records and survey records. License reviewers have the proper signature authority for the cases they review. No significant health and safety issues were identified.

The 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.

3.4.4 New York State Department of Environmental Conservation

The team examined completed permits (licenses) and casework for six permitting actions in six permit files, representing the work of three permit reviewers. The permit reviewers and Section Chief were interviewed, when needed, to supply additional information regarding permitting decisions or file contents. The permit casework was selected to provide a representative sample of permitting actions which had been completed in the review period and to include work by all reviewers. The sampling included the following types of permits issued under Part 380 of the New York State Code of Regulations: air effluents, incinerators, and water discharge. Permitting actions reviewed included two new permits, one renewal, one modification (amendment), and two cancellations (terminations). A list of the six permits reviewed with case specific comments may be found in Appendix D.

The review team found that the permitting actions were thorough, complete, consistent, of high technical quality, and 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 upper 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 holder's compliance history appeared to be always taken into account when reviewing renewal applications as determined from documentation in the permit files and discussions with the permit reviewers.

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% exemption limit. The casework review indicated that permitting staff follow their guides during the review process to ensure that permit holders submit the information necessary to support the permit. The 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 applications. Permit tie-down conditions were stated clearly, backed by information contained in the file, and inspectable. Each permitting action receives a supervisory chain review. Letters of deficiency clearly state regulatory positions, are used at appropriate times and are signed by upper management. Permit documents are signed by various Regional Directors throughout the State.

3.4.5 Indicator Summary

The review team found that the licensing (and permitting) actions for all four Agencies were thorough, complete, consistent, of good technical quality, and with health and safety issues properly addressed.

NYC is not requiring licensees to submit financial assurance instruments as required by New York regulations. 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.

The review team identified errors in the NYC and DOL financial assurance regulation tables. Program management indicated that they would ensure that corrections were made to the regulations. Specific information on the errors in these tables can be found in Section 4.1.2.

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

3.5 Response to Incidents and Allegations

In evaluating the effectiveness of the State's actions in responding to incidents, the review team examined the responses to the questionnaire relative to this indicator, reviewed the incident reports for New York in the National Materials Event Database (NMED) against those contained in the Agency files, and evaluated reports and supporting documentation for 26 incidents. A list of the incident casework examined with case-specific comments is included in Appendix E. The review team also reviewed the Agencies' response to 19 allegations involving radioactive material, 12 of which were referred to New York by the NRC during the review period. The incidents selected for review included the following categories: misadministrations, lost and stolen radioactive material, contaminated waste, personnel contamination and exposure, leaking source, equipment damage, and equipment failure.

3.5.1 New York City Department of Health and Mental Hygiene

The review team examined NYC's response to the questionnaire relative to this indicator, reviewed the incident reports for NYC in NMED against those contained in NYC's files, and evaluated reports and supporting documentation for seven incidents and one allegation.

NYC treats radioactive material incidents and allegations similarly and does not maintain a database to track them. The incident reports are filed in chronological order, without a comprehensive index. The team physically combed through the incident files for the period covered by this review, and selected seven incidents that were potentially reportable.

Incident response was prompt and generally thorough with emphasis placed on licensee performance. As with inspection reports (see Section 3.2.1) documentation of incident response was lacking in completeness and depth. The method of logging incidents, dispatching inspectors, and recording the results was inconsistent, ranging from no apparent supervisory review through on-site visits by an inspector and the supervisor. Not all incidents were copied to the inspection/licensing files for follow-up at the next inspection. See recommendation in Section 3.5.5.

A total of 15 incidents were forwarded to the NRC during the review period. Little consistency was identified in reporting information to the NMED database. An incident in February 2002, requiring 24-hour notification, was not reported to NRC until July 2002. NYC personnel stated that information was transmitted to the NRC via State and Tribal Programs (STP), and they depended upon that office to evaluate and provide information to the NMED contractor. The review team discussed with NYC management the requirement to report incidents to the NRC Operations Center rather than STP. NYC management stated that they would institute a procedure to report incidents to the NRC for inclusion in NMED and would use the current

version of STP Procedure SA-300 "Reporting Material Events." They also stated that a procedure would be drawn up and used to track incidents.

Evaluation of one allegation file, that was referred by the NRC, indicated that NYC took prompt and appropriate action in response to the alleger's concerns. These actions included detailed interviews with the alleger, prompt investigation and routine follow-up at the next inspection. The alleger's identity was protected from disclosure. The review of the casework and interviews of staff determined that NYC staff provided appropriate feedback to the alleger regarding NYC's investigation into the allegation. NYC management did not specifically distinguish any other allegations received during the review period. The review team searched incident/allegation files, but did not identify any other allegations reported to the program.

3.5.2 New York State Department of Labor

The review team evaluated DOL's handling of 10 incidents and six allegations. Five of the six allegations were either referred by NRC or involved a licensee common to both the State and NRC. The review team found that DOL's responses to incidents and allegations were complete and comprehensive. Initial responses were prompt and well-coordinated. The level of effort was commensurate with the health and safety significance of the event. Inspectors were dispatched for on-site investigations when appropriate and DOL took suitable enforcement action when indicated. Allegers' identities were adequately protected from disclosure and feedback was provided to the allegers, as warranted.

The review team's evaluation of the incident casework revealed a lack of consistent reporting incidents to the NRC for inclusion in NMED. Three of the incidents reviewed that required reporting to the NRC were not reported and another was reported 20 months late. The team assessed DOL's process for reporting significant incidents (immediate or 24-hour notification). DOL was inconsistent in reporting significant events to NRC, mainly due to philosophical differences with NRC policy. The Program Manager does not feel an obligation to promptly report incidents to the NRC that do not directly impact NRC licensees or licensees from other Agreement States. As identified in Appendix E, the three incidents not reported to the NRC (Appendix E, DOL Files 1, 2, and 8) were a stolen moisture-density gauge, a damaged moisture-density gauge, and a coronary afterloader brachytherapy source which became stuck during a source exchange. The Program Manager stated, that if an incident involved an NRC or other State licensee or was generic in nature, prompt notifications would be made. In April 2001, DOL provided a summary report of nine incidents for inclusion in the NMED system at the request of the NRC. See recommendation in Section 3.5.5.

3.5.3 New York State Department of Health

In evaluating the effectiveness of DOH's actions in responding to incidents, the review team examined DOH's response to five incidents and 10 allegations. The incident and allegation reports are filed in chronological order, without a comprehensive index. The review team selected for review five incidents that were potentially reportable to the NRC. The vast majority of incidents reported to DOH involved alarms at non-radioactive waste or recycling facilities, caused in most cases by naturally-occurring radioactive material or patient waste.

The review team found that DOH has a procedure requiring the prompt, in-depth, and documented review of incidents reportable to DOH within 30 days. In all of the five cases reviewed, documentation of DOH's response was either missing or incomplete. Of the three cases examined that required a report to DOH within 30 days, DOH determined that one of the incidents required a prompt visit by DOH staff. In that case, the inspector's report contained only scant information about the incident, which involved two therapeutic misadministrations on the same day. Another case file for an event that required reporting did not show if a site visit was required or if one was performed. Subsequent to the on-site review, DOH located documentation that indicated that an on-site review was not necessary. The documentation for the other two cases reviewed by the team indicated that investigations failed to adequately address certain issues. Specifically, the team was unable to determine if the incident had been investigated and how DOH intended to ensure follow-up during the next routine inspection, as there was no reference to this event in the licensing/inspection file, nor any cross-reference to the investigation file. See Appendix E for specific details.

In three of the five cases reviewed, the licensee provided appropriate corrective actions. DOH staff reviewed those actions, and the investigations were closed on that basis. DOH does not perform a formal supervisory review of closed investigations, but DOH staff stated that supervisors are generally kept aware of the progress of investigations, and discuss when closure of the investigations is appropriate. The lack of formality in 1) the tracking of these incidents, 2) the documentation of these incidents, 3) the cross-referencing of these incidents with the license files, and 4) the supervisory review of the investigation documentation all appear to contribute to the overall lack of rigor in the depth, quality, timeliness, and documentation of investigations. See recommendation in Section 3.5.5.

The reporting of incidents to the NRC by DOH was inconsistent. Fifteen incidents were reported to the NRC for inclusion in NMED during the review period. For the five incidents reviewed by the team, three clearly required reporting, but only one was reported to the NRC, some six months after the event was reported to DOH by the licensee. The other two incidents' reporting status could not be clearly ascertained from information in the files. DOH staff stated that they provide quarterly reports to STP and that they presumed these reports met their reporting obligations. The team explained that incident reporting responsibilities are outlined in STP Procedure SA-300 and require reporting to the NRC Operations Center. DOH indicated they would re-evaluate their reporting procedures, and consider complying with STP Procedure SA-300, however they expressed concerns that New York State law may prohibit them from providing certain information, such as licensee names or other identifying information. See recommendation in Section 3.5.5.

The review team evaluated 10 DOH allegations, five of which were referred from the NRC. Allegations are handled in the same manner as incidents. In general, based on staff discussions and file evaluation, the team determined that DOH took prompt and appropriate action in response to allegers' concerns. Alleger identities were protected from disclosure. Staff indicated that feedback is provided to allegers regarding DOH's investigations.

3.5.4 New York State Department of Environmental Conservation

The review team evaluated the response to four incidents to which DEC responded. DEC's response to incidents was generally complete and comprehensive. Initial responses were prompt and well-coordinated, and the level of effort was commensurate with the health and safety significance. DEC dispatched inspectors for on-site investigations when appropriate, and took suitable enforcement and follow-up actions. DEC did not have any incidents reportable to NMED.

Evaluation of two allegation files (one referred by NRC) indicated that DEC took prompt and appropriate action in response to the allegers' concerns. These actions included detailed interviews with the allegers, prompt investigation and routine follow-up at the next inspection. The allegers' identities were protected from disclosure. The evaluation of the casework and interviews of staff determined that DEC staff provided appropriate feedback to the allegers regarding their investigations.

3.5.5 Indicator Summary

Overall, New York's response to incidents was adequate and prompt. As discussed above, however, the review team identified deficiencies in the DOH's documentation of their investigations into incidents. The review team recommends that DOH provide prompt, in-depth, documented reviews of events with the potential for significant health and safety consequences.

For the national NMED system to effectively identify any security concerns or generic problems with equipment or procedures in a timely manner, all States, including New York, should routinely submit the vital information on the incidents that occur in their jurisdiction to the NMED system. Since 1997, when the Commission policy on Adequacy and Compatibility was published in the Federal Register, Agreement State participation in the NMED system became mandatory. In 1998, STP issued an implementing procedure (STP Procedure SA-300) for Agreement State reporting of material events to comply with this policy change.

The review team recommends that NYC, DOL, and DOH 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.

Based on the IMPEP evaluation criteria, the review team recommends that New York State's performance with respect to the indicator, Response to Incidents and Allegations, be found satisfactory with recommendations for improvement.

4.0 NON-COMMON PERFORMANCE INDICATORS

IMPEP identifies four non-common performance indicators to be used in reviewing Agreement State programs: (1) Legislation and Program Elements Required for Compatibility; (2) Sealed Source and Device Evaluation Program; (3) Low-Level Radioactive Waste Disposal Program; and (4) Uranium Recovery Program. The New York Agreement does not cover the uranium recovery program, so only the first three non-common performance indicators were applicable

to this review. Note: due to the nature of the non-common performance indicators, the information presented has not been divided into sub-sections by Agency as was done with the common performance indicators.

4.1 Legislation and Program Elements Required for Compatibility

4.1.1 Legislation

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's radiation program is delegated from the DOH program under Part 16 of the New York State Health Code which provides for delegation to local governments when covering greater than two million individuals. DOL's legislative authority to administer its portion of the Agreement State program is granted in Section 27 of the Labor Law and Article 28-D of the General Business Law. 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. 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. There has been no legislation passed since the last IMPEP review that affected any of the four Agencies responsible for the Agreement State program in New York.

4.1.2 Program Elements Required for Compatibility

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

DOL 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) that apply to all commercial and industrial uses of radioactive material. DOL requires a license for possession and use of all radioactive material for commercial and industrial purposes including naturally occurring radioactive material, such as radium, and accelerator-produced radionuclides. DOL's regulatory adoption process is a seven-step process that takes at least 12 months to complete.

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 that apply to 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 naturally occurring radioactive material, such as radium, and accelerator-produced radionuclides for medical, academic, or research and development. DOH also requires registration of all equipment designed to produce x-rays or other ionizing radiations. DOH's regulatory adoption

process is a ten-step process that takes approximately 12 to 18 months, depending on the complexity of the action.

DEC regulations are found in Title 6, Parts 380, 381, 382, and 383 of the New York Codes, Rule, and Regulations that apply to environmental releases and the disposal of radioactive material. DEC requires a permit for release of radioactive material to the environment including the disposal of radioactive material, including naturally occurring radioactive material, such as radium, and accelerator-produced radionuclides. DEC's regulatory adoption process is a ten-step process that takes approximately 18 to 24 months.

The review team found that all four Agencies provide the opportunity for public comment during the regulatory adoption process. The regulations for all four Agencies are not subject to sunset provisions. The regulatory adoption process for the three state-wide Agencies (DOL, DOH and DEC) include a review of proposed regulations by the Governor's Office for Regulatory Reform. This office evaluates proposed regulations for impact on the State's business community.

The review team assessed the status of the regulations required for adoption, evaluated the Agency responses 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 STP 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.

Since the previous IMPEP review, NYC adopted 1 regulation amendment that became effective in April 1999 and adopted 2 additional amendments by legally binding requirements. Since the previous IMPEP review, DOL adopted 13 NRC amendments in a rule package that became effective in April 1999. In addition, DOL indicated that the following NRC amendment is met by existing language in Section 38.15 of their regulations. The team reviewed the relevant section of the regulation and concluded that the essential elements of the NRC amendment have been met. However, DOL needs to submit the legally binding requirement for NRC review per STP Procedure SA-201, Review of State Regulations.

- "Recognition of Agreement State Licensees in Areas Under Exclusive Federal Jurisdiction Within an Agreement State," 10 CFR 150 amendment (62 FR 1662) that became effective February 27, 1997.

During the review period, DOH adopted 4 amendments through legally binding requirements. They also indicated that Article 12-b of the New York Public Health Law addressed another requirement. DEC adopted one amendment by legally binding requirements, and a proposed regulation has also been drafted and is currently undergoing review. Legally binding requirements should be submitted to the NRC for review per STP Procedure SA-201.

The review team determined that the following regulations were not adopted and were overdue at the time of the review. They have not been incorporated in license conditions or other legally binding requirements.

NYC has neither drafted nor adopted:

- "Timeliness in Decommissioning Material Facilities," 10 CFR Part 30, 40 and 70 amendments (59 FR 36026) that became effective August 15, 1994.
- "Radiation Protection Requirements: Amended Definitions and Criteria," 10 CFR Parts 19 and 20 (60 FR 36038) that became effective August 14, 1995.
- "Clarification of Decommissioning Funding Requirements," 10 CFR Parts 30, 40 and 70 (60 FR 38235) that became effective November 24, 1995.
- "Medical Administration of Radiation and Radioactive Materials," 10 CFR Parts 20 and 35 amendments (60 FR 48623) that became effective October 25, 1995.
- "Termination or Transfer of Licensed Activities: Recordkeeping Requirements," 10 CFR Parts 20, 30, 40, 61 and 70 amendments (61 FR 24669) that became effective June 17, 1996.
- "Recognition of Agreement State Licensees in Areas Under Exclusive Federal Jurisdiction Within an Agreement State," 10 CFR 150 amendment (62 FR 1662) that became effective February 27, 1997.
- "Radiological Criteria for License Termination," 10 CFR Parts 20, 30, 40, and 70 amendments (62 FR 39057) that became effective August 20, 1997.
- "Deliberate Misconduct by Unlicensed Persons," 10 CFR Parts 30, 40, 61, 70, and 150 amendments (63 FR 1890 and 63 FR 13773) that became effective February 12, 1998.
- "Minor Corrections, Clarifying Changes and a Minor Policy Change," 10 CFR Parts 20, 35 and 36 amendments (63 FR 39477 and 45393) that became effective October 26, 1998.

DOL has not adopted:

- "Termination or Transfer of Licensed Activities: Recordkeeping Requirements," 10 CFR Parts 20, 30, 40, 61 and 70 amendments (61 FR 24669) that became effective June 17, 1996. DOL has not drafted this amendment.
- "Radiological Criteria for License Termination," 10 CFR Parts 20, 30, 40, and 70 amendments (62 FR 39057) that became effective August 20, 1997. DOL has not drafted this amendment but has implemented this regulation and associated guidance by legally binding requirement.
- "Deliberate Misconduct by Unlicensed Persons," 10 CFR Parts 30, 40, 61, 70, and 150 amendments (63 FR 1890 and 63 FR 13773) that became effective February 12, 1998. DOL's legal counsel has reviewed this amendment and determined that its beyond the

scope of DOL's regulatory authority which is limited to licensees and registrants. The Program Director indicated that in the case of a sub-contractor or other third party whose deliberate misconduct resulted in a licensee violating DOL regulations, the DOL's recourse would be the pursuit of enforcement action against the licensee. The team considers this an acceptable alternative to meet the essential elements of this NRC amendment."

- "Minor Corrections, Clarifying Changes and a Minor Policy Change," 10 CFR Parts 20, 35 and 36 amendments (63 FR 39477 and 45393) that became effective October 26, 1998. DOL has not drafted this amendment.

DOH has drafted, but has not yet adopted:

- "Radiation Protection Requirements: Amended Definitions and Criteria," 10 CFR Parts 19 and 20 (60 FR 36038) that became effective August 14, 1995.

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

- "Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14 Urea," 10 CFR Part 30 amendment (62 FR 63634) that became effective January 2, 1998.

- "Minor Corrections, Clarifying Changes and a Minor Policy Change," 10 CFR Parts 20, 35 and 36 amendments (63 FR 39477 and 45393) that became effective October 26, 1998.

DEC has not adopted:

- "Radiation Protection Requirements: Amended Definitions and Criteria," 10 CFR Parts 19 and 20 (60 FR 36038) that became effective August 14, 1995. A proposed regulation has been drafted and is currently undergoing review.

- "Termination or Transfer of Licensed Activities: Recordkeeping Requirements," 10 CFR Parts 20, 30, 40, 61 and 70 amendments (61 FR 24669) that became effective June 17, 1996. A proposed regulation has been drafted and is currently undergoing review.

- "Radiological Criteria for License Termination," 10 CFR Parts 20, 30, 40, and 70 amendments (62 FR 39057) that became effective August 20, 1997. A proposed regulation has been drafted and is currently undergoing review.

- "Deliberate Misconduct by Unlicensed Persons," 10 CFR Parts 30, 40, 61, 70, and 150 amendments (63 FR 1890 and 63 FR 13773) that became effective February 12, 1998. DEC has not drafted this amendment.

- "Minor Corrections, Clarifying Changes and a Minor Policy Change," 10 CFR Parts 20, 35 and 36 amendments (63 FR 39477 and 45393) that became effective October 26, 1998. A proposed regulation has been drafted and is currently undergoing review.

- "Transfer for Disposal and Manifests: Minor Technical Conforming Amendment," 10 CFR Part 20 amendment (63 FR50127) that became effective November 20, 1998. DEC has not drafted this amendment.

All four Agencies will need to address the following regulations in upcoming rulemakings or by adopting alternate legally binding requirements within three years of the date adopted by the NRC.

NYC will need to adopt the following NRC amendments:

- "Respiratory Protection and Controls to Restrict Internal Exposures," 10 CFR Part 20 amendment (64 FR 54543; 64 FR 55524) that became effective February 2, 2000.

- "Revision of the Skin Dose Limit," 10 CFR Part 20 amendment (67 FR 16298) that became effective April 5, 2002.

- "Medical Use of Byproduct Material," 10 CFR 20, 32, and 35 amendments (67 FR 20249) that became effective October 24, 2002.

DOL will need to adopt the following NRC amendments:

- "Respiratory Protection and Controls to Restrict Internal Exposures," 10 CFR Part 20 amendment (64 FR 54543; 64 FR 55524) that became effective February 2, 2000.

- "Energy Compensation Sources for Well Logging and Other Regulatory Clarifications," 10 CFR Part 39 amendment (65 FR 20337) that became effective May 17, 2000.

- "New Dosimetry Technology," 10 CFR Parts 34, 36, and 39 amendments (65 FR 63749) that became effective January 8, 2001.

- "Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material," 10 CFR Part 32 amendments (65 FR 79162) that became effective February 16, 2001.

- "Revision of the Skin Dose Limit," 10 CFR Part 20 amendment (67 FR 16298) that became effective April 5, 2002.

- "Medical Use of Byproduct Material," 10 CFR 20, 32, and 35 amendments (67 FR 20249) that became effective October 24, 2002. DOL will need to adopt only those changes to the pharmacy requirements.

DOH will need to adopt the following NRC amendments:

- "Respiratory Protection and Controls to Restrict Internal Exposures," 10 CFR Part 20 amendment (64 FR 54543; 64 FR 55524) that became effective February 2, 2000.
- "Revision of the Skin Dose Limit," 10 CFR Part 20 amendment (67 FR 16298) that became effective April 5, 2002.
- "Medical Use of Byproduct Material," 10 CFR 20, 32, and 35 amendments (67 FR 20249) that became effective October 24, 2002.

DEC will need to adopt the following NRC amendment:

- "Revision of the Skin Dose Limit," 10 CFR Part 20 amendment (67 FR 16298) that became effective April 5, 2002.

4.1.3 Indicator Summary

The review team noted that all four Agencies have at least four NRC amendments that are overdue and will be adopted in a time frame greater than three years after the effective date of their adoption by the NRC. 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 programmatic issues. The review team recommends that each New York Agency (NYC, DOH, DEC and DOL) adopt NRC regulations in accordance with the current NRC policy on adequacy and compatibility.

As discussed in Section 3.4, the team identified errors in NYC and DOL regulations which affect the amount of surety required to be addressed by licensees. Article 175.101(n) contains the NYC requirement for financial assurance. The section references 175.101 Appendix B (Exempt Quantities) to determine appropriate financial assurance. This table does not include americium or plutonium. A more appropriate table for NYC to use would be in Article 175.03, Appendix C (Quantities of Licensed or Registered Material Requiring Labeling).

In Section 12 NYCRR Part 38.41, Table 4 (Quantities of Licensed Materials) of DOL regulations, which is also used for financial assurance, the quantity for carbon-14 is listed as 1000 microcuries whereas the equivalent NRC table (10 CFR 30, Appendix B) has a carbon-14 value of 100 microcuries. This table has a compatibility category of B, requiring essentially identical quantities. Program management indicated that they would ensure that corrections were made to the regulations.

Based on the IMPEP evaluation criteria, the review team recommends that New York's performance with respect to the indicator, Legislation and Program Elements Required for Compatibility, be found satisfactory with recommendations for improvement.

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

Only DOL performs this portion of the Agreement for the State of New York. Three sub-indicators were used to evaluate DOL's performance regarding their SS&D Evaluation Program. These sub-indicators are: (1) Technical Quality of the Product Evaluation Program; (2) Technical Staffing and Training; and (3) Evaluation of Defects and Incidents Regarding SS&Ds.

In assessing DOL'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, DOL indicated that no SS&D reviews had been performed since the previous IMPEP. During the on-site review, the review team and DOL staff identified one SS&D evaluation that was performed in 2001. The team observed the staff's use of various appropriate guidance documents and procedures, and interviewed the staff and Program Manager involved in SS&D evaluations.

4.2.1 Technical Quality of the Product Evaluation Program

DOL processed one new SS&D application since the last review and performed no amendments to existing SS&D evaluations. The casework review indicated that DOL staff follows their, or NRC, guidance during the review process to ensure that licensees submit the information necessary to support the product. DOL demonstrated that they have modified guidance from the NRC for their specific use. The tie-down condition is stated clearly and is inspectable/enforceable. Deficiency letters clearly stated regulatory positions and were used at the proper time. A concurrent review was accomplished by a second SS&D evaluation-qualified reviewer. Additional specific comments are listed in Appendix F.

The review team interviewed the staff and supervisor responsible for SS&D evaluations, and examined the staff's use of new guidance documents and procedures. DOL staff has improved in following NRC guidance and conferring with NRC or other experienced DOL staff. The team found no health and safety issues relative to the SS&D evaluation which was reviewed.

In 2000, another Agreement State requested that New York update a Registry sheet to identify device changes approved by DOL since the sheet was last issued in 1976. NRC also requested that DOL update the sheet to maintain a viable national registry. DOL indicated that a proper review of the device was performed and it was found acceptable for distribution to general licensees. Instead of updating the Registry, DOL offered the State and NRC a copy of the license amendment which was issued to the device manufacturer. In 2001, NRC again requested an updated Registry sheet from New York, but since then, the manufacturer sold that portion of their business to a company in another Agreement State. The review team contacted that State and was informed that the successor company had filed an SS&D Registry request with them. DOL has terminated the manufacturer's possession and distribution license.

The review team identified the need to inactivate several registrations (only one contains byproduct material authorization) formerly held by a company no longer in business. DOL management's agreed to address the inactivations as time and resources permit.

4.2.2 Technical Staffing and Training

The Program Manager and two health physicists are the reviewers qualified to conduct and sign safety evaluations of SS&D applications in accordance with the NRC/OAS Training Work Group recommendations. Specific procedures for documenting training requirements for qualification as a SS&D reviewer were created. 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. The team determined that the reviewers meet the technical training required for SS&D reviews as described under the guidance. Similarly, the team determined that the staffing level of qualified reviewers is sufficient in view of the relatively low number of licensees who need registration certificates in New York.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

DOL staff were not aware of any defects or incidents involving devices reviewed by their program. The review team conducted a search of the NMED system and DOL files to determine whether incidents might have taken place that were not known to DOL staff. No incidents were identified related to devices considered during the review.

4.2.4 Indicator Summary

Only one SS&D review was performed since the last IMPEP review. The evaluation was adequately performed, however, the DOL Program Manager is aware, with this limited number of device reviews performed by New York, that expertise is difficult to maintain. He committed to conferring with NRC or other Agreement State SS&D programs if a complex device evaluation is required which surpasses DOL expertise.

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

4.3 Low-Level Radioactive Waste (LLRW) Disposal Program

New York has two former radioactive waste disposal sites: the State Licensed Disposal Area at West Valley (West Valley), and the University of Cornell Radiation Disposal Site at Lansing (Cornell).

West Valley was operated as a commercial low-level radioactive waste disposal facility authorized by DOL and DOH from 1963 to 1975. The site ceased operations in 1975, and has since been under State ownership and control. Nuclear Fuel Services (NFS), Inc., was the commercial operator of the site. The wastes, approximately 2.4 million cubic feet, that were received from various places such as nuclear power plants, government facilities, industries,

waste brokers, and decontamination companies, were placed in 14 parallel trenches. The trenches range from approximately 450 to 650 feet in length and are approximately 20 feet deep. In addition to the trenches, West Valley contains three lagoons which were excavated and used to hold water pumped from the trenches during disposal operations. In 1974 regulatory responsibility for West Valley was transferred from DOH to DEC. NYSERDA assumed responsibility for West Valley in 1983.

Currently, NYSERDA holds two permits from DEC for West Valley. DEC is responsible for all environmental releases and the permitting of the disposal units. One of the permits authorizes the emission of radionuclides from the vent system of the West Valley leachate storage tank and the other permit 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. NYSERDA also holds a radioactive material license from DOL which covers the on-site radiation control program, occupational exposure of individuals, and control of radioactive material as it affects occupational exposures.

Disposal operations at Cornell occurred between 1956 and 1978. The disposal site is about 290 by 300 feet in size. Wastes were buried in trenches excavated 6 to 12 feet deep. Low-level radioactive laboratory material were buried at Cornell, as were solvents such as paradioxane. Cornell currently operates under a broad scope radioactive material license from DOH.

Cornell is being remediated through a substantive permit under a consent order. DEC issued a permit in April 2002 which includes the requirements imposed by the consent order. The team reviewed the permit which authorizes discharge of water containing radioactive material from a groundwater treatment system located at the site. It was noted on the permit that the treatment system is for a non-radiological contaminant, paradioxane, and that the radionuclide discharge is incidental to this treatment process. Upon completion of all activities under the consent order, DEC will issue a permit for the monitoring activities at this site.

4.3.1 Status of Low-Level Radioactive Waste Inspection

The review team found that DEC and DOL inspect West Valley at the required annual frequency and that DEC inspects Cornell at the required annual frequency as well.

Regarding the timeliness of the DEC inspection reports, the review team noted that for an inspection conducted on September 18, 2001, the report was completed on December 3, 2001. This exceeded the 15-working day requirement for report completion specified in the inspection procedure document. The report was reviewed by the inspector's supervisor on December 11, 2001, and the formal inspection letter, signed by the inspector notifying the licensee of the inspection findings was sent to the licensee on December 11, 2001. The team found that DOL issued their inspection findings to NYSERDA within 15 days of completion of the inspection.

4.3.2 Technical Quality of Inspections

The review team evaluated the latest DEC and DOL inspection reports and found the scope and quality of the reports to be complete and thorough, and emphasized public health and safety, as well as protection of the environment. DEC inspects the burial sites on an annual basis 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 annual inspection, pre-operational and follow-up inspections are conducted by the DEC staff.

DEC conducts environmental monitoring at the burial sites which includes gamma radiation measurements using 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 are collected from the three creeks.

The DEC inspector was accompanied by his supervisor in June 1998, but has not been accompanied since. The review team recommends that DEC perform annual supervisory accompaniments of the inspector (See recommendation in Section 3.2.5 of this report). The supervisory accompaniments of DOL inspectors is discussed in Section 3.2.2.

On July 19, 2002, a site visit at West Valley was conducted by a review team member accompanied by the DEC inspector. Prior to and during the site visit, the inspector provided the team a detailed explanation of the site background, site description, storage facilities, and current activities, including environmental monitoring by DEC at West Valley. Another team member accompanied the DEC inspector to Cornell on May 29, 2002, during a pre-operational inspection of the radiation treatment system. A discussion of inspector accompaniments can be found in Section 3.2.

4.3.3 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. The training, experience, and the educational qualifications for the inspector were evaluated and were found to be adequate. The review team commented on the need for a back-up inspector trained to inspect the West Valley facility. The comment was noted and acknowledged by DEC management.

Qualifications of DOL inspectors were reviewed by the team and found to be adequate. See Section 3.3.2 for additional detail.

4.3.4 Technical Quality of Licensing

DOL 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 team reviewed one of the licensing actions issued by DOL for this license and found the review thorough, complete, and of excellent quality.

A separate file is maintained for each licensing action. All correspondence related to the issuance of the license was well documented. Technical reviews and issuance of the licenses are conducted by the DOL staff in the Albany office. The licenses are issued for three years unless renewed, suspended, revoked, or terminated by DOL. Three months prior to license expiration, DOL notifies the licensee of the expiration date. A tracking system is maintained for all actions.

DEC has issued two permits to NYSERDA. One of the permits authorizes the emission of radionuclides from the vent system of the West Valley leachate storage tank and the other permit 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. Renewal of the maintenance and monitoring permit is in process. The air permit will soon be terminated and relevant provisions will be combined with the maintenance and monitoring permit upon renewal. The team reviewed licensing actions completed by DEC and found the reviews thorough, complete, and of excellent quality.

A separate file is maintained for each permit. All correspondence and telephone calls related to the issuance/termination of the permits were well documented. Guidance documents for terminating permits were maintained on file. Technical reviews for the permits are conducted by the DEC staff in the Albany office. A draft is sent to the DEC regional offices for issuance/final action. The permits are issued for five years unless renewed, suspended, revoked or terminated by DEC. A tracking system is maintained for all permitting actions.

4.3.5 Response to Incidents and Allegations

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

4.3.6 Indicator Summary

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

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

5.0 SUMMARY

As noted in Sections 3 and 4 above, the review team found New York's performance to be satisfactory for five performance indicators, and satisfactory with recommendations for improvement for the indicators: 1) Status of Materials Inspection Program; 2) Response to Incidents and Allegations; and 3) Legislation and Program Elements Required for Compatibility. The MRB found the New York Agreement State program to be adequate to

protect public health and safety and compatible with NRC's program. Based on the results of the current IMPEP review, the review team recommended, and the MRB agreed, that the next full review should be in approximately four years.

Below are the recommendations, as mentioned earlier in the report, for evaluation and implementation, as appropriate, by the State.

RECOMMENDATIONS:

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)

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)

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)

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

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)

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)

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)

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)

LIST OF APPENDICES AND ATTACHMENTS

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
James Lynch, Region III	Team Leader Response to Incidents and Allegations Inspector Accompaniments
Duncan White, Region I	Legislation and Program Elements Required for Compatibility Response to Incidents and Allegations Technical Quality of Licensing Actions Inspector Accompaniments
David Fogle, Texas	Technical Quality of Licensing Actions Sealed Source and Device Evaluation Program
Deborah Piskura, Region III	Technical Quality of Inspections Response to Incidents and Allegations
Barbara Hamrick, California	Status of Materials Inspection Program Response to Incidents and Allegations
Tony Gaines, Region IV	Technical Staffing and Training Response to Incidents and Allegations
David Collins, Region II	Response to Incidents and Allegations
Muhammadali Abbaszadeh, Texas	Low-Level Radioactive Waste Disposal Program

APPENDIX B-1

New York City Department of Health & Mental Hygiene

Office of Radiological Health

ORGANIZATION CHARTS
ML022490410

The Department's mission is to protect and promote the health and mental health of all New Yorkers, to promote the recovery of those with mental illness and chemical dependencies, and the realization of full potential of those with mental retardation and developmental disabilities.

PROPOSED – DEPARTMENT OF HEALTH & MENTAL HYGIENE

Draft Proposed Table of Organization
Effective July 1, 2002

Legislative Body -- Board of Health
Advisory Boards:
-Community Services Board/Mental Hygiene Advisory Board
-Federation for Mental Health, Mental Retardation and Alcoholism Services
-Local Early Intervention Coordinating Council
-HIV Prevention Planning Group
-Ryan White Planning Council
and others

Community Services Board and Federation Only

Commissioner

Office of the Chief Medical Examiner

Chief of Staff

Agency Chief Contracting Office

Equal Employment Opportunity Office

Division of Mental Hygiene

- Office of Mental Hygiene Management Services
- Mental Health
- Early Intervention and Developmental Disabilities
- Chemical Dependency and Health Promotion

Division of Financial and Strategic Management

- Finance
  - Budget
  - Contract Audits
  - Contract Payments
  - Expenses
  - Internal Accounting
  - Payroll
  - Revenue
- Policy, Planning, Quality and Development
  - Best Practices Library
  - Business Systems Improvement Development
  - Grants Management
  - Performance/Quality Improvement
  - Policy Analysis/Strategic Planning
  - Program Audits
- Communications
  - Community Relations
  - Cross-Cultural Communications
  - Health Media and Marketing Group
  - Internet Content
  - Media
  - Mental Hygiene Public Education
  - Website Content
- Information Technology
  - Data Processing
  - Internet and Intranet Support
  - MIS
  - Technology Policy Development

Division of Disease Control
- Communicable Disease Emergency Management
- HIV/AIDS Surveillance, Services & Research
- Public Health Laboratory
- STD Prevention & Control
- Tuberculosis Control
- Vaccine Preventable Diseases

Division of Environmental Health
- Environmental Disease Prevention
- Environmental Sciences and Engineering
- Field Operations and Inspections
- Poison Control Center
- Veterinary & Pest Control

Division of Epidemiology
- Data Analysis
- Data Integration and Dissemination
- Epidemiologic Training
- Library
- Vital Records/Vital Statistics

Division of Health Care Access and Improvement
- Contracted Primary Care Services
- Data Analysis and Reporting
- Health Insurance Services (incl. PHCP & CBHCN)
- Managed Care and Professional Services
- Oral Health

Division of Health Promotion and Disease Prevention
- Asthma Initiative
- Call Center
- Chronic Disease Prevention
- Day Care
- Gay and Lesbian Health
- Maternal Infant and Reproductive Health
- Minority Health
- Neighborhood Initiative
- School Health
- Tobacco Control

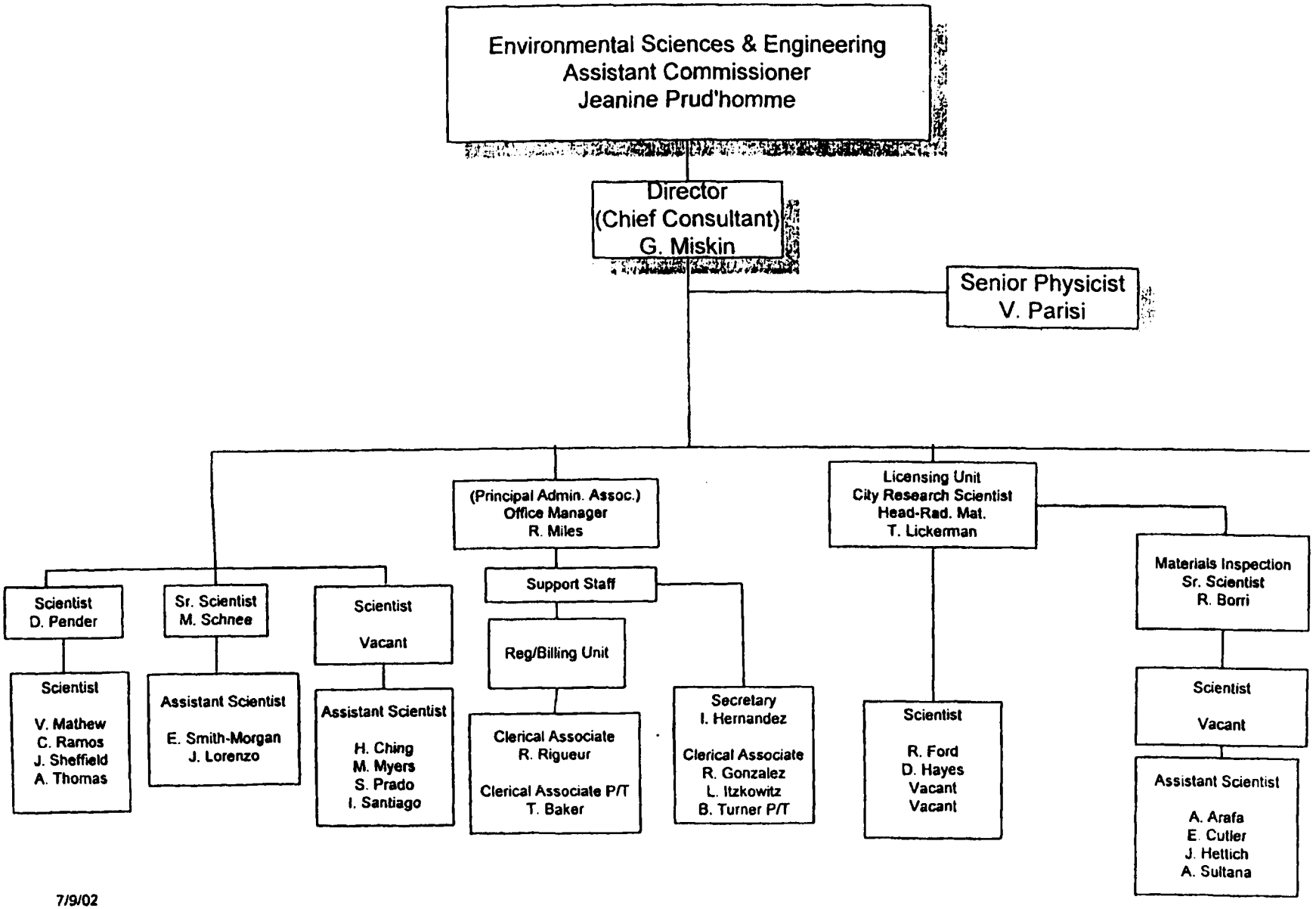
Office of the General Counsel for Public Health
- IRB

Office of the General Counsel for Mental Hygiene
- Intergovernmental Affairs

Division of Administration
- ACCO/Procurement
- EEO
- Facilities/Building Operations
- Human Resources
- Operations

Draft 12
June 14, 2002

OFFICE OF RADIOLOGICAL HEALTH



7/9/02

APPENDIX B-2

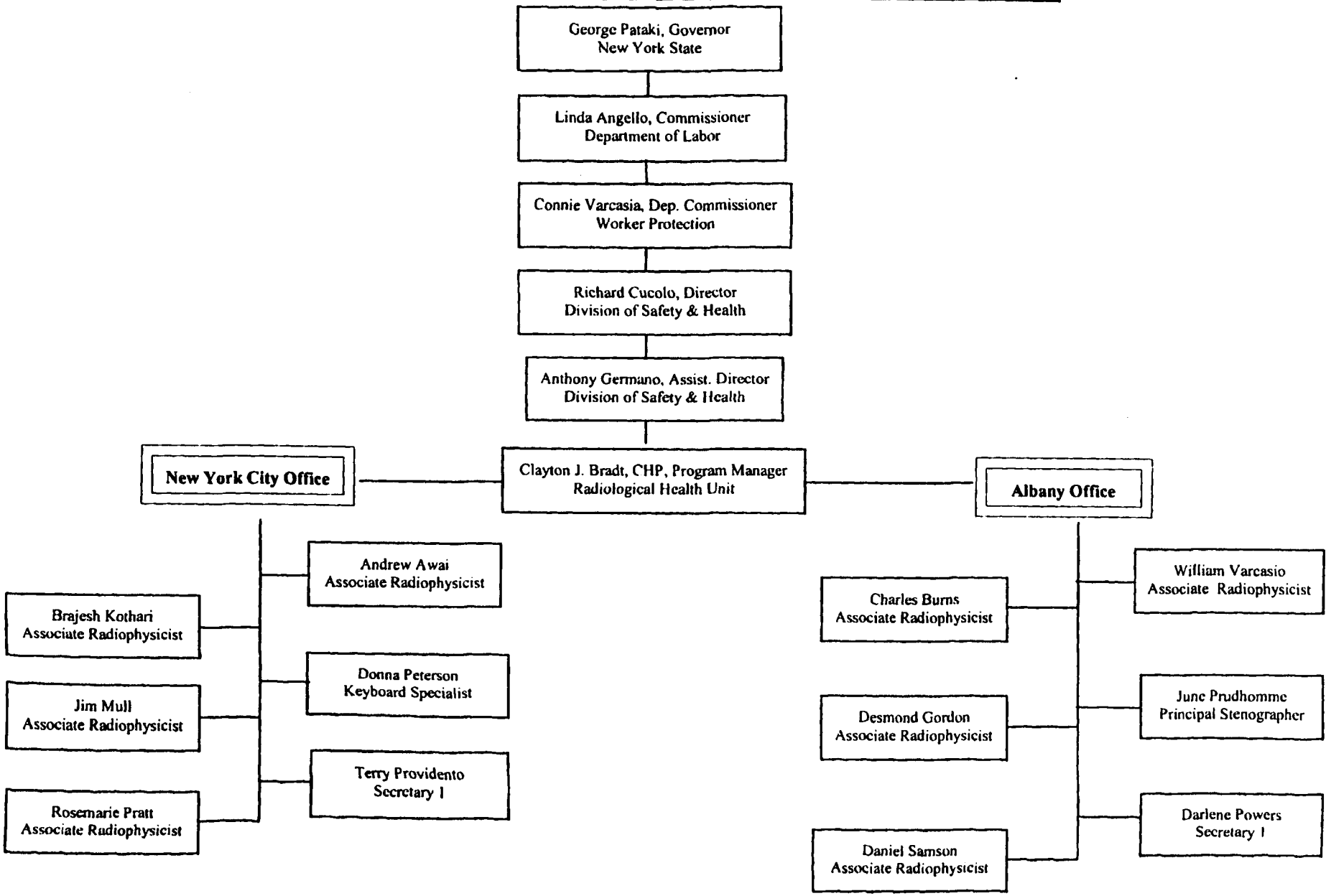
New York State Department of Labor

Radiological Health Unit

ORGANIZATION CHART
ML022490413

New York State Department of Labor
Radiological Health Unit
Organizational Chart

June 2002



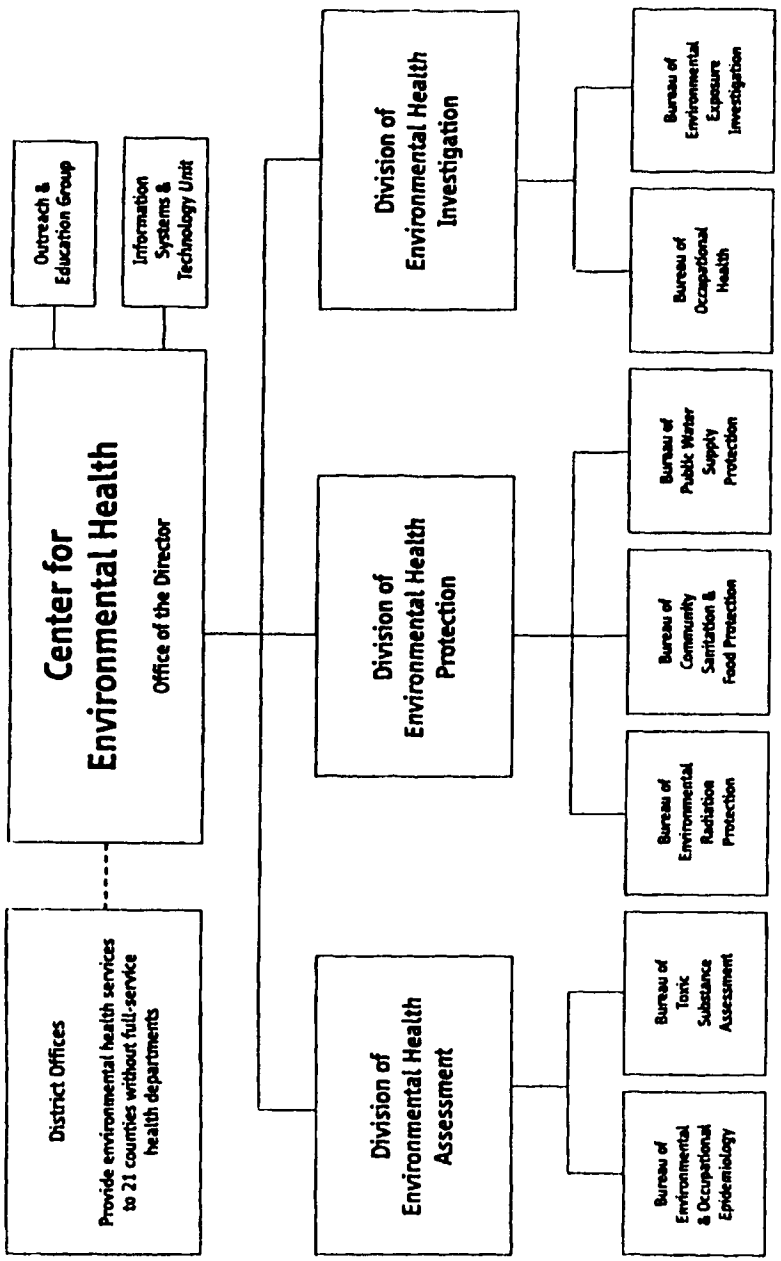
APPENDIX B-3

New York State Department of Health

Bureau of Environmental Radiation Protection

ORGANIZATION CHARTS

ML022490414

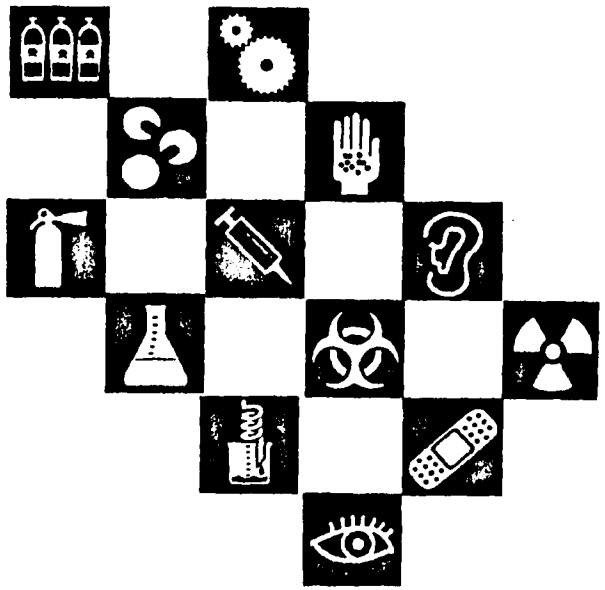


Center for Environmental Health

New York State Department of Health
Flanigan Square, 547 River Street
Troy, NY 12180-2216

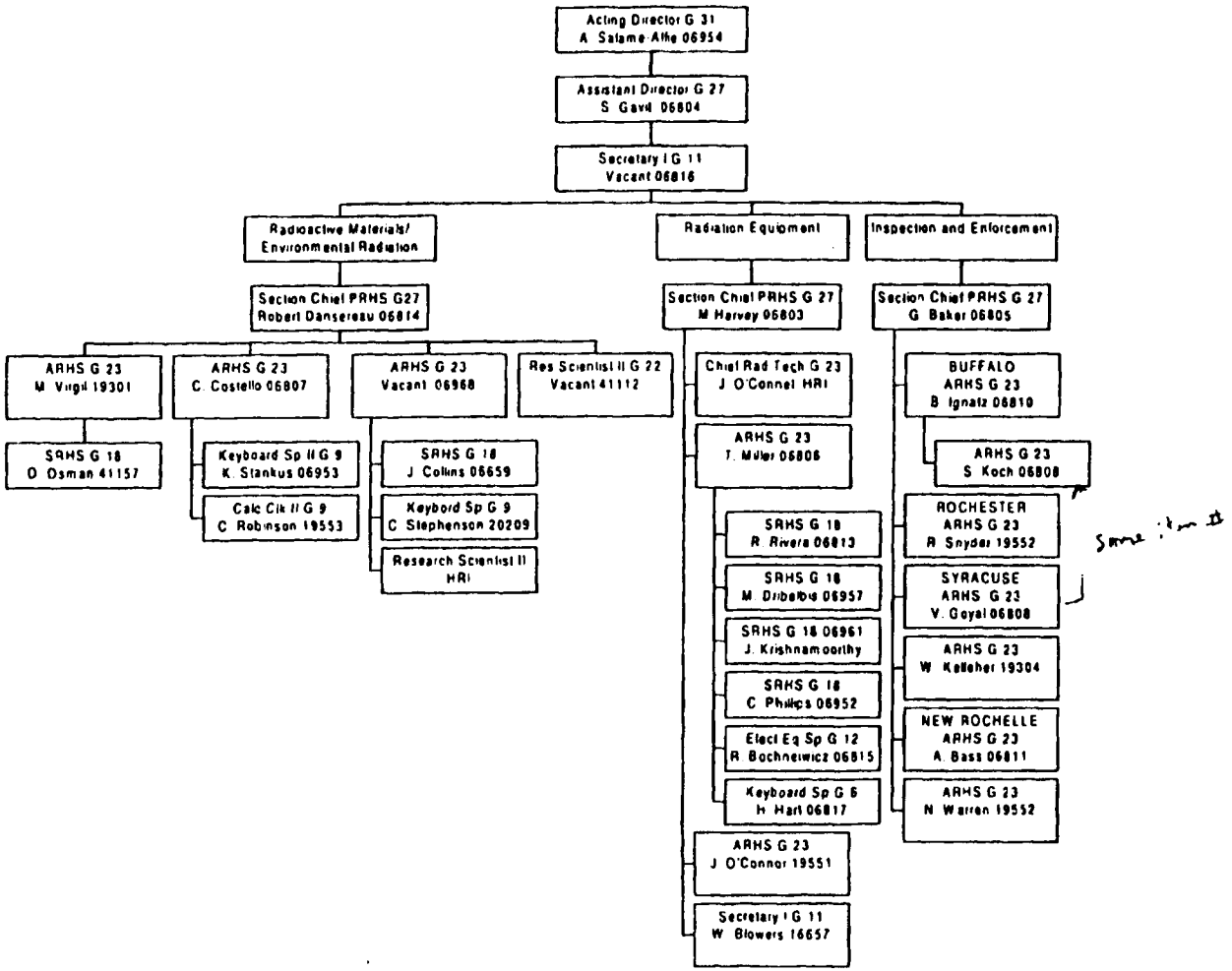
Welcome to the New York State Health Department's Center for Environmental Health. The Center applies scientific, medical, engineering, and public health expertise to identify, understand, prevent, and mitigate risks to human health from New York State's living and working environments. This directory describes the environmental health responsibilities and activities for each division, bureau, and program group within the Center.

A list of telephone numbers for each of the programs is provided on Page 8. Phone numbers for local health departments and district offices are listed on Page 9.



The Center's e-mail address is **ceheduc@health.state.ny.us**
Environmental health and occupational health information for consumers, providers, and researchers is available from the New York State Health Department's web site at **www.health.state.ny.us**

Bureau of Environmental Radiation Protection



APPENDIX B-4

New York State Department of Environmental Conservation

Division of Solid and Hazardous Materials

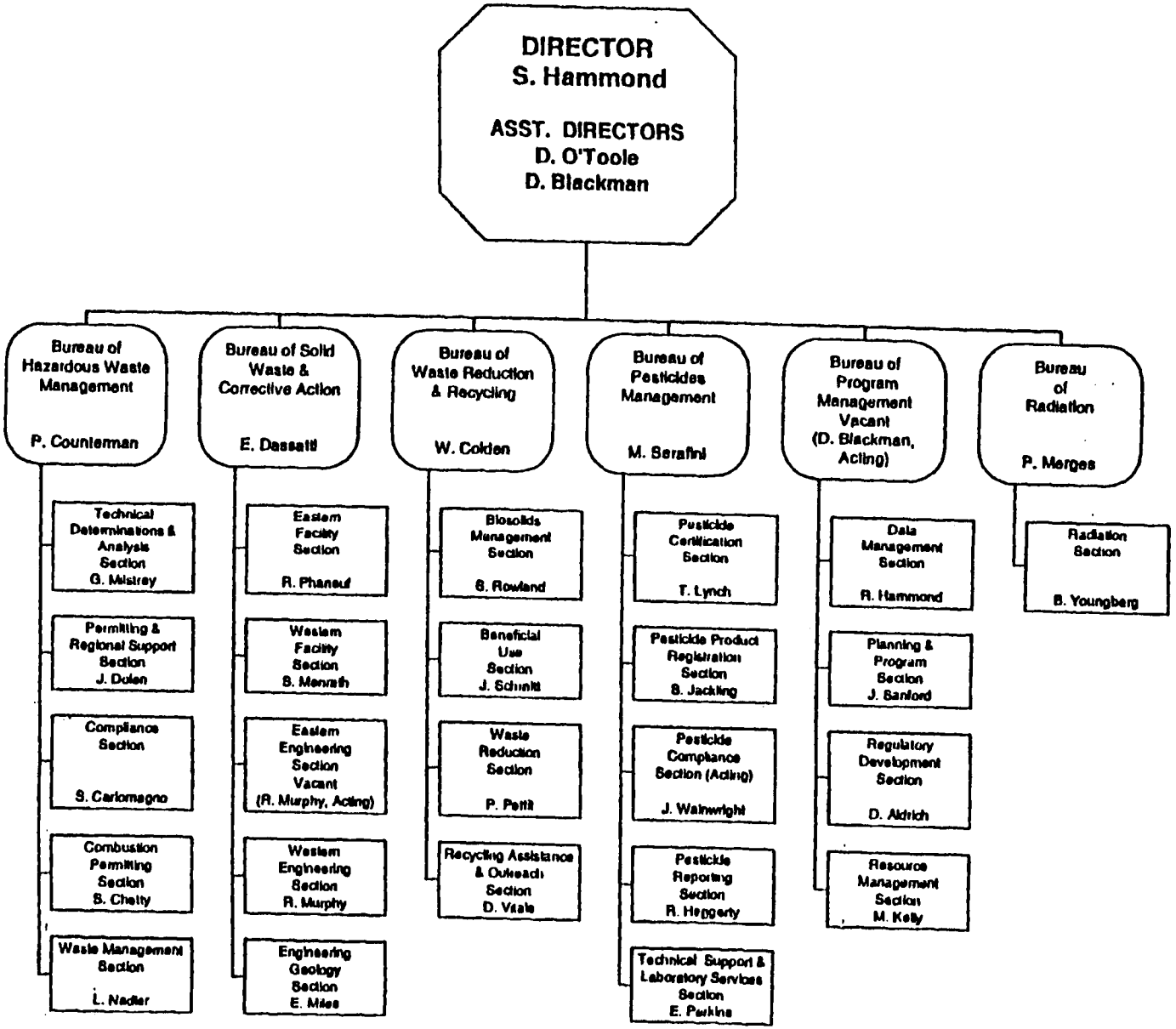
Bureau of Radiation

ORGANIZATION CHARTS
ML022490415

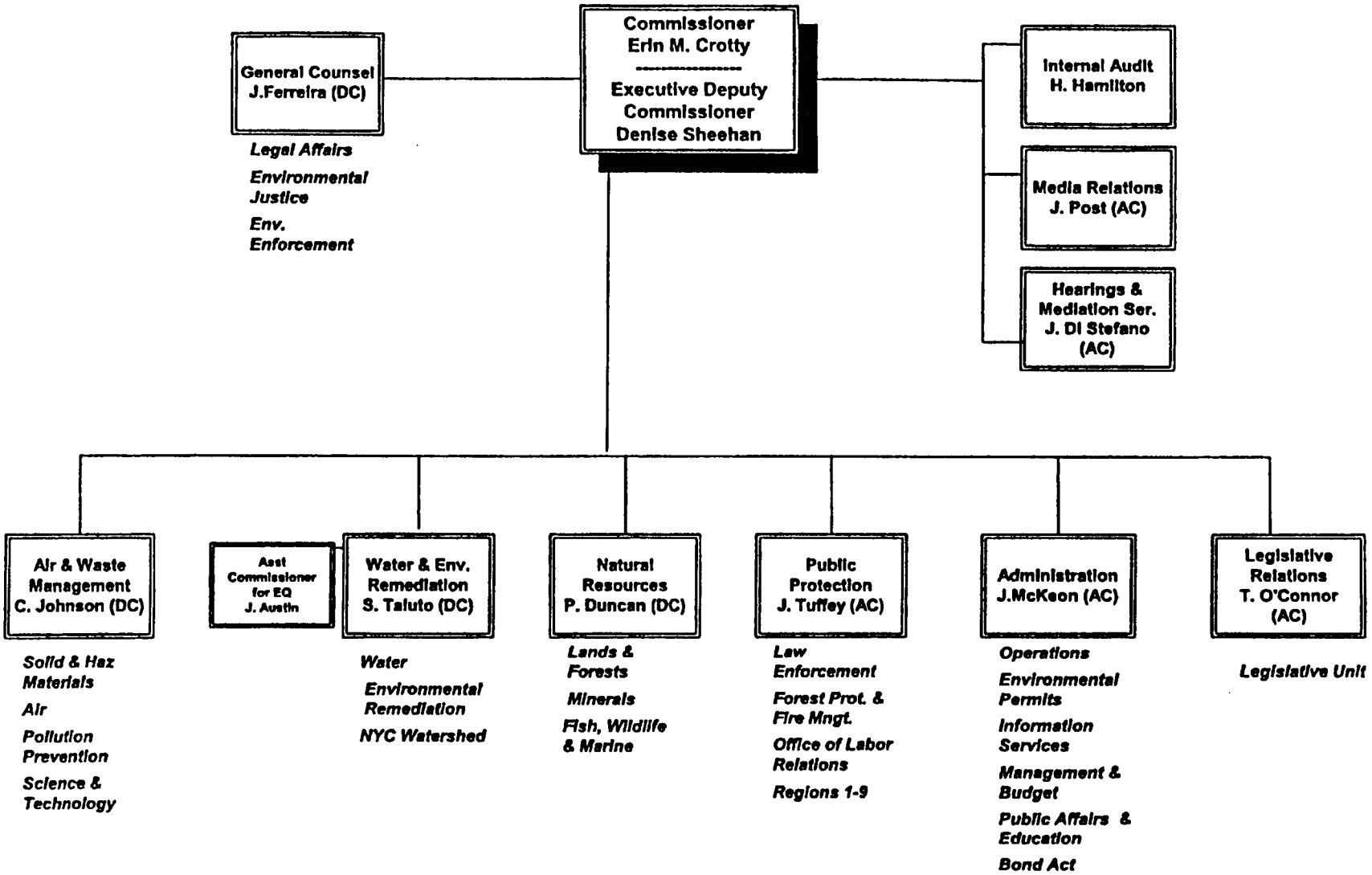
NEW YORK STATE DEPARTMENT OF ENVIRONMENTAL CONSERVATION

DIVISION OF SOLID & HAZARDOUS MATERIALS

March 13, 2002



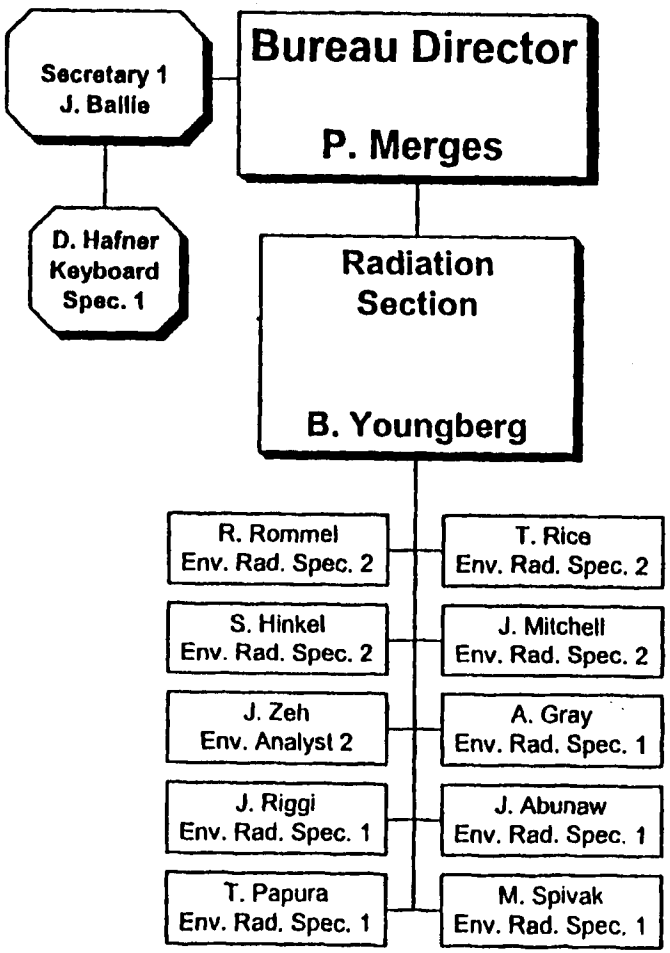
New York State Department of Environmental Conservation
Executive



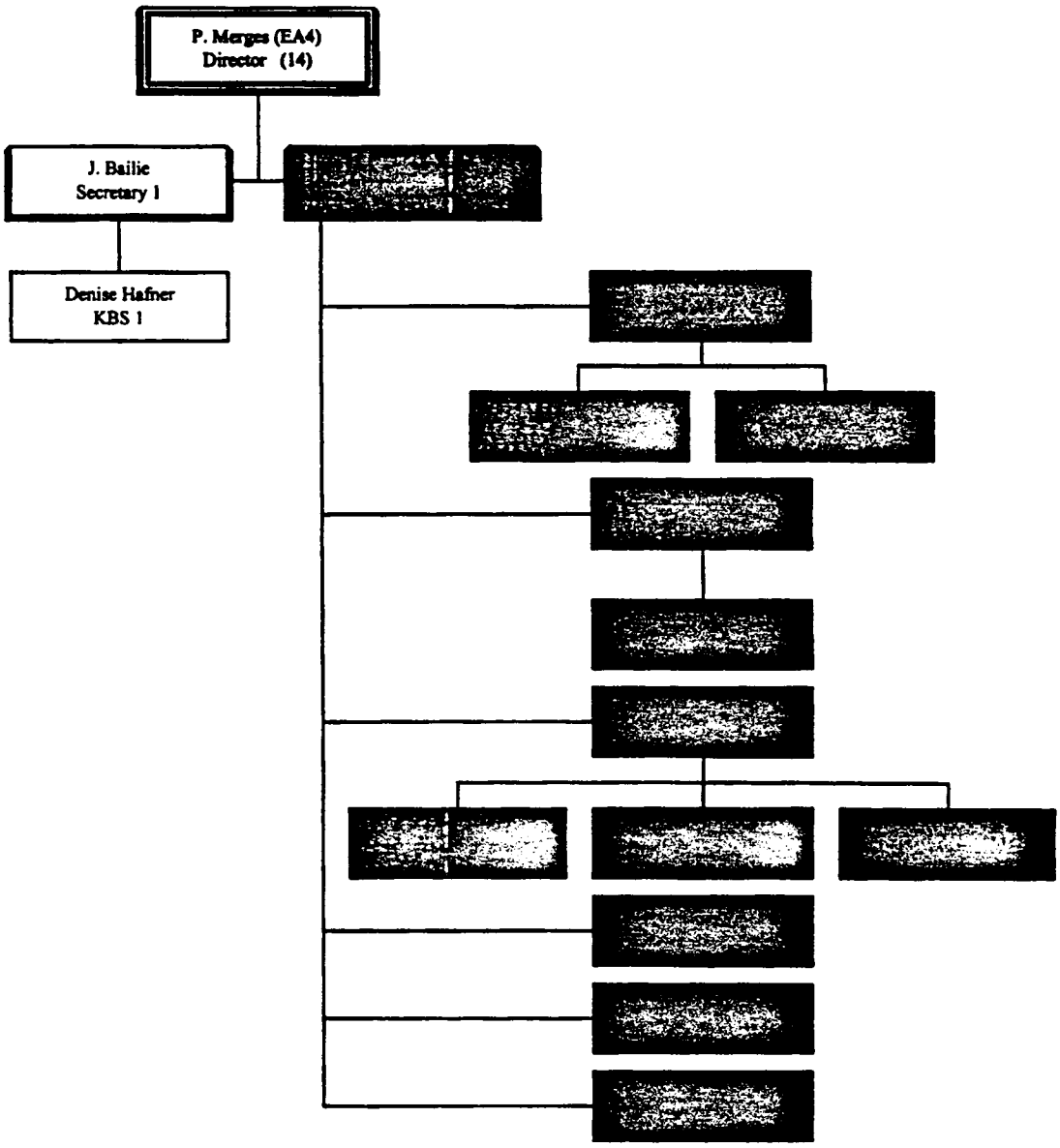
DIVISION OF SOLID & HAZARDOUS MATERIALS

BUREAU OF RADIATION

March 13, 2002



Bureau of Radiation
7/23/02



KEY:
EPS - Environmental Program Specialist
ERS - Environmental Radiation Specialist
KBS - Keyboard Specialist

ATTACHMENT 1

INCOMING RESPONSE TO DRAFT REPORT

Attachment 1-A	October 28, 2002 Electronic mail from Gene Miskin New York City Department of Health Response to Draft IMPEP Report - ML02302436
Attachment 1-B	October 24, 2002 Electronic mail from Clayton J. Bradt New York State Department of Labor Response to Draft IMPEP Report - ML023020290
Attachment 1-C	October 21, 2002 Letter from Adela Salame-Alfie New York State Department of Health Response to Draft IMPEP Report - ML023020674
Attachment 1-D	October 4, 2002 Letter from Stephen Hammond New York State Department of Environmental Conservation Response to Draft IMPEP Report - ML022910079

From: "Gene Miskin" <gmiskin@health.nyc.gov>
To: <adw@nrc.gov>
Date: 10/28/02 4:21PM
Subject: One error in Draft IMPEP for NYC

Hi. I keep trying to email Lance Rakovan with this but it doesn't seem to be getting to him. On page 20, third paragraph states our peer reviews of licensing actions are not documented. Actually, they are documented on forms signed and dated by the license reviewer and the peer reviewer and these forms are then placed into the licensing section of the license folders.

From: "Bradt, Clayton" <Clayton.Bradt@Labor.State.Ny.Us>
To: "'ljr2@nrc.gov'" <ljr2@nrc.gov>
Date: 10/24/02 4:08PM
Subject: Draft IMPEP report - comments

Lance,

NYS DOL does not wish to comment on the draft IMPEP report at this time, but reserves the right to comment later.

Thanks.

Clayton J. Bradt, CHP
Principal Radiophysicist
NYS Dept. of Labor
Radiological Health Unit
voice: (518) 457-1202
fax: (518) 485-7406
e-mail: usccjb@labor.state.ny.us

STATE OF NEW YORK
DEPARTMENT OF HEALTH

Flanigan Square, 547 River Street, Troy, New York 12180-2216

Antonia C. Novello, M.D., M.P.H., Dr.P.H.
Commissioner

Dennis P. Whalen
Executive Deputy Commissioner

October 21, 2002

Paul H. Lohaus, Director
Office of State and Tribal Programs
Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Mr. Lohaus,

As requested in your September 12, 2002 letter, attached please find New York State Department of Health comments on the draft report "Integrated Materials Performance Evaluation Program Review of New York Agreement State Program, July 15-26, 2002" dated September 12, 2002. Though we agree with the overall team's conclusion that the New York State program is adequate but needs improvement, we are concerned with the report's conclusions and tone with regard to the indicator - Incident Response. Our specific comments to the report are provided in Attachment 1.

The report is critical of our follow-up and documentation of investigations of certain incidents and gives the impression that our response to certain incidents was not sufficient. This is of particular concern, since it appears that the review team was rushed for time and may not have reviewed all available information on these incidents.

For example, on the last day of the review (late Thursday afternoon (7/25)), the principal reviewer for this indicator stated that they still had questions regarding our response to certain incidents. Staff offered to go over the incidents, the reviewer stated that they were done and were leaving. The next morning before the closeout meeting, Mr. Lynch called our office to express concern on the proposed outcome regarding that indicator (he felt there was insufficient information on incident response). Staff located the necessary files, and met with Mr. Lynch and one of the reviewers just before the IMPEP exit meeting. Unfortunately, Mr. Lynch and the reviewer only had 15 minutes to review this information. It was obvious to our staff and to the Team that some of this information (that was in the files) was missed during the review (see attached comments on each incident). Further, there are concerns raised in the draft report, such as taking enforcement action for certain incidents that were not discussed with Bureau staff during the review. We believe this could have been adequately resolved if the team had discussed this with our staff.

The goals as established in SA-105, are clearly stated – to ensure adequate response to incidents. We do not believe the team got a complete picture of our incident response. It is now apparent that these issues could have been better resolved through greater discussion between the team and staff. Tight time constraints, an unfamiliarly with our recordkeeping, loss of a team member to illness, as well as an unplanned events (power outage) also contributed to this problem.

Please note that any identifying information such as facility name and license number for any of the misadministrations must be redacted from the report as state law protects this information.

If you have any question or need additional information, please contact me.

Sincerely,

Adela Salame-Alfie, Ph.D., Director
Bureau of Environmental Radiation Protection

cc: James Lynch

Attachment I

The following comments on the draft IMPEP report are in the order in which they appear in the report:

Page 5, item 12 – "The DOH Inspection Procedures Manual was not revised to be consistent with NRC IMC 2800".

DOH Inspection Procedures Manual, page 2, section- Inspection Priorities, states: "Initial inspections of Priority 1 shall be inspected within 12 months of license issuance, within 6 months of receipt of material, or within 6 months of beginning licensed activities, whichever comes first." How is this not consistent with IMC 2800?

Page 9 - SNM licenses are listed as a separate type on our database with an inspection priority of 4. This is a carry over from a previous database adopted from another state program. We continue to use SNM as a category for tracking purposes. We have no licenses that are only SNM. All SNM is at broad scope academic licenses, which have an inspection priority of 2.

Page 9 – We list mobile NM as priority 2 (same as NRC). Our mobile NM equipment service (emphasis added) is priority 4. This is because the mobile NM equipment service is only authorized for sealed sources for calibration of equipment. Diagnostic imaging is authorized under the client license. The mobile NM equipment service license is inspected at each client facility they service during the inspection of the client's license. Which typically is more often than every 4 years.

Page 15 – "Although the inspection casework ...several incidents with a lack of depth and quality in the documented investigation results, failure to ensure appropriate and timely follow-up...". We disagree. See response below. As mentioned, the team did not review all available information on our response to the incidents reviewed. All five incidents identified in the report were evaluated upon receiving the report.

Page 18; last paragraph – For other than a trainee position, Radiological Heath Specialists positions requires at least two years experience. A masters or Doctorate degree in health physics can be substituted for one or two years of experience respectively.

Page 23 – "DOH currently does not require the submittal and/or review of financial assurance for decommissioning during new license application or renewal application reviews." This is not correct.
New license applications are almost exclusively for small private practice medical offices and occasionally a small academic program. Since financial assurance would not apply to these facilities, it is not requested as part of the license application. If an application for a large facility were submitted financial assurance would be included in the review. As was discussed with the IMPEP team, all current licenses were reviewed several years ago; we identified only 24 licensees that require financial assurance. Of these 12 are state owned facilities (universities) and 12 are private universities or medical centers. Financial assurance for private universities is covered during the license renewal. State facilities are self-insured. Financial assurance is not

contained in regulatory guidance. However we do require submittal of information on financial assurance during renewal. The Standard License Condition was amended since only a few of our licensees are required to have FA and this is covered during renewal. Therefore it is not necessary to have a generic license condition for all licensees. We did not eliminate FA from the licensing process. We eliminated it from the regulatory process as this was adequately addressed during licensing. The results of the FA study were available and offered to the team.

Page 24, 3.4.5 – "The review team recommends that NYC and DOH 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." As mentioned we already completed this evaluation and have addressed financial assurance through the licensing process for private universities. Attached is the result of our review.

Page 24, 3.4.5 "Two Agencies are not requiring licensees to submit financial assurance instruments as requires by New York regulations". There are no New York regulations for financial assurance. This is addressed through licensing and was acceptable in the last IMPEP review.

Page 26 – Regarding the report's conclusion "failure to ensure appropriate follow-up." This issue could have been better address through greater discussions with staff. We disagree with this assessment. All five incidents were evaluated and we believe appropriate follow-up was conducted. See comments on each incident.

Page 26, last two paragraphs – We agree that the documentation in the file may have been limited however there was very limited discussion of these incidents with staff. We disagree with the implications of the report.

The incident involving the loss of a single I-125 seed (~0.3mCi) was evaluated and action taken commensurate with the potential health and safety significance. The licensee promptly investigated the incident including the use of an outside consultant, reenactments, interviews with staff, dose calculations and conducting a meeting of the Radiation Safety Committee. Documentation of these actions was submitted with the report and in the file. From the licensee's investigation they determined the most likely cause of the loss was that it was disposed of with other medical waste. All medical waste is handled using universal precautions. Since the licensee's report and plan of corrective action appeared reasonable and complete and the next routine inspection was due the next month, we determined this could be investigated during that time. The routine inspection was not completed in September but was delayed until January due in part to events of September 11, 2001. However this delay was not of great significance since this did not pose a significant health and safety threat.

We did review the report of the misadministration involving I-125 and discussed this with the licensee. This incident occurred because the dosimeterist misinterpreted the Authorized User's written order. Contributing factors were that they did not follow normal protocol for this procedure (they did the treatment plan during set up in the OR rather than doing a pre plan) and were rushed and the AU did not properly review the treatment plan. This was clearly documented in the licensees' report including their plan of corrective action. This was discussed

with Bureau staff including Dr. Kirshmorthy, DABMP (therapeutic medical physics) and it was determined that little additional information will be obtained by conducting an on-site investigation. In order to maximize staff resources it was determined that the licensees' response would be evaluated at the next routine inspection. We realize that our actions were not clearly documented and further complicating the issue was an e-mail note indicating that we may possibly conduct an on-site investigation. However this incident was appropriately handled.

The report of detection of Cs-137 contamination in piping (2x background) was discussed at length with the licensee (Cornell University). Cornell radiation safety staff conduct an immediate investigation and determined that the contamination was from experiments conducted years ago involving the use of soluble Cs-137 in milk as part of a fall-out study. Cornell has an excellent inspection history as well as experienced and competent radiation safety staff and an active Radiation Safety Committee. Because this incident involved low activities and Cornell was actively investigating this incident an immediate investigation was not conducted but to be reviewed later in the year during the routine inspection.

The misadministration involving Ir-192 was investigated including how and why the misadministration occurred. The investigation did not fail to adequately address significant issues (see comments below). The licensee did not fail to promptly respond to the incident – the RSO was there within 1.5 hours however the AU did not respond until the next morning. We believe the IMPEP reviewer missed some important documentation that may have been in the license file and not in the incident file.

Page 27. "DOH did not take enforcement action in any of the cases reviewed." Enforcement action was not taken as no violations of law, regulation or license condition occurred. If the team believe there was a basis for an enforcement action it did not discuss this with staff.

Page 31 – "DOH has neither drafted nor adopted:" - These regulations were drafted and proposed for adoption. See attached notice in NYS Register.

Page 39. Recommendations: #6 - as mentioned this has already been done (see attachment).
Page 40. Recommendation: #7 – We disagree with the assertion that we do not currently conduct prompt, in-depth reviews of events. Particularly those with potential for significant health and safety consequences. We agree our documentation needs to be better.

Page E.6 File No.: 1
ALL IDENTIFIERS MUST BE REOMVED AS THIS INFORMATION IS PROTECTED BY STATE LAW.
The following should be noted: This case involved the use of a Syed applicator (template and applicators or "needles"). At total of twelve applicator "needles" were used. The applicator was placed in surgery and followed by the insertion of 12 ribbons containing Ir-192 seeds into the needles. The needles are secured to the template with a portion of the needle extending beyond (outside) the template. During the night the woman climbed over the bed railing and fell on the floor. At which time the nurses responded. The RSO responded and secured one needle that was discovered on the floor. The next morning the Oncologist examined the woman and decided to terminate treatment. During his examination he carefully noted the position of the ends of the

needles with respect to the template and noted that the 11 remaining needles were in the proper position although one needle was observed loose and he removed it. The needles were observed bent –meaning the outside portion of the needle (not where the Ir-192 seeds were located). There was no indication that the sources inside the patient were dislocated. However given the condition of the needles the physician decided to terminate treatment. This is how they determined that only 33% of the original intended dose was delivered. It should also be noted that this incident was investigated by the Department's Bureau of Hospital Services which includes a review of quality of care issues.
Comment a) - This was a reportable event under Part 405 of Department regulations and was investigated. This did not constitute a misadministration as it was the Authorized User's decision to terminate treatment.
b) The medical staff involved in this incident had personnel monitoring devices. During our follow-up review the results of the personnel monitoring records for those individuals was reviewed and showed that no one received a significant dose. However copies of the personnel monitoring records may not have been in the incident file for review by the IMPEP reviewer.
c) The sources (Ir-192 seeds in nylon ribbons) were not damaged however the applicators "needles" were bent outside the template.

Page E.7 File No. 2
ALL IDENTIFIERS MUST BE REMOVED AS THIS INFORMATION IS PROTECTED BY STATE LAW.

Summary: There was no enforcement action taken since there was no violation cited. What violation has occurred?

Page E.8., File No. 4
Summary – DOH chose to investigate the incident at the next routine inspection scheduled for the next month. An enforcement action was not warranted in this case. If the IMPEP team felt that an enforcement action was necessary they should have discussed this with Bureau staff.

Page E.8., file No. 5
ALL IDENTIFIERS MUST BE REMOVED AS STATE LAW PROTECTS THIS INFORMATION.
See comments regarding Page 26 (above) on this case.

New York State Department of Environmental Conservation
Division of Solid and Hazardous Materials, 9th Floor
625 Broadway, Albany, New York 12233-7250
Phone: (518) 402-8651 • **FAX:** (518) 402-9024
Website: www.dec.state.ny.us

Erin M. Crotty
Commissioner

OCT - 4 2002

02 OCT 17 PM 5:06

STP

Mr. Paul H. Lohaus
Director
Office of State and Tribal Programs
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Mr. Lohaus:

This responds to your September 12 letter regarding the Agreement State review conducted in July under United States Nuclear Regulatory Commission's (NRC) Integrated Materials Performance Evaluation Program (IMPEP). With your letter, you provided a copy of the draft IMPEP report for our review.

We have reviewed the draft report. We appreciate the IMPEP team's comments on the high quality of our staff's technical reviews and inspections. With regard to the proposed recommendations, we recognize the opportunities for improving our program. We will address each recommendation specifically, when we receive the final report. In general, we expect to work toward implementing them, as our funding and staffing levels permit.

There is one correction needed in the report. In Section 4.3, describing the Low-Level Radioactive Waste Disposal Program, the second paragraph on page 36 refers to "waste package receipt and inspection and temporary storage of waste prior to emplacement in the waste disposal units." That sentence should be deleted, as waste disposal operations at West Valley ceased in the mid-1970s.

The staff of our radiation program reported that the IMPEP team conducted a thorough review. We thank the team for its efforts and the NRC for the opportunity to review the draft report. Thank you, too, for the offer to provide travel to the Management Review Board meeting.

Sincerely,

for Stephen Hammond, P.E.
Director
Division of Solid & Hazardous Materials

cc: R. Trannontano, NYSDOH
R. Cucolo, NYSDOL
J. Prud'homme, NYCDOH
J. Spath, NYSERDA

ATTACHMENT 2

New York State Department of Health Response to Draft IMPEP Report;
Resolution of Comments Document - ML023026072

New York State Department of Health Response to Draft IMPEP Report
Resolution of Comments Document

Comment 1
Page 5, item 12 – "The DOH Inspection Procedures Manual was not revised to be consistent with NRC IMC 2800".

DOH Inspection Procedures Manual, page 2, section- Inspection Priorities, states: "Initial inspections of Priority 1 shall be inspected within 12 months of license issuance, within 6 months of receipt of material, or within 6 months of beginning licensed activities, whichever comes first." How is this not consistent with IMC 2800?

Response
The above states that "initial inspections of *Priority 1* licensees shall be inspected within 12 months..." (emphasis added). Initial inspections of *all* licensees should be performed within the timeframes quoted above, and not just Priority 1 licensees. The report will be revised to reflect that DOH amended their manual regarding initial inspections of Priority 1 licensees.

Comment 2
Page 9 - SNM licenses are listed as a separate type on our database with an inspection priority of 4. This is a carry over from a previous database adopted from another state program. We continue to use SNM as a category for tracking purposes. We have no licenses that are only SNM. All SNM is at broad scope academic licenses, which have an inspection priority of 2.

Response
The review team believes that the language in the report generally reflects this policy. The report will be amended, however, to reflect that all SNM is possessed under broad scope academic licenses, which have an inspection Priority 2.

Comment 3
Page 9 – We list mobile NM as priority 2 (same as NRC). Our mobile NM equipment service (emphasis added) is priority 4. This is because the mobile NM equipment service is only authorized for sealed sources for calibration of equipment. Diagnostic imaging is authorized under the client license. The mobile NM equipment service license is inspected at each client facility they service during the inspection of the client's license. Which typically is more often than every 4 years.

Response
The review team agrees with this comment. The language involving this difference in inspection priority will be removed from the report.

Comment 4
Page 15 – "Although the inspection casework ...several incidents with a lack of depth and quality in the documented investigation results, failure to ensure appropriate and

timely follow-up...". We disagree. See response below. As mentioned, the team did not review all available information on our response to the incidents reviewed. All five incidents identified in the report were evaluated upon receiving the report.

Response
Incident response is addressed in Section 3.5. This paragraph will be removed.

Comment 5
Page 18; last paragraph – For other than a trainee position, Radiological Heath Specialists positions requires at least two years experience. A masters or Doctorate degree in health physics can be substituted for one or two years of experience respectively.

Response
The review team agrees with this comment. The language in the report will be clarified to reflect the requirements for a Radiological Health Specialist.

Comment 6
Page 23 – "DOH currently does not require the submittal and/or review of financial assurance for decommissioning during new license application or renewal application reviews." This is not correct.

New license applications are almost exclusively for small private practice medical offices and occasionally a small academic program. Since financial assurance would not apply to these facilities, it is not requested as part of the license application. If an application for a large facility were submitted financial assurance would be included in the review. As was discussed with the IMPEP team, all current licenses were reviewed several years ago; we identified only 24 licensees that require financial assurance. Of these 12 are state owned facilities (universities) and 12 are private universities or medical centers. Financial assurance for private universities is covered during the license renewal. State facilities are self-insured. Financial assurance is not contained in regulatory guidance. However we do require submittal of information on financial assurance during renewal. The Standard License Condition was amended since only a few of our licensees are required to have FA and this is covered during renewal. Therefore it is not necessary to have a generic license condition for all licensees. We did not eliminate FA from the licensing process. We eliminated it from the regulatory process as this was adequately addressed during licensing. The results of the FA study were available and offered to the team.

Response
The review team agrees with this comment. The report will be changed to reflect that: (1) financial assurance for decommissioning is required for private universities during the initial application or renewal process; (2) public institutions do not require financial assurance for decommissioning; and (3) these state institutions are self-insured.

Comment 7
Page 24, 3.4.5 – "The review team recommends that NYC and DOH 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." As mentioned we already completed this evaluation and have addressed financial assurance through the licensing process for private universities. Attached is the result of our review.

Response
See response to Comment 6.

Comment 8
Page 24, 3.4.5 "Two Agencies are not requiring licensees to submit financial assurance instruments as requires by New York regulations". There are no New York regulations for financial assurance. This is addressed through licensing and was acceptable in the last IMPEP review.

Response
See response to Comment 6.

Comment 9
Page 26 – Regarding the report's conclusion "failure to ensure appropriate follow-up." This issue could have been better address through greater discussions with staff. We disagree with this assessment. All five incidents were evaluated and we believe appropriate follow-up was conducted. See comments on each incident.

Comment 10
Page 26, last two paragraphs – We agree that the documentation in the file may have been limited however there was very limited discussion of these incidents with staff. We disagree with the implications of the report.

The incident involving the loss of a single I-125 seed (~0.3mCi) was evaluated and action taken commensurate with the potential health and safety significance. The licensee promptly investigated the incident including the use of an outside consultant, reenactments, interviews with staff, dose calculations and conducting a meeting of the Radiation Safety Committee. Documentation of these actions was submitted with the report and in the file. From the licensee's investigation they determined the most likely cause of the loss was that it was disposed of with other medical waste. All medical waste is handled using universal precautions. Since the licensee's report and plan of corrective action appeared reasonable and complete and the next routine inspection was due the next month, we determined this could be investigated during that time. The routine inspection was not completed in September but was delayed until January due in part to events of September 11, 2001. However this delay was not of great significance since this did not pose a significant health and safety threat.

We did review the report of the misadministration involving I-125 and discussed this with the licensee. This incident occurred because the dosimeterist misinterpreted the Authorized User's written order. Contributing factors were that they did not follow normal protocol for this procedure (they did the treatment plan during set up in the OR rather than doing a pre plan) and were rushed and the AU did not properly review the treatment plan. This was clearly documented in the licensees' report including their plan of corrective action. This was discussed with Bureau staff including Dr. Kirshmorthy, DABMP (therapeutic medical physics) and it was determined that little additional information will be obtained by conducting an on-site investigation. In order to maximize staff resources it was determined that the licensees' response would be evaluated at the next routine inspection. We realize that our actions were not clearly documented and further complicating the issue was an e-mail note indicating that we may possibly conduct an on-site investigation. However this incident was appropriately handled.

The report of detection of Cs-137 contamination in piping (2x background) was discussed at length with the licensee (Cornell University). Cornell radiation safety staff conduct an immediate investigation and determined that the contamination was from experiments conducted years ago involving the use of soluble Cs-137 in milk as part of a fall-out study. Cornell has an excellent inspection history as well as experienced and competent radiation safety staff and an active Radiation Safety Committee. Because this incident involved low activities and Cornell was actively investigating this incident an immediate investigation was not conducted but to be reviewed later in the year during the routine inspection.

The misadministration involving Ir-192 was investigated including how and why the misadministration occurred. The investigation did not fail to adequately address significant issues (see comments below). The licensee did not fail to promptly respond to the incident – the RSO was there within 1.5 hours however the AU did not respond until the next morning. We believe the IMPEP reviewer missed some important documentation that may have been in the license file and not in the incident file.

Response

Although discussion time was limited during the on-site review, the review team believes that there was sufficient time to adequately assess this indicator. Even though DOH has provided additional information in their response to the draft report, the review team believes that the report accurately portrays the performance of DOH in responding to incidents. There will be no change to the report due to this comment and the review team is prepared to discuss these issues at the November 5, 2002 MRB meeting.

Comment 11

Page 27. "DOH did not take enforcement action in any of the cases reviewed." Enforcement action was not taken as no violations of law, regulation or license condition occurred. If the team believe there was a basis for an enforcement action it did not discuss this with staff.

Response
The team agrees with this comment. This sentence will be deleted from the report.

Comment 12
Page 31 – "DOH has neither drafted nor adopted:" - These regulations were drafted and proposed for adoption. See attached notice in NYS Register.

Response
The review team agrees with this comment. The language will be revised to state "DOH has drafted, but has not yet adopted..."

Comment 13
Page 39. Recommendations: #6 - as mentioned this has already been done (see attachment).

Response
The team agrees with this comment. DOH has been removed from the recommendation.

Comment 14
Page 40. Recommendation: #7 – We disagree with the assertion that we do not currently conduct prompt, in-depth reviews of events. Particularly those with potential for significant health and safety consequences. We agree our documentation needs to be better.

Response
See response to Comments 9 and 10.

Comment 15
Page E.6 File No.: 1
ALL IDENTIFIERS MUST BE REMOVED AS THIS INFORMATION IS PROTECTED BY STATE LAW.

Response:
All identifiers will be removed from the report.

Comment 16
The following should be noted: This case involved the use of a Syed applicator (template and applicators or "needles"). At total of twelve applicator "needles" were used. The applicator was placed in surgery and followed by the insertion of 12 ribbons containing Ir-192 seeds into the needles. The needles are secured to the template with a portion of the needle extending beyond (outside) the template. During the night the woman climbed over the bed railing and fell on the floor. At which time the nurses responded. The RSO responded and secured one needle that was discovered on the floor. The next morning the Oncologist examined the woman and decided to terminate treatment.

During his examination he carefully noted the position of the ends of the needles with respect to the template and noted that the 11 remaining needles were in the proper position although one needle was observed loose and he removed it.

The needles were observed bent –meaning the outside portion of the needle (not where the Ir-192 seeds were located). There was no indication that the sources inside the patient were dislocated. However given the condition of the needles the physician decided to terminate treatment. This is how they determined that only 33% of the original intended dose was delivered. It should also be noted that this incident was investigated by the Department's Bureau of Hospital Services which includes a review of quality of care issues.
Comment a) - This was a reportable event under Part 405 of Department regulations and was investigated. This did not constitute a misadministration as it was the Authorized User's decision to terminate treatment.

b) The medical staff involved in this incident had personnel monitoring devices. During our follow-up review the results of the personnel monitoring records for those individuals was reviewed and showed that no one received a significant dose. However copies of the personnel monitoring records may not have been in the incident file for review by the IMPEP reviewer.

c) The sources (Ir-192 seeds in nylon ribbons) were not damaged however the applicators "needles" were bent outside the template.

Response
See response to Comments 9 and 10.

Comment 17
Page E.7 File No. 2
ALL IDENTIFIERS MUST BE REMOVED AS THIS INFORMATION IS PROTECTED BY STATE LAW.

Response:
All identifiers will be removed from the report.

Comment 18
Summary: There was no enforcement action taken since there was no violation cited. What violation has occurred?

Response
The review team agrees with this comment. The language involving enforcement will be removed from the report.

Comment 19
Page E.8., File No. 4
Summary – DOH chose to investigate the incident at the next routine inspection scheduled for the next month. An enforcement action was not warranted in this case. If the IMPEP team felt that an enforcement action was necessary they should have discussed this with Bureau staff.

Response
See response to Comments 9 and 10.

Comment 20
Page E.8., file No. 5
ALL IDENTIFIERS MUST BE REMOVED AS STATE LAW PROTECTS THIS INFORMATION.

Response:
All identifiers will be removed from the report.

Comment 21
See comments regarding Page 26 (above) on this case.

Response
See response to Comments 9 and 10.

10/28/2002