

DATED: NOVEMBER 30, 1998

SIGNED BY: HUGH L. THOMPSON, JR.

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New York, NY 10013

Mr. James J. McGowan
Commissioner
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Barbara A. DeBuono, M.D., M.P.H.
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Empire State Plaza
Albany, NY 12233

Mr. John P. Cahill
Commissioner
Department of Environmental Conservation
50 Wolf Road
Albany, NY 12233

Dear Commissioners:

On September 1, 1998, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the New York Department of Labor program that implements a portion of the Agreement with the State of New York. The other three programs, the New York City Department of Health (NYCH), New York State Department of Health (NYSH), and New York State Department of Environmental Conservation (NYDEC), as well as the New York State Energy Research and Development Authority (NYSERDA), listened in by telephone during this meeting. The MRB made a finding that the New York program is adequate to protect public health and safety and compatible with NRC's program. The revised final report is enclosed.

The MRB directed the review team to assess the apparent discrepancy between NYCH and NYDEC's ratings for the common performance indicator, Technical Staffing and Training. In response, the team has revised NYCH's rating for this indicator to "satisfactory." This matter was presented to the MRB for final resolution at the September 1, 1998 MRB meeting and the MRB agreed with the change. The MRB also directed the team to clarify the recommendations on the reporting of incidents and events to the NRC. The revised recommendation was presented at the September 1, 1998 MRB meeting and the MRB agreed with the revised recommendation. The MRB requested that Section 4.2, Sealed Source and Device Evaluation Program, be revised prior to the MRB making a decision on the rating for this indicator. The review team revised the Section and submitted it to the MRB which agreed with the team's finding of Satisfactory with Recommendations for Improvement. The revised Section was sent to New York for comment. Ms. R. Aldrich's comments on the revised Section and the review team's response to the comments are attached to the revised final report.

Section 5, page 44, of the enclosed revised final report presents the IMPEP team's suggestions, recommendations, and good practices. We request your evaluation and response to the recommendations within 30 days from the receipt of the revised final report. NYSH's letter dated August 17, 1998 fully responded to the recommendation for NYSH in the report and no further response is needed from NYSH.

The review team recommended that there be a follow-up review of the New York City Department of Health program in approximately one year with a full State review in four years. The NRC staff will be contacting New York City staff to make arrangements for the follow-up review.

I appreciate the courtesy and cooperation extended to the IMPEP teams during the reviews and your support of the respective New York programs. I look forward to our agencies continuing to work cooperatively in the future.

Sincerely, */RA/*

Hugh L. Thompson, Jr.
Deputy Executive Director
for Regulatory Programs

Enclosures:
As stated

cc: Gene Miskin, Director
Bureau of Radiological Health, NYCH

Rita Aldrich, Principal Radiophysicist
Radiological Health Unit, NYDL

Karim Rimawi, Ph.D., Director
Bureau of Environmental Radiation Protection, NYSH

Paul J. Merges, Ph.D., Chief
Bureau of Pesticides and Radiation, NYDEC

John P. Spath, Director
Radioactive Waste Policy and Nuclear Coordination, NYSERDA

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John P. Spath, Director
Radioactive Waste Policy and Nuclear Coordination, NYSERDA

bcc: Chairman Jackson
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF NEW YORK AGREEMENT STATE PROGRAM

January 26 - April 24, 1998

REVISED 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 New York program is divided into four independent programs which were reviewed separately with the results of those reviews integrated into this report. The reviews were conducted during the period January 26 - April 24, 1998, by four separate review teams comprised of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement States of Alabama, Florida, North Carolina, and Tennessee. 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 25, 1997, revised NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period March 31, 1995 to April 24, 1998, were discussed with New York management on May 12, 1998.

A draft of this report was issued to all four programs in the State of New York for factual comment on June 24, 1998. The programs responded in letters dated July 15, 1998 by NYCH; July 27, 1998 by NYDL; July 20, 1998 by NYSH; and July 24, 1998 by NYDEC. The programs' comments were considered by the team and accommodated in the report. On August 18, 1998, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on three of the four programs that implement the Agreement with the State of New York. The three programs represented at the MRB meeting were the New York City Department of Health (NYCH), New York State Department of Health (NYSH), and New York State Department of Environmental Conservation (NYDEC). The MRB made a preliminary finding that the New York program is adequate to protect public health and safety and compatible with NRC's program.

On September 1, 1998, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the New York Department of Labor program that implements a portion of the Agreement with the State of New York. The other three programs, the New York City Department of Health (NYCH), New York State Department of Health (NYSH), and New York State Department of Environmental Conservation (NYDEC), as well as the New York State Energy Research and Development Authority (NYSERDA), listened in by telephone during this meeting. The MRB made a finding that the New York program is adequate to protect public health and safety and compatible with NRC's program.

The MRB directed the review team to revise NYCH's rating for the common performance indicator, Status of the Materials Inspection Program, from "unsatisfactory" to "satisfactory with recommendations for improvement" based on their actions taken to correct their licensee database. The review team was directed to assess the apparent discrepancy between NYCH and NYDEC's ratings for the common performance indicator, Technical Staffing and Training. In response, the team has revised NYCH's rating for this indicator to "satisfactory." This matter was presented to the MRB for final resolution at the September 1, 1998 MRB meeting and the MRB agreed with the change. The MRB also directed the team to clarify the recommendations on the reporting of incidents and events to the NRC. The revised recommendation was presented at the September 1, 1998 MRB meeting and the MRB agreed with the revised recommendation.

The MRB requested that Section 4.2, Sealed Source and Device Evaluation Program, be revised prior to the MRB making a decision on the rating for this indicator. The review team revised the

Section and submitted it to the MRB which agreed with the team's finding of Satisfactory with Recommendations for Improvement. The revised Section was sent to New York for comment. Ms. R. Aldrich's comments on the revised Section and the review team's response to the comments are attached to the revised final report.

The New York Agreement State program is administered by: (1) the New York City Department of Health, Bureau of Radiological Health (NYCH), 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 (NYDL), which has jurisdiction over commercial and industrial uses of radioactive materials, including the possession of radioactive material to be disposed of at a commercial disposal site; (3) the New York State Department of Health (NYSH), which has jurisdiction over medical, academic, and research uses of radioactive materials except in New York City; and (4) the New York State Department of Environmental Conservation, Bureau of Pesticides and Radiation (NYDEC), 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 1500 specific licenses, including all types of major licensees except for uranium mill tailings.

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

In preparation for the review, a questionnaire addressing the common and non-common performance indicators was sent to: (1) NYCH, November 21, 1997; (2) NYDL, December 15, 1997; (3) NYSH, February 6, 1998; and (4) NYDEC, February 12, 1998. Each New York program provided a response to the questionnaire on: (1) NYCH, January 14, 1998; (2) NYDL, January 27, 1998; (3) NYSH, March 13, 1998; and (4) NYDEC, March 27, 1998. During the review, discussions with each program's staff resulted in the responses being further developed. A copy of these final responses are included in Appendix G to the proposed final report issued August 7, 1998.

The teams' general approach for conduct of these reviews consisted of: (1) examination of New York programs' responses to the questionnaire; (2) review of applicable New York State and City statutes and regulations; (3) analysis of quantitative information from the radiation control programs' licensing and inspection data bases; (4) technical review of selected licensing and inspection actions; (5) field accompaniments of at least one inspector from each program; and (6) interviews with staff and management to answer questions or clarify issues. The teams evaluated the information that they gathered against the IMPEP performance criteria for each common and non-common performance indicator as applicable to each program and made a preliminary assessment of each radiation control program's performance for each indicator.

Section 2 below discusses each programs's actions in response to recommendations made following the previous 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 and recommendations. Recommendations made by the team are comments that relate directly to each program's performance. A response is requested from each program to all recommendations in the revised final report. Suggestions are comments that the team believes

could enhance each of the individual programs. Each program is requested to consider suggestions, but no response is requested.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous routine review, which concluded on March 30, 1995, ten recommendations were made and the results were transmitted to the respective Secretaries/Commissioners of the three New York State agencies and the New York City agency on March 18, 1996. The team's review of the current status of these recommendations is as follows:

NEW YORK CITY DEPARTMENT OF HEALTH (NYCH)

- (1) Status and Compatibility of Regulations. NYCH needed to revise its QM rule definitions by December 6, 1996 in order to maintain compatibility with the NRC.

Current Status: The NRC reinitiated an evaluation of whether the QM rule should be used as a basis for the determination of an Agreement State program's compatibility. It was decided that pending the completion of the re-evaluation, the absence of a compatible QM rule would not be used as a basis for withholding of a finding for compatibility. The compatibility category of the QM rule under the new Commission policy on Adequacy and Compatibility, which became effective on September 6, 1997, has been set as "D" with paragraphs (a), (b), and (c) of the rule identified as having provisions important to Health and Safety. Based on the above, and because Part 35 is being amended in its entirety, the team determined that this recommendation should be closed.

- (2) Inspection Procedures. It was recommended that NYCH develop a formal written policy on conducting unannounced inspections.

Current Status: As part of the review of the indicator "Technical Quality of Inspections" (see Section 3.2.1), the team examined NYCH's inspection procedures manual. In Section 5.C.3.a. of the manual, there is a discussion regarding NYCH's policy regarding announced versus unannounced inspections. This section of the manual clearly states it is the general policy of NYCH to perform routine inspections on an unannounced basis. The review team also determined that NYCH inspectors were following the City's policy regarding the conduct of routine inspections on an unannounced basis. Based on these findings, the team determined that this recommendation should be closed.

NEW YORK STATE DEPARTMENT OF LABOR (NYDL)

- (1) Status and Compatibility of Regulations. It was recommended during the last review that NYDL reconsider its decision not to adopt the amendments to 10 CFR Part 36, "Licenses and Radiation Safety Requirements for Irradiators" that became effective on July 1, 1993.

Current Status: During this review, the team determined that NYDL has prepared a package of regulations, including those for Part 36, which is currently in legal review (see Section 4.1.2.2). As part of the team's review of the indicators "Technical Quality of Licensing" and "Technical Quality of Inspections," the team noted that NYDL was implementing the requirements of Part 36 through the use of checklists during the licensing and inspection of the only commercial irradiator facility under NYDL's jurisdiction. Use of the checklist ensures that the licensee has committed to all the requirements in 10 CFR Part 36 even though not required to by regulation. The licensee's commitments are incorporated into the licenses. Based on the team's finding that NYDL is implementing Part 36 through licensing and inspection until the adoption of the rule, the team determined that this recommendation should be closed.

NEW YORK STATE DEPARTMENT OF HEALTH (NYSH)

- (1) Status and Compatibility of Regulations.
- a. It was recommended that NYSH adopt the Decommissioning Rule as soon as possible to maintain compatibility with the NRC.

Current Status: The NYSH has implemented the rule through license conditions. The team reviewed the list of licensees that are subject to the financial assurance requirements and reviewed the application of these license conditions. The team found that the licensees requiring financial assurance either had license conditions in place or had been issued letters requesting additional information prior to issuance of license conditions. The NYSH also implements other decommissioning provisions through regulations and other decommissioning license conditions (see Section 4.1.2.2). The team considers this approach to implementing the financial assurance and decommissioning requirements to be acceptable, and determined that this recommendation should be closed.

- b. The NYSH needed to revise its QM rule definitions by December 6, 1996 in order to maintain compatibility with the NRC.

Current Status: The NRC reinitiated an evaluation of whether the QM rule should be used as a basis for the determination of an Agreement State program's compatibility. It was decided that, pending the completion of the re-evaluation, the absence of a compatible QM rule would not be used as a basis for withholding of a finding for compatibility. The compatibility category of the QM rule under the new Commission policy on Adequacy and Compatibility, which became effective on September 6, 1997, has been set as "D" with paragraphs (a), (b), and (c) of the rule identified as having provisions important to Health and Safety. Based on the above, and because Part 35 is being amended in its entirety, the team determined that this recommendation should be closed.

- c. The NYSH should perform a review of its licensees based on the requirements of the emergency planning (EP) rule, document the review, and if any licensees meet the requirements of the rule, incorporate applicable section of the rule into licenses until the rule can be promulgated.

Current Status: The team reviewed NYSH's evaluation of its licensees against the requirements of the EP rule and concurred with NYSH's conclusion that the possession limits of all licensees were below that requiring an EP plan. The team determined that this recommendation should be closed.

- (2) Responses to Incidents and Allegations. It was recommended that NYSH perform timely and on-site investigations to independently assess allegations based on health and safety considerations; develop criteria to determine which allegations can be referred to licensees; assess licensee's evaluation of allegations; and maintain complete files.

Current Status: During the review of the common indicator "Response to Incidents and Allegations" (see Section 3.5.3), the team evaluated NYSH's response to these recommendations. Based on the findings detailed in Section 3.5.3 of this report, the team determined that this recommendation should be closed.

NEW YORK STATE DEPARTMENT OF ENVIRONMENTAL CONSERVATION (NYDEC)

- (1) Technical Quality of Licensing Actions. It was recommended that NYDEC expeditiously complete the inspection of NYCH licensees to determine if any were subject to NYDEC permitting requirements.

Current Status: The team evaluated NYDEC's response to this recommendation during its review of the common indicators "Technical Quality of Licensing" and "Technical Quality of Inspections." The team concluded that NYDEC staff took prompt action to identify those NYCH licensees requiring NYDEC permits. Periodic memoranda to NYDEC management documenting the progress of this evaluation were prepared by staff. Based on the team's findings during this review, the team determined that this recommendation should be closed.

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 team focused on four factors in reviewing this indicator: inspection frequency, overdue inspections, initial inspection of new licenses, and timely dispatch of inspection findings to licensees. This 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 managers and staff.

3.1.1 New York City Department of Health (NYCH) - Status of Materials Inspection Program

NYCH's inspection priority system closely matches NRC's system. The team's assessment of the current inspection priorities verified that inspection frequencies for various types or groups of licensees are equivalent to or more frequent than those listed in NRC Inspection Manual Chapter 2800 (IMC 2800) frequency schedule. In reviewing NYCH's priority schedule, the team noted that NYCH continues to have priority categories which are inspected more frequently than those of the NRC. The NYCH has only five categories of licensees, with a total of three priorities. The NYCH priorities are either Priority 1 for once every 12 months, Priority 2 for once every 24 months, or Priority 3 for once every 36 months.

In their response to the questionnaire, NYCH indicated that as of January 1998, six licenses identified as core inspections in IMC 2800 were overdue by more than 25 percent of NRC's frequency. The NYCH's current inspection schedule identified 21 Priority 1 licenses; however, the team discovered that the software-based system did not identify approximately 19 additional Priority 1 licenses for inspection purposes. Tracking of those, five were overdue at the time of the review and were not scheduled for inspection. Overall, NYCH's inspection scheduling system tracked only 243 of the 440 active licenses. The team estimates that NYCH would need to perform approximately 220 inspections each year in order to keep pace with its due inspections (the estimate assumes that all Priority 1 licenses, one-half of all Priority 2 licenses, and one-third of all Priority 3 licenses were inspected each year). Each year of the review period, NYCH budgeted approximately 266 inspections for completion. In fiscal years (July to June) 1995, 1996 and 1997, NYCH completed 127, 263, and 154 inspections, respectively. Due to difficulties in obtaining information from NYCH's inspection tracking system, the true status of the materials inspection program could not be accurately assessed.

Since there was not an adequate database to evaluate the status of inspections, the team did a sampling by examining the inspection histories of 25 out of the 40 total NYCH Priority 1 licenses. Since the last review, 33 inspections of those licenses have been completed. Of those inspections (33 percent), 19 inspections (58 percent) were overdue based on NYCH's priority at the time that the NYCH conducted them; however, only 11 inspections were overdue (33 percent) based on IMC 2800 priorities (8 of the 19 were teletherapy). The review team recommends that the NYCH correct the software anomalies that limit NYCH's ability to effectively track licenses for inspection, set and adhere to yearly inspection goals, and communicate NYCH management's expectations with regard to inspection goals, such that NYCH is able to eliminate all overdue inspections.

With respect to initial inspections of new licenses, the team reviewed the inspection tracking system and found that initial inspections were usually entered into the system together with existing licenses. The NYCH's inspection supervisor assigns all inspections, and is able to identify new licenses by the license number. NYCH currently has a six month inspection frequency for all initial inspections, which is consistent with NRC's initial inspection requirement in IMC 2800.

From the review of the inspection database and examination of license files, NYCH was not consistently implementing its six month initial inspection policy. The team examined 22 new licenses issued since February 1995. Of those new licenses, NYCH conducted initial inspections

within six months of issuance for nine licenses (41%). The inspections that did not meet the six month inspection goal ranged from 8 to 22 months after the licenses were issued. The review team recommends that all initial inspections of licensees be performed within six months of license issuance or within six months of the licensee's receipt of material and commencement of operations, consistent with IMC 2800 and NYCH policy.

The timeliness of the issuance of inspection findings was also evaluated during the inspection file review. Of the 15 files examined, in 11 cases the inspection correspondence was sent to the licensee within 30 days of the inspection date. Correspondence from three of the remaining inspections was sent between 32 and 39 days. In the fourth case, Brooklyn Hospital Center, License No. 91-2924-01, NYCH completed its inspection on June 21, 1996, but did not transmit the inspection findings until November 1, 1996 (134 days).

Based on the sampling done by the team, it appears that NYCH is not conducting its inspection program for core licensees in accordance with IMC 2800. The lack of an adequate tracking system significantly contributed to this finding which was presented at the exit meeting with NYCH on January 30, 1998. In response to the teams's findings presented at the exit meeting on January 30, 1998, Mr. Kenneth R. Daniel, Jr., Deputy Director, Bureau of Radiological Health, Department of Health, submitted a letter dated February 17, 1998 (Attachment 1), providing additional information regarding this indicator. The letter indicated that the software anomaly had been corrected and that NYCH was able to effectively track all of its licenses for inspection. The team's review of the inspection due list for the following 12 months ending in February 1999 appeared to indicate that all licenses were now captured in the scheduling system. However, the team could not reconcile the inspection dates in the updated list with the last known inspection dates identified during the review. Through further discussions with NYCH, some of these discrepancies have been cleared up; however, the database needs additional quality control that will occur over time with the use of the database. The NYCH's February 17, 1998, letter did not address the team's findings with regard to the conduct of initial inspections. The NYCH will need to continue to address the tracking, the timely scheduling and completion of inspections for all current licenses, and initial inspections for new licenses.

Based on the IMPEP evaluation criteria, the review team initially recommended that NYCH's performance with respect to the indicator, Status of the Materials Inspection Program, be found unsatisfactory. Based on the actions taken by NYCH since the review to correct their database and schedule inspections to meet the criteria, the MRB directed that NYCH's performance with respect to this indicator be changed to satisfactory with recommendations for improvement.

3.1.2 New York State Department of Labor (NYDL) - Status Materials of Inspection Program

The team's review verified that NYDL's inspection priorities are at least as frequent as similar license types or groups listed in NRC IMC 2800. Of particular note is the greater number of inspections completed by NYDL choosing to designate its 110 Moisture/Density Gauge licenses as inspection Priority 2, while the NRC frequency for a similar licensee is Priority 5. Designating such a large number of licensees under such a high priority requires NYDL to perform more frequent inspections of such licensees, while allowing some flexibility in inspection frequency in comparison to IMC 2800.

Similar to IMC 2800, NYDL management has the ability to extend the interval between inspections for licensees on the basis of good licensee performance. In 1997, NYDL extended 37 license inspections by approximately one year due to good compliance histories.

As noted in their response to the questionnaire, no routine inspections completed by NYDL during the review period were overdue by more than 25% of the scheduled frequency set out in IMC 2800.

In June 1994, the NYDL reciprocity limit was changed to thirty days in a calendar year. As a result, companies that perform work in New York with any frequency are required to apply for and receive a license from NYDL. This resulted in the issuance of licenses to 47 out-of-state companies. These licensees are scheduled for inspections at the same priority interval as in-state licensees.

Fifty-four companies requested reciprocity during 1997 and 10 were inspected while performing licensed activities in the State. The NYDL does not keep records of the types or the priorities of reciprocity licensees. Thus, NYDL does not schedule reciprocity inspections consistent with a priority schedule. It is the decision of NYDL management to focus resources on NYDL licensee inspections, and thus complete reciprocity inspections only as resources allow.

The team also examined NYDL's performance in completing initial inspections of new licensees, and noted that in general, initial inspections are not always completed within six months of the commencement of licensed activities. The team sampled 10 newly issued licenses during the review period, and found that three received an initial inspection within the six month guideline. Of the remaining seven, five of them received an initial inspection within seven months of the commencement of licensed activities. The two remaining initial inspections were performed 56 days and 314 days beyond the six month guideline. The review team recommends that NYDL perform initial inspections of licensees within six months of the licensees' receipt of licensed material, or commencement of licensed activities.

Contrary to IMC 2800, NYDL does not complete an initial inspection of a licensee within one year of the issuance of the license if the licensee does not receive licensed material. If no material is received by a licensee within six months of license issuance, NYDL begins correspondence with the licensee to ensure knowledge of the receipt of licensed material. At the same time, NYDL attempts to persuade the licensee to cancel their license if the licensee believes no radioactive material will be received. The team recognizes this policy as an acceptable alternative to the guidelines established in IMC 2800.

The timely dispatch of inspection findings was also evaluated during the inspection file review. Of 20 inspection findings examined, the correspondence for 17 inspections was sent to the licensee within 30 days of the inspection date. For the other two inspections, the correspondence was sent to the licensee from 1 and 35 days beyond the 30 day guideline. The team does not believe that the issuance of inspection findings is a problem for this program.

Based on the IMPEP evaluation criteria, the review team recommends that NYDL's performance with respect to the indicator, Status of Materials Inspection Program, be found satisfactory.

3.1.3 New York State Department of Health (NYSH) - Status of Materials Inspection Program

The team's review of NYSH's inspection priorities verified that NYSH's inspection frequencies for various types or groups of licenses are at least as frequent as similar license types or groups listed in the NRC IMC 2800 frequency schedule. Fourteen program codes are scheduled for more frequent inspections by NYSH than similar NRC licensees.

With respect to initial inspections of new licenses, the team evaluated the inspection tracking data system and verified that initial inspections were entered into the computerized tracking system together with existing licenses. A review of the inspection tracking system showed that initial inspections are differentiated from routine inspections by including the issuance date of the license in bold in the column listing the last inspection. Although new licenses are clearly marked in the tracking system and scheduled within six months of issuance, a significant number (12 of 27) of the initial inspections were not completed within six months as suggested by IMC 2800.

A review of the database identified 67 new licenses issued since the 1995 review of NYSH. The team selected 27 of these licenses in which the initial inspection was due. Of these 27, 11 licenses were inspected within the six month window, four were inspected one month late, seven were inspected two to six months late, and five were inspected over six months late. The team determined that NYSH policy is that initial inspections are to be scheduled for inspection within six months of issuance. The NYSH management assigns inspections to inspectors twice a year and monitors the progress of inspections completed on a monthly basis. However, inspectors are not required by management to complete new inspections within six months. The review team recommends that NYSH modify its 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 IMC 2800.

In their response to the questionnaire, NYSH indicated that three inspections were overdue by more than 25% of the scheduled frequency. At the time of the on-site review, these inspections had been performed. The timeliness of inspection of core licensees at regular intervals in accordance with IMC 2800 was evaluated during the inspection file review. The team selected 31 inspections for review and determined that three of the inspections were performed at intervals that exceeded IMC 2800 inspection frequencies by more than 25%. These three inspections were overdue by one, two and three months when next inspected.

The timeliness of the issuance of inspection findings was also evaluated during the inspection file review. Of 16 inspection findings examined, the correspondence for all of these inspections was sent to the licensee within 30 days of the inspection date. This total included five escalated enforcement actions that required more documentation to be prepared and reviewed by NYSH staff and management.

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

3.1.4 New York State Department of Environmental Conservation (NYDEC) - Status of Materials Inspection Program

The team's review of NYDEC's inspection priorities showed that inspection frequencies are based primarily on the magnitude of the permitted discharge of radioactive material to the environment (i.e., the maximum average annual concentration of the effluent that may be discharged to the environment) instead of IMC 2800. The inspection priorities range from one to four years. Based on the limited scope of NYDEC's regulatory oversight for facilities (i.e., discharges to environment only) and the priorities of the inspections, the team concluded that these frequencies were adequate to protect public health and safety and to assure permittee (licensee) compliance.

In their response to the questionnaire, NYDEC indicated that it had no overdue inspections. The team confirmed this by reviewing the current permittee list which indicates the last inspection of the permittee and by file review. Since the NYDEC only regulates environmental discharges, low level radioactive waste and transportation, reciprocity does not apply to this portion of the New York program.

It was noticed by the team that the procedures for inspection priorities utilized by NYDEC states that “new permittees will continue to receive pre-permit inspection whenever possible, and will always receive an initial inspection within the first year of operation.” The IMC 2800 states that the initial inspection be done within six months. The NYDEC has been inspecting almost all initial permittees within six months and performs a pre-permit inspection of the facilities. In order to make NYDEC’s initial inspection policy consistent with NRC policy and practice, the Program Director stated that the wording of the inspection priority memo would be revised to require an initial inspection within six months instead of within one year. In response to the draft IMPEP report, NYDEC indicated that the inspection priority memo has been revised to require initial inspections within six months.

For initial inspection of new licensees, the team reviewed the inspection schedules for the review period. For the seven new permits that were issued, inspections were conducted at six facilities within six months, and the other was done at eight months. In addition to the initial inspection, the permittees also receive a pre-permitting inspection.

During inspection file reviews, the team evaluated NYDEC’s timeliness in issuing inspection findings. The team found that inspection findings were generally sent well within the 30 day time frame with two of ten inspections exceeding the 30 day guideline (one at 49 days and one at 335 days).

Based on the IMPEP evaluation criteria, the review team recommends that NYDEC’s performance with respect to the indicator, Status of the Material Inspection Program, be found satisfactory.

3.2 Technical Quality of Inspections

3.2.1 New York City Department of Health (NYCH) - Technical Quality of Inspections

The team reviewed the inspection reports, enforcement documentation, and inspection field notes and interviewed inspectors for 15 materials inspections conducted during the review period. The 15 inspections selected for review included at least one inspection for each of the NYCH’s inspectors and two team inspections of major broad scope licenses. The inspections included four medical broad scope licenses, two academic broad scope licenses, two teletherapy licenses, five limited medical use licenses, and two private practice physicians. Appendix C-1 lists the inspection files reviewed in depth with case-specific comments.

Of the 15 inspections reviewed, seven resulted in no violations being identified. For the remaining eight, violations were identified in transmittal letters to licensees. Of those violations, 13 were not described in the field notes documenting the results of the inspections. In a majority of the cases reviewed, the inspections identified technically valid violations; however, neither the techniques employed nor the manner in which inspections were documented provided many insights into the performance of NYCH’s licensees, other than the status of the licensees’ compliance with NYCH regulations. The review team recommends that NYCH inspectors follow

the guidance in the NYCH inspection procedure manual which includes the information necessary for properly documenting violations. In NYCH's letter dated February 17, 1998, the NYCH responded to this recommendation by stating that a copy of the student manual for the Inspecting for Performance course has been obtained and they plan to conduct an in-house training course in the near future for their materials inspectors.

For 14 of the violations issued in the inspections reviewed, the licensees provided information in their responses that appeared to dispute the violation. When a licensee disputes a Notice of Violation (NOV), the licensee must take the dispute to the Tribunal. If the licensee does not appear, the NOV stands and the fine must be paid. In none of these cases, did NYCH's files indicate whether the violations were upheld or retracted. The team could not determine the status of these violations and their final disposition. The review team suggests that NYCH establish a policy that the results of all Tribunal's be placed in the appropriate inspection files.

The NYCH has a policy of performing annual supervisory accompaniments of inspectors. In response to the questionnaire, NYCH reported that each inspector was accompanied by the supervisor at least once a year during the review period. Interviews of NYCH inspectors determined that the supervisor accompanies the inspectors more frequently, but in those other occasions, the supervisor acted as the lead inspector. Following those inspections, the supervisor provided feedback to the inspector.

Four inspection accompaniments identified in Appendix C were performed by two team members. During the week of October 28 - 31, 1997, a team member performed accompaniments of three inspectors on an inspection of an academic broad scope licensee. A second team member performed accompaniments of four inspectors during an inspection of a medical broad scope licensee that included the source loading of a gamma knife unit, during the week of December 1 - 5, 1997. Two additional inspection accompaniments were performed on January 20 and 21, 1998 with each of newest inspectors in the program. These accompaniments were performed at licensees that these inspectors were qualified to independently inspect.

The team determined that the performances of the inspectors during team inspections were compliance, rather than performance, oriented. For example, during the December 1997 inspection exit meeting attended by the team member, the reviewer was not able to determine whether the inspection findings discussed were violations, concerns, or recommendations. The NYCH's exit did not reference specific regulatory requirements that were violated, or distinguish poor practices from violations. In a few cases, the inspectors appeared to impose their personal preference in the conduct of some operations rather than limit themselves to the enforcement of NYCH's regulations. The review team recommends that NYCH inspectors follow the guidance in NYCH inspection procedure manual which emphasizes the use of performance-based inspection techniques rather than compliance-based techniques and provide training to its inspectors through NRC's Inspecting for Performance Materials Course or similar course.

During the inspection accompaniments performed in January 1998, the two inspectors demonstrated appropriate inspection skills and knowledge of the regulations. The inspectors were thorough in their review of the licensee's radiation safety program. Inspection techniques were observed to be generally performance oriented. These inspections were adequate to assess the licensee's radiological health and safety performance.

The team noted that the NYCH has an adequate number of portable radiation detection instruments for use during routine inspections and response to incidents and emergencies. The NYCH uses an outside vendor for instrument service and calibration. The portable instruments used during the inspector accompaniments were operational and calibrated.

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

3.2.2 New York State Department of Labor (NYDL) - Technical Quality of Inspections

The team reviewed the inspection reports, enforcement documentation, and the data base information for 21 materials inspections conducted during the review period. The casework included NYDL's three materials inspectors and covered a sampling of different license types as follows: two broad scope commercial; one research and development; three portable gauges; two fixed gauges; three industrial radiography; three nuclear pharmacies; two service; one manufacturer; one waste broker; one gas chromatograph; one storage; and one commercial irradiator. Appendix C-2 provides a list of the inspection cases reviewed in-depth with case-specific comments.

The inspection procedures and techniques utilized by NYDL were reviewed and determined to be generally consistent with the inspection guidance provided in IMC 2800. Specific guidance for certain classes of licensees or facilities are also included in the procedures manual maintained in the Manhattan office where all inspectors are based. The team reviewed inspection reports and found them to be comparable with the types of information and data collected under NRC Inspection Procedure 87100. Inspections are generally performed on an announced basis.

The inspection field notes provided excellent, consistent documentation of inspection findings. The NYDL uses supplementary field notes for different types of inspections covering the areas of manufacturing (quality assurance), industrial radiography, fixed gauge, and gas chromatograph licenses.

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 materials, equipment, use of materials, transfer, and disposal. The reports were also checked to determine if the reports adequately documented operations observed, interview of workers, independent measurements, status of previous noncompliance items, substantiation of all items of noncompliance, and the substance of discussions during exit interviews with management. The reviewer completes an inspection review form which becomes part of the inspection file. Overall, the team found that peer review of the inspection documentation and correspondence resulted in their consistent excellent quality. The review team noted a good practice in that NYDL's inspection field notes and inspection correspondence are peer reviewed by one of the senior inspectors to ensure consistency, thoroughness, and quality of reports.

Routine enforcement letters were drafted and issued to licensees by the inspector. When the licensee responds to a NOV, the inspector evaluates the licensee's submittal and prepares a response. Once the inspector determines that the licensee has satisfactorily responded to the NOV and has acknowledged their response, the inspection field notes and correspondence is given to another senior inspector for review. The inspectors told the team that they discuss any atypical 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 NOV's, NYDL 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. The program manager stated that escalated enforcement action beyond the issuance of NOV's was limited to the issuance of orders. The NYDL held four enforcement conferences which resulted in the issuance of orders. The team discussed with NYDL management at the exit meeting that the incorporation of a wider range of enforcement tools into the enforcement policy such as severity levels and civil penalties would provide NYDL with alternative methods to emphasize the importance of prompt, comprehensive identification and correction of conditions important to safety.

One inspector accompaniment identified in Appendix C-2 was performed by a team member on December 11 and 12, 1997 at an industrial radiography storage location and a temporary job site of the licensee. The remaining two inspectors were accompanied during the previous review. During the accompaniment, the inspector demonstrated appropriate inspection skills and knowledge of the regulations. The inspector was well prepared and thorough in the review of the licensee's radiation safety program and performance of licensed activities in the public domain. Inspection techniques were observed to be performance oriented, and the technical performance of the inspector was at a high level. The inspection was adequate to assess the licensee's radiological health and safety performance.

The NYDL program manager performs annual supervisory accompaniments of all inspectors and documents each evaluation on an inspection accompaniment form.

The team noted that NYDL has an ample number of portable radiation detection instruments for use during routine inspections and response to incidents and emergencies. Instrument calibration is performed by NYDL inspectors at the Manhattan office using NIST traceable alpha, beta, and gamma sources. The NYDL procedures also include laboratory and instrument calibration procedures. The NYDL uses an outside vendor for instrument service. The portable instruments used during the inspector accompaniment was observed to be operational and calibrated. The instrument storage area is co-located with the radiation counting laboratory and storage area for emergency response kits. A sampling of portable instruments maintained were found to be within calibration. The NYDL's radiation counting laboratory includes a low background alpha and beta proportional counter, liquid scintillation counter, and a sodium iodide detector coupled to a multichannel analyzer. The program's germanium lithium detector is no longer functional and has not yet been replaced. The inspection staff is responsible for analyzing their own samples and maintaining the laboratory counting equipment.

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

3.2.3 New York State Department of Health (NYSH) - Technical Quality of Inspections

The team reviewed the inspection reports, enforcement documentation, and inspection field notes and interviewed inspectors for 16 materials inspections conducted during the review period. The casework included 11 of the NYSH's materials license inspectors, and covered inspections of various types including medical, academic, teletherapy and pharmacy. Appendix C-3 lists the inspection files reviewed in depth with case-specific comments. During the week of

February 23, 1998, a team member performed accompaniments of four NYSH inspectors on separate inspections of licensed facilities.

During the 1995 review of NYSH, there was a preliminary recommendation to modify the inspection report format to include sections to identify how previous items of noncompliance were addressed by the licensee and to document findings presented to licensee management during exit meetings. The NYSH has modified its field note format to include both of these topics. The NYSH now documents whether or not previous items of noncompliance were resolved and there is now an area to document the exit meeting and subsequent discussions. During this review, the team noted that there was a lack of documentation of the substance of discussions at the exit meetings. The review team suggests that the NYSH's inspection documentation of exit meetings should contain substantive discussions of issues with the Radiation Safety Officer (RSO) and/or licensee management.

The inspection procedures and techniques utilized by NYSH were reviewed and determined to be generally consistent with the inspection guidance provided in IMC 2800. The team reviewed inspection reports and found them to be comparable with the types of information and data collected under NRC Inspection Procedure 87100 and NYSH procedures. Thirteen of the 16 inspections reviewed were performed on an unannounced basis.

The inspection field notes provided good, consistent documentation of inspection findings. The NYSH 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.

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 materials, equipment, use of materials, transfer, and disposal. The reports were also checked to determine if the reports adequately documented operations observed, interview of workers, independent measurements, status of previous noncompliance items, substantiation of all items of noncompliance, and the substance of discussions during exit interviews with management. Although it is evident that some workers were interviewed, it is rarely documented that ancillary personnel, authorized users, or the RSO were involved in this process. Of the 16 inspections reviewed, not one documented interviewing ancillary personnel. The review team suggests that NYSH incorporate a field for documentation of interviewing ancillary personnel, authorized users, technicians, and RSOs into their field notes.

To assure consistency and quality of reports, it was evident the Radioactive Material Section Field Supervisor and Section Chief provided thorough reviews but until recently did not document this review. Six out of the 16 inspections reviewed did not have documented supervisor review. Also, the inspection correspondence and field notes are not signed by supervision. Only the inspector's signature is available on this paperwork. The NYSH has initiated a new process to have the field supervisor and/or the section chief sign a separate memo sized paper documenting their review. This piece of paper 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 NYSH procedures.

When the licensee responded to a NOV, the response was given to the inspector to evaluate the licensee's response and, in each case, a response was sent to the licensee within 30 days of

receipt. The team, as noted previously, identified a concern related to the documentation of supervisory review of enforcement letters and licensee responses.

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 and that escalated enforcement action in the process of Administrative Tribunals (Hearing Board) occurred only five times. A thorough review of all Administrative Tribunals 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. Four of the five cases reviewed were dealt with expeditiously through negotiation with NYSH which is a preliminary step in the Tribunal process. All five cases have been inspected or have been scheduled to be inspected within the next 6 to 12 months.

Four inspector accompaniments identified in Appendix C-3 were performed by a team member. During the accompaniments, inspectors demonstrated appropriate inspection skills and knowledge of the regulations. The inspectors were well prepared and thorough in the review of licensee radiation safety programs. The technical performance of the inspectors was at a high level. During these accompaniments, the reviewer observed that the inspectors focused on records reviews and checking off the field notes instead of observing the licensees operations; therefore, the reviewer identified that the inspectors would benefit from more training in inspecting for performance. The inspections were adequate to assess radiological health and safety at the licensed facilities. The review team suggests that the NYSH inspectors attend additional training in inspecting for performance techniques.

The NYSH has a policy of performing annual supervisory accompaniments of inspectors. In response to the questionnaire, NYSH reported that 10 out of the 12 inspectors had accompaniments in 1997. The two inspectors that did not have accompaniments were a field supervisor and another inspector not assigned inspections for 1997.

The team noted that NYSH has an ample number of portable radiation detection instruments for use during routine inspections and response to incidents and emergencies. The NYSH has a dedicated person in the Department for assuring and performing all instrument calibrations. The portable instruments used during the inspector accompaniments were observed to be operational and calibrated. The instrument storage area is located within the Department and at each field office. A sampling of portable instruments maintained at each location was available and found to be within calibration.

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

3.2.4 New York State Department of Environmental Conservation (NYDEC) - Technical Quality of Inspections

The team reviewed the inspection reports, enforcement documentation, and interviewed inspectors for 10 materials inspections conducted during the review period. The casework included seven of the NYDEC's materials license inspectors, and covered inspections of various types including air, water, and incinerator permits. Appendix C-4 lists the inspection files reviewed in depth with case-specific comments.

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 among the inspector, their supervisor, and the Radiation Section Supervisor 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 team reviewed the latest version of Part 380 Permit Inspection Procedures, revised September 1996, Enforcement Guidance Memorandum Radiation dated May 17, 1995, and all current inspection forms. In general, all procedures and forms appear to be consistent with the applicable guidance found in IMC 2800 and IP 87100.

Supervisory accompaniments of inspectors are conducted on a routine basis. All of the inspectors have been accompanied at least once a year and most of the supervisors have been accompanied during the review period.

Two inspector accompaniments identified in Appendix C-4 were performed by a team member on April 7, 1998. Of the remaining three inspectors, two were accompanied during previous reviews and the other was re-assigned to other work within NYDEC. During the accompaniments, the inspectors demonstrated appropriate inspection skills and knowledge of the regulations. The inspectors were well prepared and thorough in the review of licensee radiation safety programs. Inspection techniques were observed to be performance oriented, and the technical performance of the inspectors was at a high level. The inspections were adequate to assess radiological health and safety of the licensee's effluent monitoring program.

The team found that NYDEC has a variety of survey instruments. The instruments include a good mix of microrentgen meters, GM meters, ion chambers, velometers, and other portable survey meters. The meters are calibrated annually using an outside vendor. The NYDEC also has available a high purity germanium detector, tritium monitor, TLD reader/irradiator, and a neutron detector. Samples are also sent to an outside laboratory for analysis.

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

3.3 Technical Staffing and Training

Issues central to the evaluation of this indicator include the radioactive materials 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 - Technical Staffing and Training

At the time of the review, NYCH's radioactive materials program was staffed by the Deputy Bureau Chief, licensing section with a supervisor and four staff, and compliance section with a

section supervisor, scientist, and five staff. The Bureau Chief position had been vacant for 18 months, filled for four months, and then vacant again as of the week after the review. In general, the team found that the current staffing level is adequate except the team noted that the vacancy at the Bureau Chief position was affecting several aspects of the program as identified in this report. At the August 18, 1998 MRB meeting, Mr. Miskin announced that he has been selected as the Bureau Chief effective August 10, 1998.

At the time of the review, all staff had been with the program for the majority of the review period. Two staff members joined the program shortly after the last review in 1995. Both performed well on their inspection accompaniments. The Bureau Chief resigned in July 1996 with a successor hired in October 1997. The new Bureau Chief resigned in January 1998, effective February 6, 1998. In addition, the Assistant Commissioner that oversees the Bureau was dismissed in mid-January 1998 with the Deputy Commissioner being dismissed in February 1998. In an additional organizational change, the Departments of Health and Mental Health are being combined into one department. The final organizational chart for this new Department will not be available until the City Council approves the reorganization. At the time of the review, it appears that the NYCH will remain intact.

From supervisor interviews and a review of the position descriptions, the team determined that successful candidates for technical positions 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 the NYCH has been able to hire qualified individuals. The NYCH has one Certified Health Physicist (CHP) and one individual that has passed Part 1 of the CHP examination.

In interviews with the staff and a review of documents, the team determined that there was no written training policy or qualifications criteria. The review team recommends that NYCH 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. In NYCH's letter dated February 17, 1998, the NYCH responded to this recommendation by indicating that although their Policy and Procedures Manual contains a written policy for staff training, the manual is currently being updated and will include these recommendations.

The team's review of NYCH's training records and interviews with the staff identified that several staff members should attend at least one course to fully address their training needs. 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. The review team recommends that NYCH review the staff's training against their training requirements, clearly document how the training was achieved, and acquire the necessary training, as appropriate.

Based on the IMPEP evaluation criteria, the review team initially recommended that NYCH's performance with respect to the indicator, Technical Staffing and Training, be found satisfactory with recommendations for improvement. At the August 18, 1998 MRB meeting, the MRB requested that the team reassess its basis for the recommendation stated above. The team's reassessment concluded that the personnel performance is addressed in the indicator, Technical Quality of Inspections, and that the recommendation for this indicator should be changed to satisfactory. The MRB agreed with this change at the September 1, 1998 meeting.

3.3.2 New York State Department of Labor - Technical Staffing and Training

At the time of the review, NYDL's radioactive materials program was staffed by the principal radiophysicist and seven associate radiophysicists. In general, the team found that the current staffing level is adequate, except that the team noted that the inspection staff has a very heavy workload attributed to the fact that one of the four inspectors was restricted to office duties only. The principal radiophysicist also carries a very heavy licensing caseload that may have affected the status of regulatory development. The staffing and training will be impacted by the recommendations in the SS&D section (4.2) with the recommendation for significant additional training for both of the SS&D staff. The review team suggests that NYDL management consider whether additional staffing is warranted when considering the impacts of the licensing and inspection workloads, the regulation development needs, and the SS&D program improvement needs.

The licensing and inspection functions of the program are segregated with all the licensing conducted in Albany and inspections conducted out of the Manhattan office. Licensing duties are performed by the principal radiophysicist and three associate radiophysicists. Inspection duties are performed by four associate radiophysicists. All staff perform duties in incident and emergency response. At the time of the review, all staff had been with the program for the entire review period.

From supervisor interviews and a review of the position descriptions, the team determined that successful candidates for technical positions 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. The NYDL program has one CHP with one other person working on their certification.

In interviews with the staff and review of documents, the team determined that there was no written training policy. The principal radiophysicist committed in a memo to upper management to follow the recommendations in the NRC/OAS Training Working Group report as the program's overall training plan. They also are required to submit annual training plans to upper management. All formal training is documented complete in a computer database. On-the-job training is documented in signature cards signed by the mentoring staff person. The review of their training records and interviews with the staff identified that one staff member should attend the industrial radiography course and that most staff desired additional training in internal dosimetry and decommissioning. The review team recommends that NYDL document its training program to include overall policy and minimum training requirements for both the licensing and compliance staff.

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

3.3.3 New York State Department of Health (NYSH) - Technical Staffing and Training

At the time of the review, the NYSH radioactive materials program was staffed by the Director, two supervisors, and eleven staff. The team found that the current staffing level appeared adequate.

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

At the time of the review, all staff, except one, had been with the program for the entire review period. The new individual was transferred from the laboratory to the licensing/compliance staff in Albany. The individual has attended several training courses and is a senior staff member based on his 20 plus years working as a radiochemist in the laboratory. All work, by this individual both inspections and licensing actions, is reviewed by qualified staff prior to issuance.

From supervisor interviews and a review of the position descriptions, the team determined that successful candidates for technical positions are required to have a Bachelor's degree in science and at least 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 review team concluded that the State has been able to hire qualified individuals. There is one certified health physicist (CHP) in the NYSH program with six others that have passed Part I of the CHP examination.

The NYSH has a written training policy and requirements. The team reviewed the policy and requirements and found them acceptable. The NYSH has a training matrix where they enter the courses that have been completed. The review of this matrix identified several courses which are needed for individual staff. These were: two for inspection procedures, one for licensing practices and procedures, most of the staff for teletherapy/brachytherapy, three for transportation of radioactive materials, and, as recommended in Section 3.2.3, additional training in inspecting for performance for the inspection staff. Although these individuals have not attended specific courses, they have had some on-the-job training and short seminars to cover these areas. The team considered that in every training area the program had multiple qualified individuals that have been provided the on-the-job training, therefore, from a programmatic standpoint, the program has sufficiently trained staff. Through management review, all staff, except for the recent transfers, have been qualified to perform independent work. NYSH's program conducts monthly TeleVideo conferences with its regional and Albany staff. These sessions cover current health physics topics and other programmatic matters, as needed. The review team considers the TeleVideo conferences to be a good practice to bring and keep their staff current on health physics and program issues.

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

3.3.4 New York State Department of Environmental Conservation (NYDEC) - Technical Staffing and Training

At the time of the review, NYDEC's radioactive materials program was staffed by the Bureau Chief, Radiation Section Leader, and ten staff. There are currently two vacancies in the radiation section. Both positions are for contaminated sites and environmental analysis to support contaminated site evaluations. In response to the draft IMPEP report, NYDEC indicated that, subsequent to the team visit, they have filled both of these positions. About half of the staff time

is spent on contaminated sites and events that are not directly covered under the agreement with NRC. The permitting (licensing) and compliance functions of the program are integrated with six staff performing both functions part of the time. All staff perform duties in incident and emergency response.

At the time of the review, all staff had been with the program for the entire review period. Two staff left the program in 1997, and one staff member was assigned work outside the Bureau which amounted to half of his time.

From supervisor interviews and a review of the position descriptions, the team determined that successful candidates for 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 the State has been able to hire qualified individuals.

In interviews with the staff and a review of documents, the team determined that there was no written training policy. Because of the small number of inspectors and permit reviewers, NYDEC does not have a formal qualification program. New staff have been trained in performing inspections and reviewing permit applications individually by the permit unit supervisor. Inspectors in training move through the following stages: (1) accompanying experienced inspectors as observers; (2) assisting experienced inspectors; (3) taking the lead in inspections, assisted by experienced inspectors; and (4) performing inspections independently. Inspectors move through these stages based on the assessment of the unit supervisor. The same staff are trained to review permit applications by reviewing first minor amendments and routine renewals, then applications of increasing complexity. All permitting decisions are reviewed by the permit unit supervisor and the radiation section supervisor. The review team recommends that NYDEC document its training program to include overall policy and minimum training requirements for both the permitting and compliance staff.

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

3.4 Technical Quality of Licensing Actions

The teams examined completed licensing casework and interviewed the reviewers for specific licenses as specified for each of the four New York programs. Licensing actions were evaluated for completeness, consistency, proper isotopes and quantities used, qualifications of authorized users, adequate facilities and equipment, and operating and emergency procedures sufficient to establish the basis for licensing actions. Licenses were reviewed for accuracy, appropriateness of the license and of its conditions and tie-down conditions, and overall technical quality. Casework was evaluated for timeliness, adherence to good health physics practices, reference to appropriate regulations, documentation of safety evaluation reports, product certifications or other supporting documents, consideration of enforcement history on renewals, pre-licensing visits, peer or supervisory review as indicated, and proper signature authorities. The files were checked for retention of necessary documents and supporting data.

3.4.1 New York City Department of Health (NYCH) - Technical Quality of Licensing Actions

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 all reviewers. The cross-

section sampling included all of NYCH's major licenses as defined by NYCH in the questionnaire, and included the following types: broad scope medical; broad scope academic; gamma knife; hospital nuclear medicine; private practice physicians nuclear medicine; teletherapy; high dose remote afterloaders; blood irradiators; bone mineral analyzers; and in vitro laboratories. Nineteen license files were reviewed. Licensing actions included three new licenses, nine renewals, 28 amendments, two terminations, and one license rescinded. A list of these licenses with case-specific comments can be found in Appendix D-1. In discussions with NYCH management, it was noted that there are no major decommissioning efforts underway with regard to agreement material in New York City. Also, there are no identified sites with potential decommissioning difficulties equivalent to those sites in NRC's Site Decommissioning Management Plan. The only exemptions issued were to physicians requesting the carbon 14 urea breath test recently approved by NRC.

The team found that the licensing actions were thorough, complete, consistent, of high 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 documentation in the license files or discussion with license reviewers. The review of the two gamma knife licenses indicates license reviewers should pay close attention to the conditions of use listed in the SS&D registry for these type of devices. The team discussed with NYCH staff how they addressed these conditions since there was limited documentation in the file. Several of the conditions were individually considered by NYCH staff and others were not because NYCH staff considered them as being covered through the manufacturer operating procedures and/or training program. The review team suggests that NYCH consider documenting how the SS&D conditions of use were addressed for the two gamma knife licenses and will be addressed in future SS&D licensee's actions. In NYCH's letter dated February 17, 1998, the NYCH responded to this suggestion by adding a memo to the license reviewer's handbook that instructs reviewers to include as license conditions the specific language from the SS&D Registry dealing with the restrictions of use or recommendations concerning safety matters as appropriate.

The team found that terminated licensing actions and the license rescinded were well documented, showing appropriate transfer records and survey records. For the case that the license was rescinded, NYCH took possession of licensed material for proper disposal.

Licenses are renewed on a 5-year frequency. Licenses that are under timely renewal are amended as necessary to assure public health and safety issues are addressed during the period that the license is in the renewal process. Each licensing action receives management review before the action is finalized and issued. Interviews with the licensing staff indicate that there is discussion between reviewers and management on complex licensing actions completed by management. The license reviewers submit all deficiency letter replies and a date stamped final licensing action to management for review and management signature. If approved, management signs the action, then the license is held for license fee payment. The date of payment is the issuance date of the license action. The difference between these two dates may cause initial inspection scheduling difficulties. The review team suggests that NYCH list the date the licensing action is issued (date of fee payment) on the license and in their database, instead of the date of management signature. In NYCH's letter dated February 17, 1998, the NYCH responded to this suggestion by upgrading their radiation database to trigger an inspection due date based on the actual date of issuance of the new license rather than the date the license was signed.

The casework was reviewed for adequacy and consistency with the NYCH procedures. The casework review also indicated that the NYCH reviewers follow their licensing guides during the review process to ensure that licensees submit the information necessary to support the license. The licensing guides are similar to NRC guides.

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

3.4.2 New York State Department of Labor (NYDL) - Technical Quality of Licensing Actions

The team examined completed licenses and casework for 16 license actions, representing the work of four 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, and to include work by all reviewers. The sampling included the following types: research and development; manufacturing and distribution; industrial radiography; portable gauges; fixed gauges; gas chromatograph; commercial broad scope, and nuclear pharmacy. Licensing actions reviewed included two new licenses, six renewals, six amendments, and two terminations. A list of these 16 licenses with case specific comments can be found in Appendix D-2. In discussions with NYDL staff, the team noted that NYDL is currently performing confirmatory measurements at the decommissioning of the Cintichem facility with regard to agreement material in New York.

The 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. Generic notices were issued to specific classes of licensees to address particular safety concerns, such as, a notice on bumpers for Amersham 660 radiography cameras.

One of the licensing actions examined by the team required the licensee to submit financial assurance. The originals of financial documents could not be located. Based on discussions with the program manager and a review of the original financial assurance documents maintained in NYDL's Manhattan office, the team determined that some licensees: (1) are no longer required to have financial assurance; (2) were inconsistent in designating the obligee; and (3) did not have a trust agreement with each financial mechanism. Prior to this review, NYDL sent a letter to its licensees requesting them to review their financial assurance and update their financial mechanism. The review team suggests that NYDL continue to audit their financial assurance files to ensure that they contain all required information and are current with NYDL requirements.

The team found that terminated licensing actions were well documented, showing appropriate transfer records and survey records. A review of the licensing actions over the period showed that most terminations were for licensees possessing sealed sources. These files showed that documentation of proper disposal or transfer was available.

Licenses are renewed on a 3-year frequency. The NYDL performs a complete review during every other 3-year cycle to ensure that the license's radiation safety program is adequate and

meets current NYDL requirements. Licenses that are under timely renewal are amended as necessary to assure that public health and safety issues are addressed during the period that the license is in the renewal process. Unless reviewed by the two individuals with signature authority, each licensing action receives a supervisory chain review.

At the time of the review, there were 57 renewals greater than a year old, and 27 amendments and two new applications greater than 6 months old. Based on discussions with NYDL program manager, the program receives approximately 300 licensing actions a year and the total number of pending actions is approximately 200 actions. The total number of pending actions has been reduced in half compared to the last review period.

The team found that the current staff is well trained and experienced in a broad range of licensing activities. The casework was reviewed for adequacy and consistency with NYDL procedures. The casework review indicated that NYDL staff follows their licensing guides during the review process to ensure that licensees submit the information necessary to support the license. The licensing guides are similar to NRC guides. The NYDL has developed simplified licenses for fixed gauges and gas chromatograph licenses that do not require a license tie-down condition. The NYDL also issues notices to its licensees to alert them to changes in regulatory requirements or to emphasize a particular area of concern identified by NYDL or another agency.

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

3.4.3 New York State Department of Health (NYSH) - Technical Quality of Licensing Actions

The team examined completed licensing casework and interviewed the reviewers for 21 specific licenses. 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 all reviewers. The cross-section sampling included all of NYSH's major licenses as defined by NYSH in the questionnaire and included the following types: academic-broad; research and development-specific; research and development-broad; irradiator; medical (broad with high dose remote afterloader, private practice, hospital, nuclear cardiology, mobile nuclear medicine site, brachytherapy, teletherapy, and high dose remote afterloader); and clinical laboratory. Licensing actions included six new licenses, seven renewals, one amendment, and seven terminations. A list of these licenses with case-specific comments can be found in Appendix D-3.

The 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. Generic notices were issued to specific classes of licensees to address particular safety concerns, such as, a notice on HDR issues.

In discussions with NYSH management, it was noted that there were no major decommissioning efforts underway with regard to agreement material in the NYSH program. Also, there were no identified sites with potential decommissioning difficulties equivalent to those sites in NRC's Site Decommissioning Management Plan. The team found that terminated licensing actions were well documented, showing appropriate transfer records and survey records.

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

3.4.4 New York State Department of Environmental Conservation (NYDEC) - Technical Quality of Licensing Actions

The team examined completed licenses and casework for 14 license actions in 14 specific license files, representing the work of six license reviewers. The license reviewers and the Section Chief were interviewed when needed 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 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, water discharge, and environmental study. Licensing actions reviewed included three new licenses, three renewals, two amendments, three terminations, and three inquiries. Inquiries are permit applications or facility evaluations initiated by the radiation staff to determine if licensees discharging radioactive materials to the environment in their effluent exceed the 10% exemption threshold. A licensee is required to have a permit if the annual average effluent concentration of the licensee's discharge exceeds 10% of the NYDEC's regulatory limit in Table II of Part 380. If the licensee's discharge is less than 10% of NYDEC limits, then a permit is not needed; however, the licensee is still required to survey and maintain appropriate records to demonstrate compliance with Part 380. A list of the 14 permits and inquiries reviewed with case specific comments can be found in Appendix D-4.

The 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 appeared to be taken into account when reviewing renewal applications as determined from documentation in the license files and/or discussions with the license reviewers. No exemptions were issued by NYDEC during this review period.

The team found that terminated licensing actions were well documented, showing either appropriate survey records or documentation that the licensee's effluents did not exceed the 10% exemption limit. A review of the licensing actions over the period showed that a majority of terminations were for permittees whose effluents were reduced to less than the 10% exemption limit.

Permits are issued or renewed with a 5-year expiration period. The radiation staff occasionally issues a permit for a shorter period, but this is done to coincide expiration dates with other NYDEC permits issued to the facility. Permits that are under renewal are amended as necessary to assure that public health and safety issues are addressed during the period that the permit is undergoing the renewal process. Each licensing action receives a supervisory chain review.

The team found that the current staff is well trained and experienced in licensing activities related to discharge of radioactive material into the environment. The casework was reviewed for adequacy and consistency with the NYDEC procedures. The casework review indicated that the radiation staff follow their licensing guides during the review process to ensure that licensees submit the information necessary to support the license. 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.

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

3.5 Response to Incidents and Allegations

3.5.1 New York City Department of Health (NYCH) - Response to Incidents and Allegations

In evaluating the effectiveness of NYCH's actions in responding to incidents and allegations, the team examined NYCH's response to the questionnaire relative to this indicator, reviewed the incidents reported for NYCH in the "Nuclear Material Events Database (NMED)", and those contained in the City's casework and license files, and supporting documentation, as appropriate for eight incidents. A list of the incident casework with comments is included in Appendix E-1. The team reviewed NYCH's response to six allegations received during the review period.

The eight incidents selected for review included two misadministrations, one lost package of radioactive material, two loss of control of radioactive material, two overexposures, and one procedural failure. Of the six allegations reviewed in detail, the NRC Region I office referred one to NYCH and the others came directly from alleged. During the review period, NRC referred 10 allegations to NYCH. All of these allegations have been closed out.

Responsibility for initial response and follow-up actions to material incidents and allegations rests with NYCH staff. When NYCH is notified of either an incident or an allegation (also referred to as "complaints") during working hours, an inspector takes the incoming notification and briefs the materials inspection supervisor or the Director of NYCH to determine the approach to be taken. Incoming complaints are considered either immediate or non-immediate based on their apparent safety significance. The supervisor assigns the complaint to one of the inspectors who will respond the same day or next if the complaint is immediate, or a longer period if non-immediate. The NYCH provides a 24-hour emergency number for anyone to report emergencies involving hazardous materials. The NYCH can also receive notification through the State Warning Point (State operated emergency line). When a radiological incident is reported after work hours, NYCH staff is contacted at home.

The review of incident casework, licensing casework, and interviews with staff revealed that incidents are promptly evaluated for the need for on-site investigations. For those incidents not requiring on-site investigations, copies of letters to licensees were in the incident and licensing files indicating that the incident would be investigated during the next scheduled inspection. In response to incidents, NYCH took prompt, appropriate action. The review of casework indicated that incident reports were thorough and well-documented. The team found that NYCH's complaint file is maintained manually with a copy in the appropriate specific license file. Documentation on incidents or allegations involving non-licensees are maintained solely in the complaint file. These reports included sections on the background, findings, conclusions/recommendations, instruments used, and signatures. The team noted that some of the non-immediate complaints were documented on a preprinted two sided "complaint control record" form. The incident reports were reviewed and signed by the inspection supervisor. The team did note that follow up to incidents at the next inspection was not always documented in the field notes. The review team suggests that NYCH investigated incidents be clearly documented in the field notes at the next inspection.

The team reviewed NYCH's process for reporting significant events immediately or 24 hour notification. The team determined that NYCH was inconsistent in reporting significant events to the NRC Operations Center, but was consistent in reporting to other NRC offices. The team also queried the incident information reported on the NMED system for NYCH which identified 11 reported material incidents. These incidents were not based on reports submitted by NYCH, but through other notification mechanisms such as preliminary notification or calls to the NRC Operations Center. Although NYCH staff has been provided training on the NMED system, they have not been providing periodic reports on reportable events. During the exit meeting on January 30, 1998, and their letter dated February 17, 1998, NYCH and Department management committed to providing information on reportable events to NMED including those reportable events that occurred during fiscal years 1996 and 1997. As of September 3, 1997 when the Commission policy on Adequacy and Compatibility was published in the Federal Register, the Agreement State participation in the NMED system became mandatory. On February 25, 1998, OSP issued an implementing procedure (SA-300) for Agreement State reporting of materials events to comply with this policy change. The review team recommends that NYCH notify NRC of significant reportable events and provide documentation for all reportable events both in accordance with SA-300.

The review of the allegation files indicated that NYCH took prompt and appropriate action in response to allegers' concerns. These actions included detailed interviews with the allegers, prompt investigation and routine follow up at the next inspection, when warranted. The NYCH protects the identity of the allegers if requested. The review of the casework and interviews of staff determined, however, that NYCH staff did not document any feedback to the allegers on NYCH's investigation into the allegation and NYCH's findings. The review team suggests that NYCH include written documentation that the allegers have been contacted regarding the results of NYCH's findings into the allegers' concerns. In NYCH's letter dated February 17, 1998, the NYCH responded to this suggestion by confirming that documentation to file will indicate that allegers were notified of the results of investigations.

Based on the IMPEP evaluation criteria, the review team recommends that NYCH's performance with respect to the indicator, Response to Incidents and Allegations, be found satisfactory.

3.5.2 New York State Department of Labor (NYDL) - Response to Incidents and Allegations

In evaluating the effectiveness of NYDL's actions in responding to incidents, the team examined NYDL's response to the questionnaire relative to this indicator, NYDL's written procedures for incident response, and the incidents reported for NYDL in the "Nuclear Material Events Database (NMED)." The team examined NYDL's incident and license files and supporting documentation for 13 incidents. In all cases reviewed, once notification was received, NYDL promptly responded and adequately protected public health and safety. Incidents were adequately documented in the files and when they involved a licensee of NYDL, the incident was also reviewed at the next routine inspection. Issues and concerns arising out of these incidents that involved other regulatory agencies were referred to the appropriate agency by NYDL. A list of the incident casework with comments is included in Appendix E-2.

The team reviewed NYDL's process for reporting significant NYDL events (immediate or 24-hour notification). The team determined that NYDL was inconsistent in reporting significant events to the NRC Operations Center but was consistent in reporting them to other NRC offices. During the review period, NYDL had made only one summary report of incidents for inclusion in the NMED system. For the NMED system to effectively identify in a timely manner any generic

problems with equipment or procedures, NYDL must routinely submit the vital information on the incidents that occur in their jurisdiction to the NMED system. As of September 3, 1997 when the Commission policy on Adequacy and Compatibility was published in the Federal Register, the Agreement State participation in the NMED system became mandatory. On February 25, 1998, OSP issued an implementing procedure (SA-300) for Agreement State reporting of materials events to comply with this policy change. The review team recommends that NYDL notify NRC of significant reportable events and provide documentation for all reportable events both in accordance with SA-300.

In evaluating the effectiveness of NYDL's actions in responding to allegations, the team examined NYDL's response to the questionnaire relative to this indicator and NYDL's written procedures for response to allegations. The team reviewed NYDL's response to seven allegations, including the allegation referred to NYDL by NRC. NRC referred a total of three allegations to NYDL. All of them have been closed out. All possible allegations are evaluated by NYDL's Director to determine the level of investigation they may merit. Not all allegations referred to NYDL by the NRC were considered allegations by NYDL. Two of the NRC referred allegations selected for review were not in NYDL's allegation files but had been answered by letters to NRC from the Director, because in her evaluation they should not be included as NYDL investigated allegations. Based on the information provided by NYDL, NRC closed these allegations. The NYDL responded promptly with on-site investigations to the four allegations reviewed with potential ongoing conditions that could lead to excessive exposures. The NYDL's response to allegations was timely and appropriate for the significance of the allegation. NYDL protects the identify of the allegor, when requested. In two of the seven files reviewed, NYDL's allegation tracking system did not document that a closed investigation had in fact been closed out. The NYDL's tracking system does not indicate if the allegor was informed of the results of the investigation nor is this required by the NYDL's allegation procedures. The review team suggests that, when each allegation is completed and closed out, NYDL update their allegation tracking systems accordingly to reflect the actual status for all allegations.

Based on the IMPEP evaluation criteria, the review team recommends that NYDL's performance with respect to the indicator, Response to Incidents and Allegations, be found satisfactory.

3.5.3 New York State Department of Health (NYSH) - Response to Incidents and Allegations

In evaluating the effectiveness of NYSH's actions in responding to incidents and allegations, the team examined NYSH's response to the questionnaire relative to this indicator, the incidents reported for New York in the "Nuclear Material Events Database (NMED)," those incidents contained in NYSH's casework and license files, and supporting documentation, as appropriate for 12 incidents. A list of the incident casework with comments is included in Appendix E-3. The team reviewed NYSH's response to five allegations received during the review period.

The 12 incidents selected for review included three misadministrations, one leaking source, two loss of control of radioactive material, one overexposure, two equipment failures, two releases of radioactive material, and one contamination event. Of the five allegations reviewed, the NRC Region I office referred one to NYSH and the others came directly from allegors.

The NYSH use the same process for handling incidents and allegations. Responsibility for initial response and follow-up actions to material incidents and allegations rests with the staff. When NYSH is notified of either an incident or an allegation during working hours, an inspector takes the incoming notification and briefs the Section Chief in Albany or the field supervisor in Syracuse

to determine the approach to be taken. Either supervisor will evaluate the potential safety significance of the incident/allegation to determine the type of response that NYSH will take. Although staff and supervisors are located in five different offices around the State, the team noted effective use of NYSH's e-mail system to communicate and document actions taken for any of the events. The NYSH has a 24-hour number to report radiological emergencies through the State Warning Point. The notification list includes after work hours phone numbers for NYSH staff.

The review of incident and licensing casework, and interviews with staff revealed that incidents are promptly evaluated for the need for on-site investigations. For those incidents not requiring on-site investigations, copies of letters to licensees were in the incident and licensing files indicating that the incident would be investigated during the next scheduled inspection. In response to incidents, NYSH had taken prompt, appropriate action. The review of casework indicated that incident reports were thorough and well-documented. The team found that incident and allegations events are tracked on a computerized system and filed on monthly basis. Each event is classified by the type of accident/incident (including a category for allegations) and includes a summary sheet with an event description, contact person, site name and responsible party, follow up, outcome, and if the event has been closed out. Detailed information on each event such as telephone conversations and close out memorandums are maintained in the incident file and, if a specific licensee is involved, in the appropriate docket file. Documentation on incidents or allegations involving non-licensees are maintained solely in the incident file. The event reports are reviewed and signed by the Bureau Chief on a monthly basis. The team did note that incidents were generally followed up at the next inspection.

The team reviewed NYSH's process for reporting significant (immediate or 24-hour notification) events. The team determined that NYSH was inconsistent in reporting significant events to the NRC Operations Center but was consistent in reporting to other NRC offices. The team also queried the incident information reported on the NMED system for NYSH which identified six reported material incidents plus one abnormal occurrence. Although NYSH staff has been provided training on the NMED system, they have not been providing periodic reports on reportable events. The team determined that NYSH last reported incidents to the NMED system in April 1997. The NMED system does not include NYSH reports since that time. During the exit meeting on April 3, 1998, NYSH staff and management indicated that a new tracking system was under development to track incidents and allegations, and that NYSH would explore interfacing their software to allow transfer of reportable events to NMED. As of September 3, 1997 when the Commission policy on Adequacy and Compatibility was published in the Federal Register, the Agreement State participation in the NMED system became mandatory. On February 25, 1998, OSP issued an implementing procedure (SA-300) for Agreement State reporting of materials events to comply with this policy change. The review team recommends that NYSH notify NRC of significant reportable events and provide documentation for all reportable events both in accordance with SA-300.

The review of the allegation files indicated that NYSH has taken prompt and appropriate action in response to the allegeders' concerns. The review of casework and interviews of staff determined staff provided feedback on the follow-up findings to the allegeder. The identity of the allegeder is protected by NYSH.

Based on the IMPEP evaluation criteria, the review team recommends that NYSH's performance with respect to the indicator, Response to Incidents and Allegations, be found satisfactory.

3.5.4 New York State Department of Environmental Conservation (NYDEC) - Response to Incidents and Allegations

In evaluating the effectiveness of NYDEC's actions in responding to incidents and allegations, the team examined NYDEC's response to the questionnaire regarding this indicator, the incidents reported for State of New York in the NMED against those contained in the NYDEC files, and the casework and supporting documentation for four material incidents and five allegations.

The four incidents selected for review included two releases of radioactive material, one damage to equipment and one release of material resulting from equipment and procedural failure and are listed in Appendix E-4. Of the five allegations reviewed, NRC Region I office referred four to NYDEC and the other one came directly to NYDEC from an allegor. The team noted during file reviews and confirmed during discussions with staff that a majority of the incidents received by the Radiation Section are radiation alarms at solid waste and regulated medical waste facilities involving patient excreta, exempt material, or NARM material.

Responsibility for initial response and follow-up actions to material incidents and allegations rests with Radiation Section staff. When the NYDEC is notified of an incident during working hours, either the Section Chief or the Program Director is consulted to evaluate the safety significance of the event and determine the course of action to be taken. For incidents during non-work hours, NYDEC's radiation management can be contacted through the New York's State Warning Point. Radiation Section management also indicated that NYDEC sometimes coordinates the response to an incident with one of the State licensing agencies (NYCH, NYSH, and NYDL) which have staff in regional offices in the vicinity of the incident.

The review of incident and licensing casework, and interviews with staff revealed that incidents are promptly evaluated for the need for on-site investigations. For those incidents not requiring on-site investigations, copies of letters to licensees were in the licensing files indicating that the incident would be investigated during the next scheduled inspection. The team noted that the Radiation Section is currently evaluating the radiation detection systems at solid waste and regulated medical waste facilities in an effort to prepare guidance for setting a radiation level for rejecting a shipment of waste containing radioactive material. Solid waste and regulated medical waste facilities are required by permit to monitor incoming waste for radioactivity, store the radioactive material in shielded areas, and report an alarm to NYDEC.

In responding to incidents and allegations, NYDEC took prompt, appropriate actions. The review of casework indicated that incident reports are thorough and well-documented. The incident reports were reviewed and signed by the section supervisor. The team noted that documentation relating to the follow up to allegations pertaining to licensed material or operations is maintained in the licensing files. The other allegations are in the incident/ allegation file. It was also noted that the Radiation Section's procedural manual does not address the handling of incidents and allegations. The review team recommends that NYDEC incorporate the handling of incidents and allegations into their inspection procedures.

The team reviewed NYDEC's process for reporting significant (immediate or 24-hour notification) events. The team determined that NYDEC was inconsistent in reporting significant events to the NRC Operations Center. The NYDEC's response to the questionnaire indicated that reporting of events to NMED is not their responsibility. During the team's discussions with NYDEC management, they indicated that the licensing agency (NYDEC issues permits) would be responsible for reporting events to NMED and to NRC. A review of the information reported on

an NMED system printout for the State of New York indicated one event reported to NMED by NYDL that NYDEC also treated as an incident. As of September 3, 1997 when the Commission policy on Adequacy and Compatibility was published in the Federal Register, the Agreement State participation in the NMED system became mandatory. On February 25, 1998, OSP issued an implementing procedure (SA-300) for Agreement State reporting of materials events to comply with this policy change. The review team recommends that NYDEC 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.

NYDEC maintains a chronological file of radiation alarms at solid waste and regulated medical waste facilities. Other incidents reported to the Radiation Section are maintained in the appropriate licensing file, but there is no corresponding incident file for these events. The review team suggests that NYDEC maintain one file for all types of incidents involving radioactive material.

Based on the IMPEP evaluation criteria, the review team recommends that NYDEC's performance with respect to the indicator, Response to Incidents and Allegations, be found satisfactory.

4.0 NON-COMMON PERFORMANCE INDICATORS

The 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.

4.1 Legislation and Program Elements Required for Compatibility

4.1.1 New York City Department of Health (NYCH) - Legislation and Program Elements Required for Compatibility

4.1.1.1 Legislation

Along with their response to the questionnaire, NYCH provided the team with the opportunity to review copies of legislation that affect the radiation control program. Legislative authority for NYCH's portion of the Agreement State program is granted in Chapter 22 of the New York City Charter (specifically Section 556(s)). NYCH's radiation program is delegated from the NYSH 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. The team noted that the legislation and delegation has not changed since being found adequate during the previous review, and found that the City Charter is adequate.

4.1.1.2 Program Elements Required for Compatibility

The NYCH Regulations for Control of Radiation, found in Article 175 of the New York City Health Code - Radiation Control, 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 materials, 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 team examined the procedures used in NYCH's regulatory process and found that it is a six step process that takes between six months to a year to complete depending on the complexity of the rule change.

The team evaluated NYCH's responses to the questionnaire and reviewed the regulations adopted by NYCH since the 1995 review to determine the status of the NYCH regulations under the Commission's new adequacy and compatibility policy. The team found that the NYCH did not promulgate any new regulations since the last review.

NYCH has not adopted the following regulations within the 3-year time frame:

- "Timeliness in Decommissioning of Materials Facilities," 10 CFR Parts 30, 40, and 70 amendments (59 FR 36026) that became effective August 15, 1994. The rule is being evaluated by NYCH's Office of General Counsel with an expected date for adoption of September 1998.
- "Frequency of Medical Examinations for Use of Respiratory Protection Equipment," 10 CFR Part 20 amendment (60 FR 7900) that became effective March 13, 1995. The NYCH has decided to not proceed with a rulemaking and will retain the more stringent requirement of annual medical examinations. At this time, NYCH does not have any licensees that use respiratory protection equipment.
- "Low-Level Waste Shipment Manifest Information and Reporting," 10 CFR Parts 20 and 61 amendments (60 FR 15649 and 25983) that became effective March 1, 1998. The Agreement States are to promulgate their regulations no later than March 1, 1998 so that NRC and the State would require this national system to be effective at the same time. NYCH has this rule under review with their General Counsel to determine whether any additional rulemaking is needed, since NYDEC has this rule in place and it applies to all NYCH licensees.

NYCH has not yet adopted the following regulations that are applicable to the NYCH program, but intends to address them in timely rulemakings or by adopting alternate generic legally binding requirements:

- "Radiation Protection Requirements: Amended Definitions and Criteria," 10 CFR Parts 19 and 20 amendments (60 FR 36038) that became effective August 14, 1995.
- "Clarification of Decommissioning Funding Requirements," 10 CFR Parts 30, 40 and 70 amendments (60 FR 38235) that became effective November 24, 1995.
- "10 CFR Part 71: Compatibility with the International Atomic Energy Agency," 10 CFR Part 71 amendment (60 FR 50248 and 61 FR 28724) that became effective April 1, 1996.
- "Medical Administration of Radiation and Radioactive Materials," 10 CFR Parts 20 and 35 amendments (60 FR 48623) that became effective October 20, 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 May 16, 1996.
- “Recognition of Agreement State Licensees in Areas Under Exclusive Federal Jurisdiction Within an Agreement State,” 10 CFR Part 150 amendment (62 FR 1662) that became effective January 13, 1997.
- “Criteria for the Release of Individuals Administered Radioactive Materials,” 10 CFR Parts 20 and 35 amendments (62 FR 1662) that became effective May 29, 1997.
- “Radiological Criteria for License Termination,” 10 CFR Part 20, 30, 40, and 70 amendments (62 FR 39058) that became effective August 20, 1997.

The review team recommends that NYCH place the regulatory changes agenda and establish specific schedules to address the regulatory changes in Section 4.1.1.2 within three years of the regulations becoming effective NRC rules.

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

4.1.2 New York State Department of Labor (NYDL) - Legislation and Program Elements Required for Compatibility

4.1.2.1 Legislation

Along with their response to the questionnaire, NYDL provided the team with the opportunity to review copies of legislation that affect the radiation control program. Legislative authority for NYDL 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. The NYDL is designated as the radiation control agency for industrial and commercial uses of radioactive materials. The team noted that the legislation has not changed since being found adequate during the previous review and found that the State legislation is adequate.

4.1.2.2 Program Elements Required for Compatibility

The NYDL Regulations for Control of Radiation, 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) apply to all commercial and industrial uses of radioactive materials. The NYDL requires a license for possession and use of all radioactive material for commercial and industrial purposes including naturally occurring materials, such as radium, and accelerator-produced radionuclides.

The team examined the procedures used in NYDL's regulatory process and found that it is a 6-step process that takes between six to 12 months to complete.

The team evaluated NYDL's responses to the questionnaire and reviewed the regulations adopted by the State since the 1995 review to determine the status of the NYDL regulations under the Commission's new adequacy and compatibility policy. The team found that the NYDL

addressed the following NRC regulation amendments; however, they have not been finalized and, therefore, they have not been adopted within the 3-year time frame:

- “Licensing and Radiation Safety Requirements for Irradiators,” 10 CFR Part 36 (58 FR 7715) that became effective July 1, 1993. See Section 2.0 for interim actions being taken by NYDL to implement this rule on a case-by-case basis.
- “Decommissioning Recordkeeping: Documentation Additions,” 10 CFR Parts 30, 40, and 70 amendments (58 FR 39628) that became effective October 25, 1993.
- “Self-Guarantee as an Additional Financial Mechanism,” 10 CFR Parts 30, 40, and 70 amendments (59 FR 1618) that became effective January 28, 1994.
- “Timeliness in Decommissioning of Materials Facilities,” 10 CFR Parts 30, 40, and 70 amendments (59 FR 36026) that became effective August 15, 1994.
- “Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use,” 10 CFR Parts 30, 32, and 35 amendments (59 FR 61767 and 65243) that became effective January 1, 1995.
- “Low-Level Waste Shipment Manifest Information and Reporting,” 10 CFR Parts 20 and 61 amendments (60 FR 15649 and 25983) that became effective March 1, 1998. Note: The Commission delayed the effective date to March 1, 1998 so that the Agreement States could promulgate and implement these requirements at the same time.

These rule changes, as well as others, are in a package that has been under review by NYDL’s General Counsel’s office for approximately a year. The requirements in these rules are being implemented through license conditions as an interim measure. The review team recommends that NYDL management take appropriate action to move the rule package through the rule promulgation process. At the State exit meeting on May 12, 1998, the team was informed that this rule package was released from the General Counsel’s office and should be final by the end of 1998.

The NYDL has not yet adopted the following regulations, but intends to address them in timely rulemakings or by adopting alternate generic legally binding requirements:

- “Radiation Protection Requirements: Amended Definitions and Criteria,” 10 CFR Parts 19 and 20 amendments (60 FR 36038) that became effective August 14, 1995.
- “Clarification of Decommissioning Funding Requirements,” 10 CFR Parts 30, 40 and 70 amendments (60 FR 38235) that became effective November 24, 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 May 16, 1996.
- “Recognition of Agreement State Licensees in Areas Under Exclusive Federal Jurisdiction Within an Agreement State,” 10 CFR Part 150 amendment (62 FR 1662) that became effective January 13, 1997.

- “Licenses for Industrial Radiography and Radiation Safety - Requirements for Industrial Radiography Operations,” 10 CFR Parts 30, 34, 71 and 150 amendments (62 FR 28947 that became effective June 27, 1997).
- “Radiological Criteria for License Termination,” 10 CFR Part 20, 30, 40 and 70 amendments (62 FR 39058) that became effective August 20, 1997.

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

4.1.3 New York State Department of Health (NYSH) - Legislation and Program Elements Required for Compatibility

4.1.3.1 Legislation

Along with their response to the questionnaire, the NYSH provided the team with the opportunity to review copies of legislation that affect the radiation control program. Legislative authority for NYSH’s portion of the agreement with the NRC is granted in New York Public Health Law, Article 2, Title II, Sections 201 and 225. NYSH is responsible for regulating the medical, academic and research uses of radioactive materials. The review team noted that the legislation has not changed since being found adequate during the previous review, and found that the State legislation is adequate.

4.1.3.2 Program Elements Required for Compatibility

The NYSH Regulations for Control of Radiation, 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 apply to ionizing radiation, whether emitted from radionuclides or devices used for medical, academic, or research and development. NYSH requires a license for possession and use of all radioactive material, including naturally occurring radioactive materials, such as radium, and accelerator-produced radionuclides for medical, academic, or research and development. NYSH also requires registration of all equipment designed to produce x-rays or other ionizing radiations.

The team examined the procedures used in NYSH's regulatory process and found that it is a ten step process that takes approximately 12 to 18 months, depending on the complexity of the action.

The team evaluated NYSH's responses to the questionnaire and reviewed the regulations adopted by the State since the 1995 review to determine the status of the NYSH regulations under the Commission’s new adequacy and compatibility policy. The team noted that NYSH addressed the following NRC regulation amendments:

- “Termination or Transfer of Licensed Activities: Recordkeeping Requirements,” 10 CFR Parts 20, 30, 40, 61 and 70 amendments (61 FR 24669) that became effective on May 16, 1996.

The NYSH has decided to address the above decommissioning and financial assurance regulations with the use of license conditions. The NYSH identified nine licensees that are subject to the financial assurance requirements. NYSH has imposed license conditions on five of these licensees and has requested information from the others so that appropriate conditions can be developed. The team reviewed the license conditions and verified that they are being used. Additional license conditions addressed the timeliness and records retention requirements in that the licensees must submit a decontamination plan to NYSH for approval 90 days prior to ceasing operations and must keep all records of spills and incidents until the license is terminated. The team considers these license conditions adequate implementation of the intent of the decommissioning and financial assurance rules.

- “Emergency Preparedness for Fuel Cycle and Other Radioactive Materials Licensees,” 10 CFR Parts 30, 40 and 70 amendments (54 FR 14051) that became effective April 7, 1990. The team reviewed the assessment done by NYSH and agree that they do not have any licensees that are subject to this requirement. Therefore, they have not adopted this rule.
- “Licensing and Radiation Safety Requirements for Irradiators,” 10 CFR Part 36 (58 FR 7715) that became effective July 1, 1993. The NYSH authority in this area would only apply to large research irradiators not commercial operations. Therefore, NYSH has not adopted 10 CFR Part 36 equivalent regulations, but has licensed a facility using the safety requirements in their Part 16.12(f), which are equivalent to the requirements moved from 10 CFR Part 20 to Part 36 when it was promulgated. In addition to these safety requirements, NYSH has imposed the other Part 36 requirements through license conditions. The team found this approach acceptable.
- “Notification of Incidents,” 10 CFR Parts 20, 30, 31, 34, 39, 40 and 70 amendments (56 FR 64980) that became effective October 15, 1991. The team reviewed the requirements in Part 16.15 and identified that they do not fully address the notification requirements in this rulemaking. The NYSH indicated that they would review this issue further.
- “Frequency of Medical Examinations for Use of Respiratory Protection Equipment,” 10 CFR Part 20 amendment (60 FR 7900) that became effective March 13, 1995. At this time, the NYSH does not have any licensees that use respiratory protection equipment. They are considering this rule in the next rule amendment package.
- “Medical Administration of Radiation and Radioactive Materials,” 10 CFR Parts 20 and 35 amendments (60 FR 48623) that became effective October 20, 1995. The team reviewed the requirements in Parts 16.123 and 16.7 and found that the objectives of the rule had been adopted.
- “Criteria for the Release of Individuals Administered Radioactive Materials,” 10 CFR Parts 20 and 35 amendments (62 FR 1662) that became effective May 29, 1997. The team reviewed the requirements in Parts 16.123 and 16.7 and found that the objectives of the rule had been adopted.

The NYSH has not yet adopted the following regulations, but intends to address them in timely rulemakings or by adopting alternate generic legally binding requirements:

- “Radiation Protection Requirements: Amended Definitions and Criteria,” 10 CFR Parts 19 and 20 amendments (60 FR 36038) that became effective August 14, 1995.
- “Recognition of Agreement State Licensees in Areas Under Exclusive Federal Jurisdiction Within an Agreement State,” 10 CFR Part 150 amendment (62 FR 1662) that became effective January 13, 1997.
- “Radiological Criteria for License Termination,” 10 CFR Part 20, 30, 40, and 70 amendments (62 FR 39058) that became effective August 20, 1997.

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

4.1.4 New York State Department of Environmental Conservation (NYDEC) - Legislation and Program Elements Required for Compatibility

4.1.4.1 Legislation

Along with their response to the questionnaire, the NYDEC provided the review team with the opportunity to review copies of legislation that affect the radiation control program. Legislative authority to create an agency and implement a portion of the agreement with the NRC is granted in New York State Environmental Conservation Law Articles 1, 3, 17, 19, 27, and 29. The NYDEC is designated as the agency responsible for effluents from licensed facilities and environmental contamination as its portion of the State's radiation control program. The review team noted that the legislation has not changed since being found adequate during the previous review, and found that the State legislation is adequate.

4.1.4.2 Program Elements Required for Compatibility

The NYDEC Regulations for Control of Radiation, found in Title 6, Parts 380, 381, 382, and 383 of the New York Codes, Rule, and Regulations (NYCRR) apply to environmental releases and the disposal of radioactive materials. The NYDEC requires a permit for release of radioactive materials to the environment including the disposal of radioactive materials, including naturally occurring materials, such as radium, and accelerator-produced radionuclides.

The team examined the procedures used in NYDEC's regulatory process and found that it is a eight step process that takes approximately 12 to 18 months. The team evaluated NYDEC's responses to the questionnaire and reviewed the regulations adopted by the State since the 1995 review to determine the status of the NYDEC regulations under the Commission's new adequacy and compatibility policy. The team found that the State addressed the following NRC regulation amendments:

- “Low-Level Waste Shipment Manifest Information and Reporting,” 10 CFR Parts 20 and 61 amendments (60 FR 15649 and 25983) that became effective March 1, 1998. The NYDEC adopted this rule by reference on July 9, 1997. The team noted that the reference listed in Section 381.18 was as of January 1, 1996. Subsequent changes were made to the regulation that are not incorporated by reference. The NYDEC will adopt the more recent regulation by reference at the next opportunity to change the rule.

- “10 CFR Part 71: Compatibility with the International Atomic Energy Agency,” 10 CFR Part 71 amendments (60 FR 50248 and 61 FR 28724) that became effective April 1, 1996. The NYDEC has adopted the DOT and NRC transportation regulations by reference on July 9, 1997; therefore, no further action is required to make this regulation effective on NYDEC permittees. The team noted that the incorporation by reference was as of January 1, 1996 which does not include the corrected tables which were published in 1996. In addition, NYDEC reference includes those items that are limited to NRC implementation. The NYDEC is reviewing these issues and will address them in a future rulemaking, if necessary.

The NYDEC has not yet adopted the following regulations, but intends to address them in timely rulemakings or by adopting alternate generic legally binding requirements:

- “Radiation Protection Requirements: Amended Definitions and Criteria,” 10 CFR Parts 19 and 20 amendments (60 FR 36038) that became effective August 14, 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 May 16, 1996.
- “Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act,” 10 CFR Part 20 amendment (61 FR 65119) that became effective January 9, 1997.
- “Criteria for the Release of Individuals Administered Radioactive Materials,” 10 CFR Parts 20 and 35 amendments (62 FR 1662) that became effective May 29, 1997.
- “Radiological Criteria for License Termination,” 10 CFR Parts 20, 30, 40 and 70 amendments (62 FR 39058) that became on effective August 20, 1997.

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

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

The NYDL has the responsibility for commercial and industrial use of radioactive materials; therefore, NYDL is the only New York program that has responsibility for SS&D evaluations and is the only program reviewed under this indicator. In assessing NYDL’s SS&D evaluation program, the team examined information provided by the NYDL in response to the IMPEP questionnaire on this indicator. A review of all completed SS&D evaluations and supporting documents covering the review period was conducted. The team interviewed the staff and supervisor responsible for SS&D evaluations, and examined the staff’s use of new guidance documents and procedures.

Since the last program review, NYDL completed one SS&D evaluation in 1997, which involved a static eliminator. NYDL has performed few SS&D reviews due to the limited number of manufacturers (currently 3 licensees) in New York. The previous SS&D review was performed over 6 years ago. Due to the infrequent number of SS&D reviews and types of designs of the SS&Ds manufactured in the State (static eliminators, small beta gauges, and tritium signs), NYDL indicated that their SS&D program efforts are at a level that is consistent with the number

and types of designs of the SS&Ds manufactured by their licensees. Since only one action was processed by the State during the review period, the team's basis for assessing the adequacy of the overall SS&D program was limited.

The NYDL identified a number of guidance documents to assist in the review of SS&Ds. These include NRC's NUREG-1550, "Standard Review Plan for Applications for Sealed Source and Device Evaluations and Registrations;" Regulatory Guide 6.9, "Establishing Quality Assurance Programs for the Manufacture and Distribution of Sealed Sources and Devices Containing Byproduct Material;" Policy & Guidance Directive 84-22, Revision 1, "What Source and Device Designs Require an Evaluation;" and a February 2, 1996 memorandum, containing draft regulations covering the licensing of manufacturers or initial transfers of products containing sealed sources to general licensees, issued as standard reviewer guidance. Staff uses the checklist from NUREG-1550 in the review of SS&Ds to determine completeness of the review. Also, the NYDL has available a number of additional guidance documents including national and international standards, various regulatory guides, and SS&D workshop manuals. NYDL also has recently received NUREG-1556, Volume 3, "Applications for Sealed Source and Device Evaluation and Registration," and indicated that they will incorporate it into their review procedures.

4.2.1 Technical Quality of the Product Evaluation Program

The team examined the one new SS&D registration certificate action and a "custom" product evaluation along with their supporting documentation. Case-specific comments for the one SS&D registration certificate issued by the NYDL are listed in Appendix F. The review team suggests that NYDL consider the comments identified in Appendix F and take action as NYDL deems appropriate.

Staff interviews indicated that the current NYDL SS&D policies and procedures were not always used or followed during the SS&D review. The team noted three items in particular, based on the interviews with staff:

- The SS&D reviewers were aware that requirements existed for persons who manufacture or initially transfer products to persons generally licensed and were aware of the February 2, 1996, memorandum. However, the SS&D reviewers did not follow this guidance and use the draft regulations during their review.
- Not all staff were aware of, or completely understood, the policy for reviewing Quality Assurance and Quality Control (QA/QC) programs for manufacturers and distributors of SS&Ds as part of licensing and during inspections using the SS&D QA/QC guide.
- Both reviewers placed primary emphasis on the use of the checklist in NUREG-1550 as an all inclusive review document and placed less emphasis on its use as a guide to identify areas requiring additional detailed review.

The team recognized that the NYDL program has a small subset of the types of sources and devices covered by the NRC guidance documents and procedures. The development of custom procedures based on the NYDL regulatory needs and practices would clarify the review process. The review team recommends NYDL establish and use customized procedures for conducting SS&D reviews based on the guidelines presented in the SS&D Workshop and tailored to NYDL's types of SS&Ds, specific policies, requirements, and regulations. The guidelines should also

identify what actions NYDL would take in the event they receive an SS&D request that is outside of those covered by the customized procedures.

There was not a consensus among the NYDL reviewers and management as to what constitutes a concurrence review and none of them indicated an understanding consistent with MD 5.6. The concurrence review performed for the registration certificate relied heavily on the work of the first reviewer and the completeness of his review (as indicated by the checklist). The NYDL's practice of allowing the reviewers to work closely and jointly on the safety evaluations tends to preclude the independence of the concurrence reviews. The review team recommends that NYDL establish a clear policy for what constitutes a concurrence review in accordance with guidelines in Management Directive 5.6.

4.2.2 Technical Staffing and Training

The NYDL reported that two staff members currently have authority to conduct and sign SS&D evaluations. The Supervisor is responsible for oversight of the SS&D evaluation program, but does not perform technical evaluations of SS&D actions. However, it is standard practice for the Supervisor to review all documents (including SS&D certificates) prior to issuance. Both reviewers have science degrees at either the bachelors or masters level with additional training in health physics. Both reviewers have attended NRC's SS&D Workshop and staff are well trained in health physics principles. Neither staff member, however, has previous on-the-job experience performing safety evaluations of products and through interviews, the team learned that neither staff member has formal training or prior design analysis experience in all areas listed in MD 5.6. To address this issue, the Supervisor indicated that the use of qualified engineering staff in another division has been proposed and was under consideration. This option was used with limited success during the "custom" review. The Supervisor indicated that the process for requesting additional technical assistance with engineering subjects was also under review and possible revision. In addition, NYDL indicated that hiring additional reviewers who already have demonstrated qualifications to perform SS&D reviews would not be cost effective given NYDL's current budget and workload.

The team identified that there is no formal written process for authorizing reviewers to perform safety evaluations and sign completed SS&D registration certificates, nor for a formal determination of a reviewer's qualifications to perform all areas of an evaluation prior to obtaining signature authority. The NYDL practice for granting signature authority is to assign signature authority to persons who both meet the minimum criteria for a materials licensing reviewer and have also attended an NRC SS&D Workshop. No further evaluation of the reviewers' qualifications is performed to ensure they meet the criteria in MD 5.6. The team noted the purpose of the criteria in MD 5.6 is to ensure that the initial evaluation, and concurrence review, are performed by two qualified individuals. The team also discussed the importance of having a formal, qualification program in the SS&D area.

The review team recommends that NYDL develop a written formal SS&D training and qualification program including minimum qualifications for signature authority. The program should ensure that reviewers meet the qualifications listed in MD 5.6, as applicable to their program and commensurate with the scope and complexity of the SS&Ds manufactured by their licensees. As appropriate for the complexity of the SS&Ds manufactured by NYDL's licensees, SS&D reviewer training should include the following subject areas as a minimum:

- engineering materials and their properties and uses

- reading and understanding engineering drawings and blueprints
- understanding the interrelationship of conditions of use and prototype testing, and
- interpreting test results (e.g., prototype and performance testing)

The program should also include a demonstration by reviewers of their ability to apply these qualifications and use applicable requirements and review guidance appropriately during SS&D evaluation. Because NYDL receives so few SS&D evaluation requests, the team concluded it does not have sufficient casework to conduct such a demonstration for the existing staff through an in-house program.

The review team recommends that NYDL 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 in the areas listed in Section 4.2.2. This training should provide the reviewers with sufficient knowledge and understanding of these areas to perform adequate SS&D safety reviews commensurate with the types, complexity, and radiation hazards associated with the SS&Ds. The team indicated that on-the-job training, which includes review critiques by more experienced SS&D reviewers, could be used to gain additional experience in conducting reviews. The team indicated that this training would be offered by the Branch within NRC responsible for performing SS&D reviews; experience indicates that two weeks per reviewer is necessary. This type training could provide the reviewers additional understanding and experience in applying SS&D procedures and applicable regulations, and additional understanding of the application of basic engineering principles as they apply to SS&D reviews. Alternatively, NYDL could obtain additional needed expertise from other appropriately qualified organizations on a case-by-case basis. The option of requesting engineering technical assistance from NRC or other Agreement States was also discussed during the MRB meeting.
- b. If NYDL 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.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

The NYDL reported one incident involving a product failure. This incident involved a Troxler portable moisture density gauge. A user reported that the tip of the source rod fell off following a measurement. The manufacturer was made aware of the incident and conducted an investigation. The manufacturer concluded that the failure was caused by abuse and lack of maintenance and was not a generic issue. The incident file did not indicate whether the NYDL agreed with this determination, but the NYDL took actions against the licensee to emphasize the importance of following appropriate use and maintenance instructions. In addition, the NYDL sent a notice to all of its portable moisture density gauge licensees also emphasizing this importance and modified NYDL's inspection procedures to add a review of maintenance records for inspections of portable moisture density gauge licensees. The team examined the NYDL's evaluation of this incident, and determined that relevant issues were addressed.

The IMPEP team members were unable to reach consensus on the rating for this indicator. Based on the IMPEP evaluation criteria in MD 5.6, the reviewer of this indicator recommended NYDL's performance be found unsatisfactory and the team leader recommended the

performance rating be found satisfactory with recommendations for improvement. When IMPEP team consensus on an indicator rating is not achievable, the team leader recommendation is used as the rating of record. During the MRB meeting on September 1, 1998, the MRB requested that the team revise appropriate portions of the SS&D section to reflect the meeting discussions. Much of those MRB discussions were directed at understanding NYDL's position that the rating for the SS&D non-common indicator should be satisfactory because of their performance in the one review that was completed. The review team considered the additional information presented at the MRB and, while there was some support for adopting the NYDL's position, the majority recommends, based on MD 5.6, that the rating of satisfactory with recommendations for improvement be retained. Additionally, the MRB concurred with the NRC's staff initiative to review the guidance in MD 5.6 for the SS&D non-common indicator, after the Organization of Agreement States completes its planned IMPEP-like assessment of NRC's SS&D program. The NYDL should consider this revision to MD 5.6 prior to developing any of the guidance recommended by the review team.

4.3 Low-Level Radioactive Waste (LLRW) Disposal Program

The New York State Department of Labor (NYDL) and the New York State Department of Environmental Conservation (NYDEC) split responsibilities for the low-level radioactive waste program in the State of New York. NYDL is responsible for the occupational exposure of individuals and control of radioactive material as it affects occupational exposures. This includes the on-site radiation control program. NYDEC is responsible for all environmental releases and the permitting of the disposal units (design, construction, and operation of the disposal facility). This includes waste package receipt and inspection and temporary storage of waste prior to emplacement in waste disposal units.

The State of New York has stopped activities for siting a commercial low-level waste disposal site. Therefore, the programs are not staffed nor prepared to process a new license application. The team finds this acceptable given the status of the LLRW siting process. The State does have two former radioactive waste disposal sites: The State Licensed Disposal Area (SDA) at West Valley, and the Radiation Disposal Site (RDS) at Cornell University.

The SDA is a portion of the West Valley Nuclear Services Center site and was operated as a commercial radioactive waste disposal site. The site ceased operations in 1975, and has been under State ownership and control. The New York State Energy, Research, and Development Authority (NYSERDA) is the State agency responsible for the site and is permitted by NYDEC and licensed by NYDL. NYDEC has issued three permits to NYSERDA for this site. One air emissions permit, one Research and Development (R&D) permit for the cover design study, and the disposal permit that limits the discharges from the disposal area itself. Now that the testing phase of the cover study is completed, the R&D permit will soon be combined with the disposal permit. NYDEC inspects the site on an annual basis with NYDEC staff and visits the site on a much more frequent basis. The team reviewed the latest inspection report (June 4, 1997, see D-4) and found the inspection thorough and timely. The disposal area has been covered with the R&D cover or a synthetic membrane cover. The State is monitoring the water levels in the trenches to determine the effect of the covers. The NYDL is responsible for the occupational activities at the site due to a storage building with a small amount of LLRW being stored. The NYDL inspects the site on an annual basis to determine if the materials are properly stored and if the licensee has maintained an acceptable radiation protection program. The NYDL has conducted these inspections during the review period.

The Cornell disposal site dates back to the early radiation programs through the mid-1970's. The NYDL has no responsibility at this site since it was not a commercial disposal site, Cornell holds a radioactive materials license from the NYSH. The site is being remediated through a consent order with a sister Bureau within the NYDEC other than the Bureau of Pesticides and Radiation (BPR). The consent order includes the requirements that would be imposed by a permit from BPR. Upon completion of all activities under the consent order, BPR will issue a permit for the ongoing monitoring activities for this site. The site has been partially remediated by covering the waste disposal area with a synthetic cover and a layer of soil to protect the synthetic cover. There is still ground water remediation needed for non-radiological contamination at the site. The Cornell site is inspected on an annual basis. The team reviewed the last inspection and determined that the scope and quality of inspection was appropriate.

Based on the IMPEP evaluation criteria, the review team recommends that NYDL's and NYDEC's performances with respect to the indicator, Low-level Radioactive Waste Disposal Program, both be found satisfactory.

5.0 SUMMARY

As noted in Sections 3 and 4 above, the review team, following review by the MRB for three of the programs, found that the performance of the four New York agreement programs with respect to each of the performance indicators to be mixed with 23 satisfactory, and 4 satisfactory with recommendations for improvement. The most significant concerns were associated with the NYCH program. Accordingly, the review teams original recommended finding for the New York program, adequate, but needs improvement, and compatible with NRC's program, was changed by the MRB to a preliminary finding of adequate to protect public health and safety and compatible with NRC's program. This preliminary finding was re-evaluated at the September 1, 1998 MRB meeting for the fourth program (NYDL) and the MRB finalized the overall finding to be adequate to protect public health and safety and compatible with the NRC's program. The review team recommends that a follow-up review be scheduled in one year for the NYCH program to assess the progress of the program in implementing their responses to the recommendations in this report. At the September 1998 MRB meeting, the MRB did not object to the follow-up review for the NYCH program. The review team recommended that the next IMPEP review for the New York agreement program be in four years. The MRB agreed with this recommendation.

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

NEW YORK CITY DEPARTMENT OF HEALTH (NYCH)

RECOMMENDATIONS:

1. The review team recommends that the NYCH correct the software anomalies that limit NYCH's ability to effectively track licenses for inspection, set and adhere to yearly inspection goals, and communicate NYCH management's expectations with regard to inspection goals, such that NYCH is able to eliminate all overdue inspections. (Section 3.1.1)
2. The review team recommends that all initial inspections of licensees be performed within six months of license issuance or within six months of the licensee's receipt of material

- and commencement of operations, consistent with IMC 2800 and NYCH policy. (Section 3.1.1)
3. The review team recommends that NYCH inspectors follow the guidance in the NYCH inspection procedure manual which includes the information necessary for properly documenting violations. (Section 3.2.1)
 4. The review team recommends that NYCH inspectors follow the guidance in NYCH inspection procedure manual which emphasizes the use of performance-based inspection techniques rather than compliance-based techniques and provide training to its inspectors through NRC's Inspecting for Performance Materials Course or similar course. (Section 3.2.1)
 5. The review team recommends that NYCH 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. (Section 3.3.1)
 6. The review team recommends that NYCH review the staff's training against their training requirements, clearly document how the training was achieved, and acquire the necessary training, as appropriate. (Section 3.3.1)
 7. The review team recommends that NYCH notify NRC of significant reportable events and provide documentation for all reportable events both in accordance with SA-300. (Section 3.5.1)
 8. The review team recommends that NYCH place the regulatory changes agenda and establish specific schedules to address the regulatory changes in Section 4.1.1.2 within three years of the regulations becoming effective NRC rules. (Section 4.1.1.2)

SUGGESTIONS:

1. The review team suggests that NYCH establish a policy that the results of all Tribunals for their licensees be placed in the appropriate inspection files. (Section 3.2.1)
2. The review team suggests that NYCH consider documenting how the SS&D conditions of use were addressed for the two gamma knife licenses and will be addressed in future licensing action. (Section 3.4.1)
3. The review team suggests that NYCH list the date the licensing action is issued (date of fee payment) on the license and in their database, instead of the date of management signature. (Section 3.4.1)
4. The review team suggests that NYCH investigated incidents be clearly documented in the field notes at the next inspection. (Section 3.5.1)
5. The review team suggests that NYCH include written documentation that the allegor has been contacted regarding the results of NYCH's findings into the allegor's concerns. (Section 3.5.1)

NEW YORK STATE DEPARTMENT OF LABOR (NYDL)**RECOMMENDATIONS:**

1. The review team recommends that NYDL perform initial inspections of licensees within six months of the licensees' receipt of licensed material, or commencement of licensed activities. (Section 3.1.2)
2. The review team recommends that NYDL document its training program to include overall policy and minimum training requirements for both the licensing and compliance staff. (Section 3.3.2)
3. The review team recommends that NYDL notify NRC of significant reportable events and provide documentation for all reportable events both in accordance with SA-300. (Section 3.5.2)
4. The review team recommends that NYDL management take appropriate action to move the rule package through the rule promulgation process. (Section 4.1.2.2)
5. The review team recommends NYDL establish and use customized procedures for conducting SS&D reviews based on the guidelines presented in the SS&D Workshop and tailored to NYDL's types of SS&Ds, specific policies, requirements, and regulations. The guidelines should also identify what actions NYDL would take in the event they received an SS&D request that is outside of those covered by the customized procedures. (Section 4.2.1)
6. The review team recommends that NYDL establish a clear policy for what constitutes a concurrence review in accordance with guidelines in Management Directive 5.6. (Section 4.2.1)
7. The review team recommends that the NYDL develop a written formal SS&D training and qualification program including minimum qualifications for signature authority. (Section 4.2.2)
8. The review team recommends that NYDL 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 in the areas listed in Section 4.2.2. This training should provide the reviewers with sufficient knowledge and understanding of these areas to perform adequate SS&D safety reviews commensurate with the types, complexity, and radiation hazards associated with the SS&Ds. The team indicated that on-the-job training, which includes review critiques by more experienced SS&D reviewers, could be used to gain additional experience in conducting reviews. The team indicated that this training would be offered by the Branch within NRC responsible for performing SS&D reviews; experience indicates that two weeks per reviewer is necessary. This type training could provide the reviewers additional understanding and experience in applying SS&D procedures and applicable regulations, and additional understanding of the application of basic engineering principles as they apply to SS&D reviews.

Alternatively, NYDL could obtain additional needed expertise from other appropriately qualified organizations on a case-by-case basis. The option of requesting engineering technical assistance from NRC or other Agreement States was also discussed during the MRB meeting.

- b. If NYDL 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.

SUGGESTIONS:

1. The review team suggests that the NYDL management consider whether additional staffing is warranted when considering the impacts of the licensing and inspection workloads, the regulation development needs, and the SS&D program improvement needs. (Section 3.3.2)
2. The review team suggests that NYDL continue to audit their financial assurance files to ensure that they contain all required information and are current with NYDL requirements. (Section 3.4.2)
3. The review team suggests that, when each allegation is completed and closed out, NYDL update their allegation tracking system accordingly to reflect the actual status for all allegations. (Section 3.5.2)
4. The review team suggests that NYDL consider the comments identified in Appendix F, and take action as NYDL deems appropriate. (Section 4.2.1)

GOOD PRACTICES:

1. The review team noted a good practice in that NYDL's inspection field notes and inspection correspondence are peer reviewed by one of the senior inspectors to assure consistency, thoroughness, and quality of reports. (Section 3.2.2)

NEW YORK STATE DEPARTMENT OF HEALTH (NYSH)

RECOMMENDATIONS:

1. The review team recommends that NYSH modify to its 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 IMC 2800. (Section 3.1.3)
2. The review team recommends that NYSH notify NRC of significant reportable events and provide documentation for all reportable events both in accordance with SA-300. (Section 3.5.3)

SUGGESTIONS:

1. The review team suggests that NYSH's inspection documentation of exit meetings should contain substantive discussions of issues with the Radiation Safety Officer (RSO) and/or licensee management. (Section 3.2.3)
2. The review team suggests that NYSH incorporate a field for documentation of interviewing ancillary personnel, authorized users, technicians, and RSOs into their field notes. (Section 3.2.3)
3. The review team suggests that the NYSH inspectors attend additional training in inspecting for performance techniques. (Section 3.2.3)

GOOD PRACTICES:

1. The review team considers monthly TeleVideo conferences to be a good practice to bring and keep their staff current on health physics and program issues. (Section 3.3.3)

NEW YORK STATE DEPARTMENT OF ENVIRONMENTAL CONSERVATION (NYDEC)

RECOMMENDATIONS:

1. The review team recommends that NYDEC document its training program to include overall policy and minimum training requirements for both the permitting and compliance staff. (Section 3.3.4)
2. The review team recommends that NYDEC incorporate the handling of incidents and allegations into their inspection procedures. (Section 3.5.4)
3. The review team recommends that NYDEC 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)

SUGGESTIONS:

1. The review team suggests that NYDEC maintain one file for all types of incidents involving radioactive material. (Section 3.5.4)

LIST OF APPENDICES AND ATTACHMENTS

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Appendix D	D-1 NYCH License File Reviews D-2 NYDL License File Reviews D-3 NYSH License File Reviews D-4 NYDEC License File Reviews
Appendix E	E-1 NYCH Incident File Reviews E-2 NYDL Incident File Reviews E-3 NYSH Incident File Reviews E-4 NYDEC Incident File Reviews
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Attachment 3	NYDL Comment Letter on Revised SS&D Section and NRC Comment Analysis

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

New York City Department of Health, Bureau of Radiological Health (NYCH)

Name	Area of Responsibility
Dennis Sollenberger, OSP	Team Leader Technical Staffing and Training Legislation and Program Elements Required for Compatibility
Duncan White, RSAO, Region I	Response to Incidents and Allegations Technical Quality of Inspections
Michael Stephens, Florida	Technical Quality of Licensing Actions
Jamnes Cameron, Region III	Status of Materials Inspection Program Technical Quality of Inspections

New York State Department of Labor, Radiological Health Unit (NYDL)

Name	Area of Responsibility
Dennis Sollenberger, OSP	Team Leader Technical Staffing and Training Legislation and Program Elements Required for Compatibility Low-Level Radioactive Waste Disposal Program
Duncan White, RSAO, Region I	Technical Quality of Licensing Actions Technical Quality of Inspections
James McNees, Alabama	Response to Incidents and Allegations Technical Quality of Inspections
Douglas Broaddus, NMSS	Sealed Source and Device Evaluation Program
Lance Rakovan, OSP	Status of Materials Inspection Program

New York State Department of Health, Bureau of Environmental Radiation Protection (NYSH)

Name	Area of Responsibility
Dennis Sollenberger, OSP	Team Leader Technical Staffing and Training Legislation and Program Elements Required for Compatibility
Duncan White, RSAO, Region I	Status of Materials Inspection Program Response to Incidents and Allegations
Lee Cox, North Carolina	Technical Quality of Inspections
Jacqueline Cook, Region IV	Technical Quality of Licensing Actions

New York State Department of Environmental Conservation, Bureau of Pesticides and Radiation (NYDEC)

Name	Area of Responsibility
Dennis Sollenberger, OSP	Team Leader Technical Staffing and Training Legislation and Program Elements Required for Compatibility Low-Level Radioactive Waste Disposal Program
Duncan White, RSAO, Region I	Technical Quality of Licensing Actions Response to Incidents and Allegations Inspector Accompaniments
Allen Grewe, Tennessee	Status of Materials Inspection Program Technical Quality of Inspections

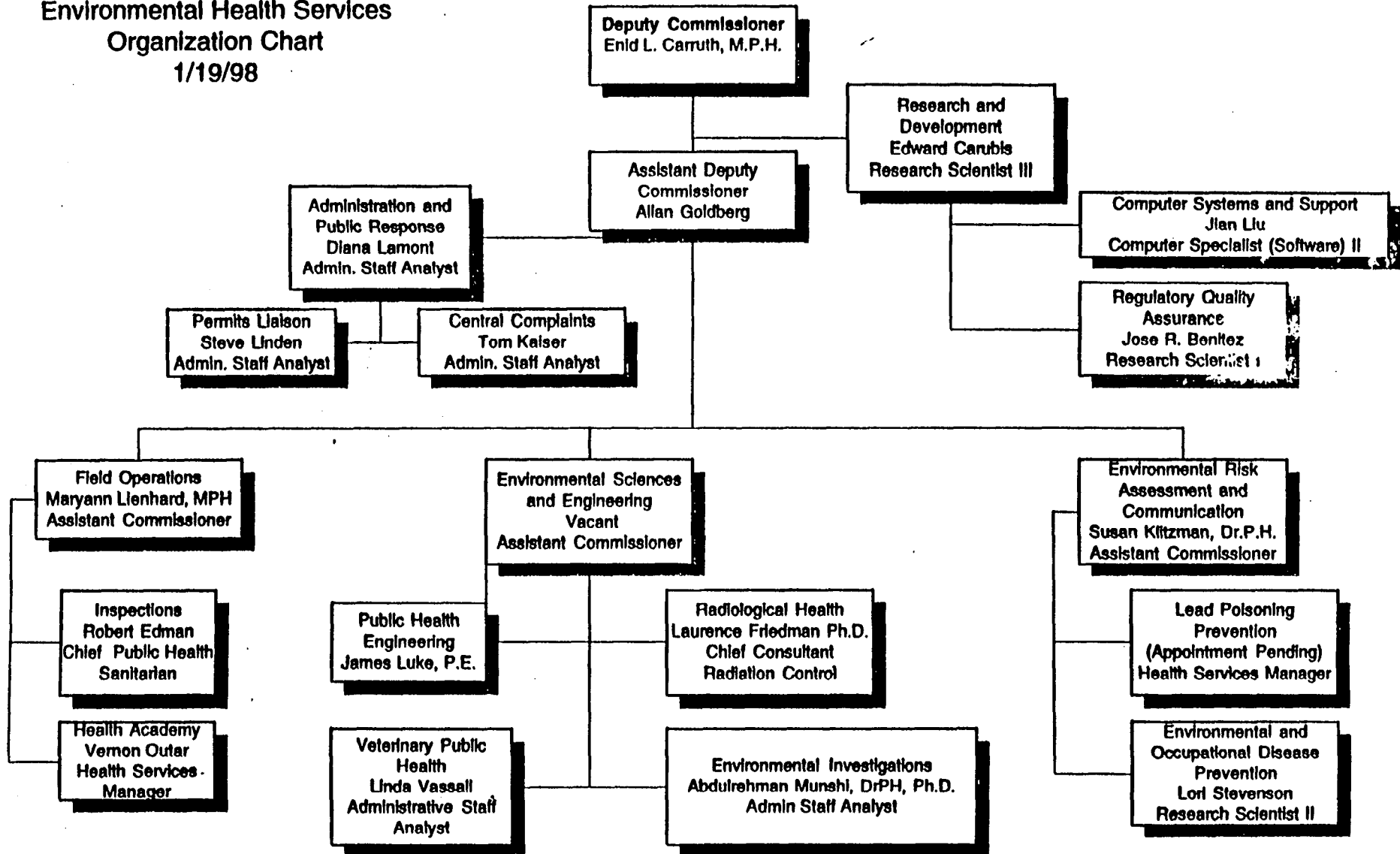
APPENDIX B-1

New York City

Department of Health, Bureau of Radiological Health (NYCH)

ORGANIZATION CHARTS

**Environmental Health Services
Organization Chart
1/19/98**



BUREAU OF RADIOLOGICAL HEALTH

APPENDIX A

Assistant Commissioner
Environmental Sciences

~~K. Collins~~ Vacant

Director
(Vacant)

as of 1/30/98

Deputy Director
K. Daniel (M-2)

Senior Physicist
J. Parisi

Asst. Director-Rad Equipt.
Senior Scientist
J. Aufrechtig

Principal Adm. Assoc.
(Vacant)

Licensing Unit
Research
Scientist
G. Miskin

Materials Inspection
Sr. Scientist
R. Borri

Senior Scientist

Scientist
M. Schnee

Scientist
K. Weiss

Reg/Billing Unit

Administrative Svcs Unit

~~Staff Analyst
M. Traub~~

Senior Scientist
Mathew
Thomas
Phillip

Assistant Scientist
K. Kalmykov
M. Myers
J. Scheffeld
E. Smith

Assistant Scientist
H. Ching
S. Prado
I. Santiago
C. Ramos

Rosy Riguer
Clerical Associate
TSA II (P/T)
P. Ritter

Secretary
I. Hernandez
Clerical Associate
R. Gonzalez
L. Itzkowitz
Crew Chief
P. Rosa

Scientist
R. Ford
D. Hayes
J. Bragg
R. Harmon

Scientist
B. Kamble
Assistant Scientist
A. Arafa
E. Cutler
T. Kirschenbaum
C. Seganich
V. Gorelsky

APPENDIX B-2

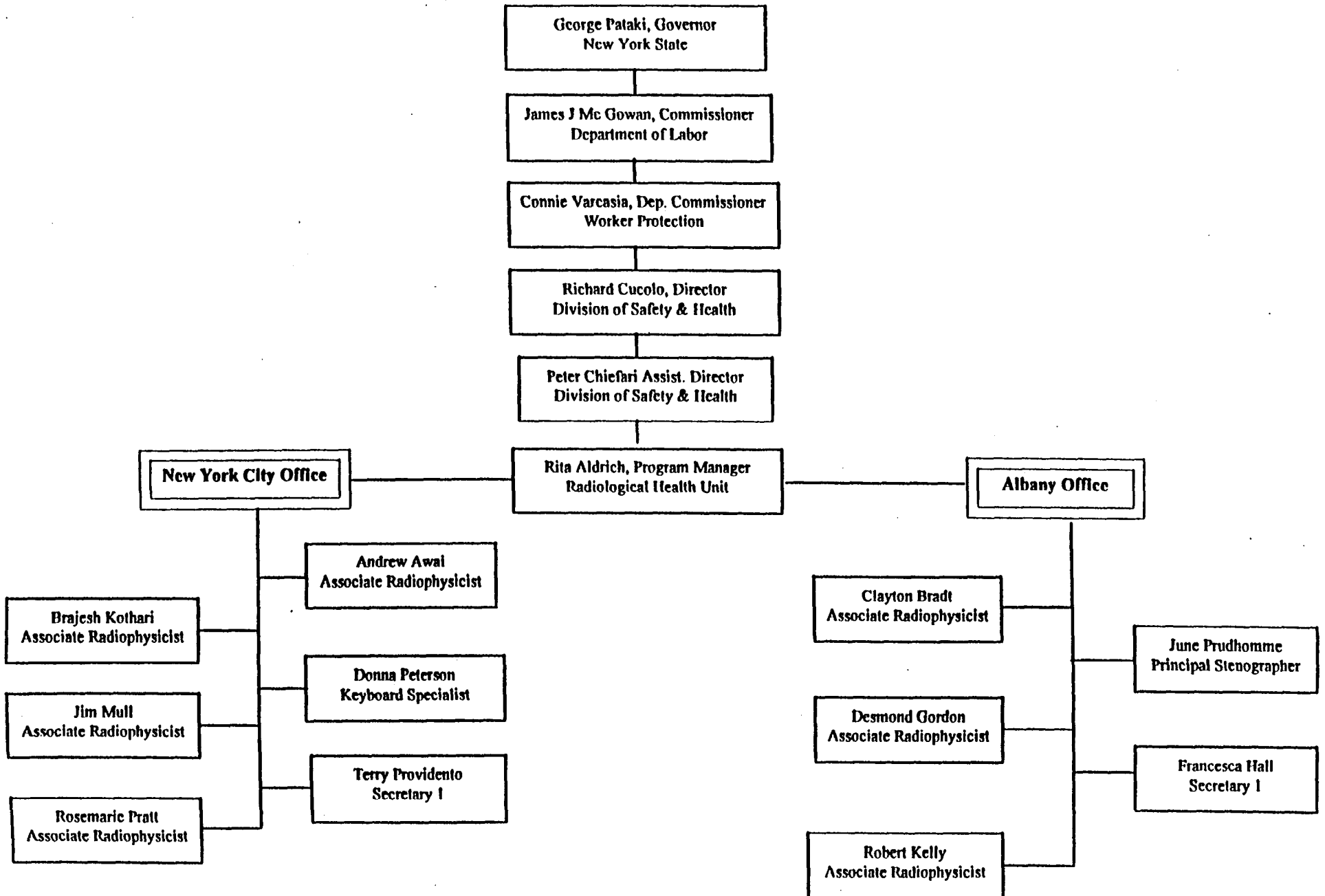
New York State

Department of Labor, Radiological Health Unit (NYDL)

ORGANIZATION CHART

New York State Department of Labor
Radiological Health Unit
Organizational Chart

February 1998



APPENDIX B-3

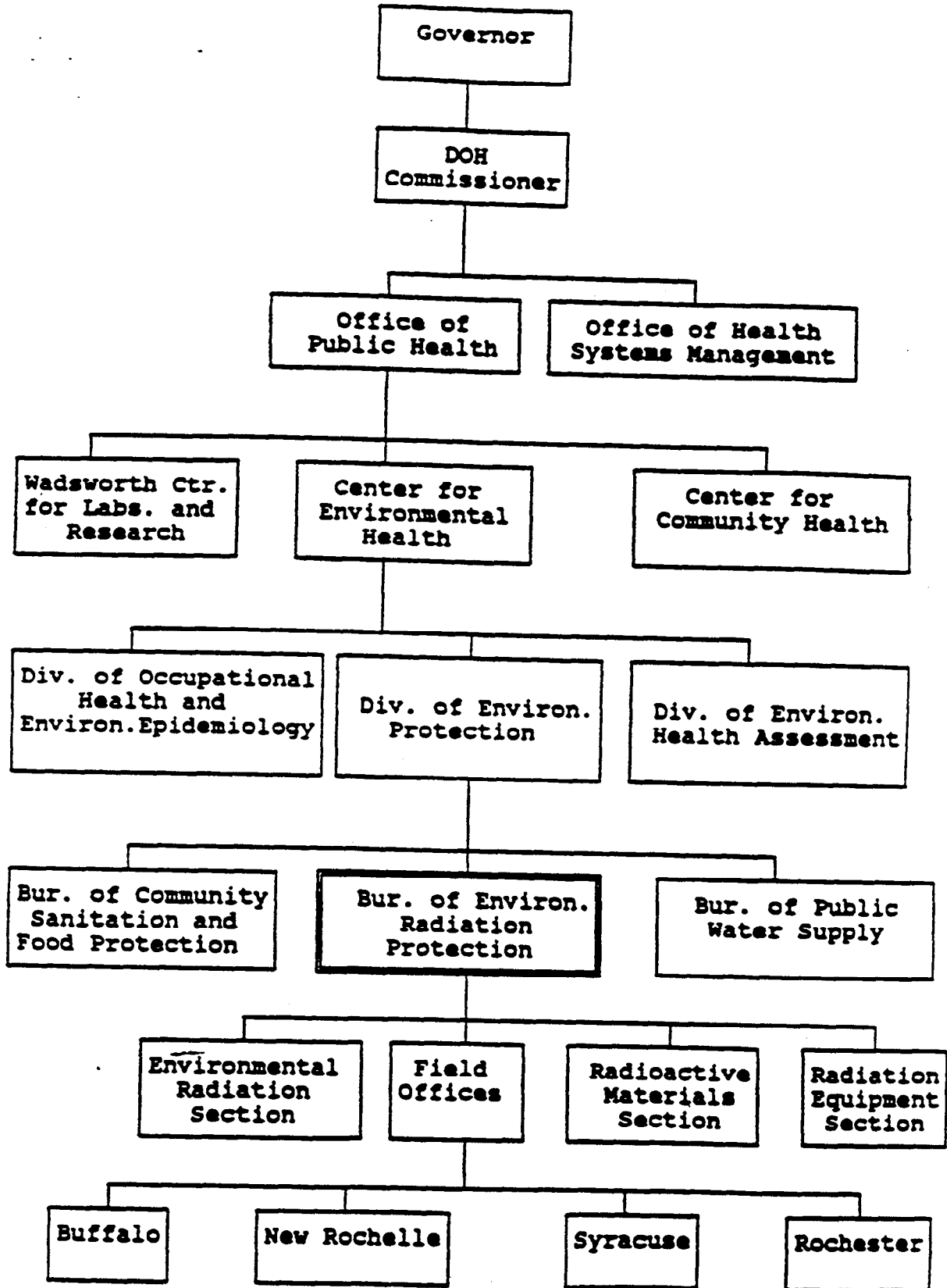
New York State

Department of Health, Bureau of Environmental Radiation Protection (NYSH)

ORGANIZATION CHARTS

ATTACHMENT II

Appendix B



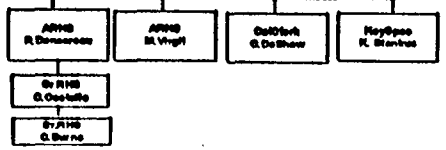
BUREAU OF ENVIRONMENTAL RADIATION PROTECTION

BUREAU DIRECTOR
KARIM RIMAWI

Secy. I
Frances Marshall

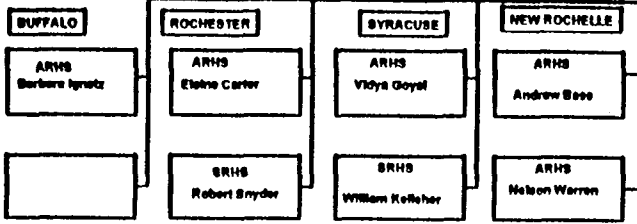
Materials Section

Section Chief
S. Davis



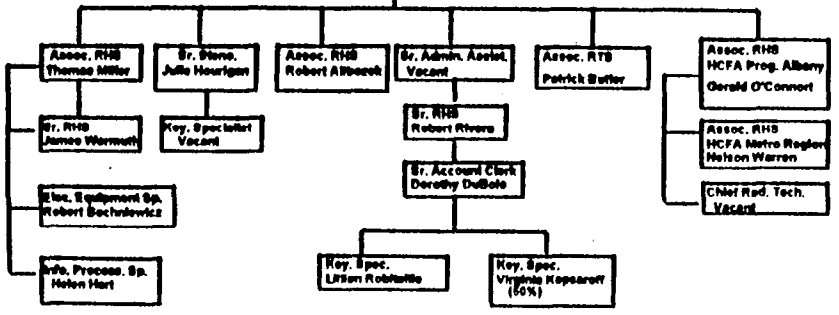
Inspection and Enforcement Section

PRHS
Gary Baker



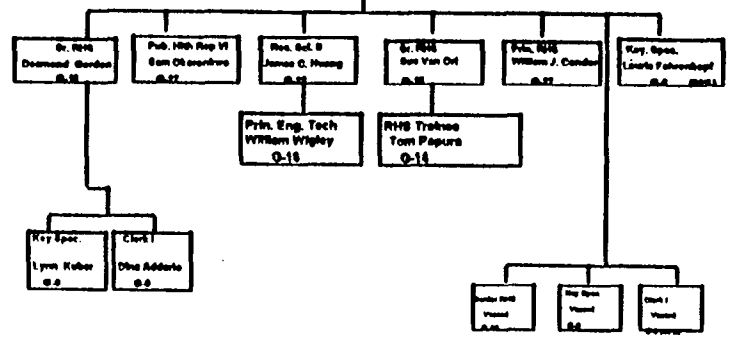
Radiation Equipment Section

Section Chief
Maryanne Harvey



Environmental Radiation Section

Section Chief
Res. Scientist V
Adela Salame-AMA Q-11



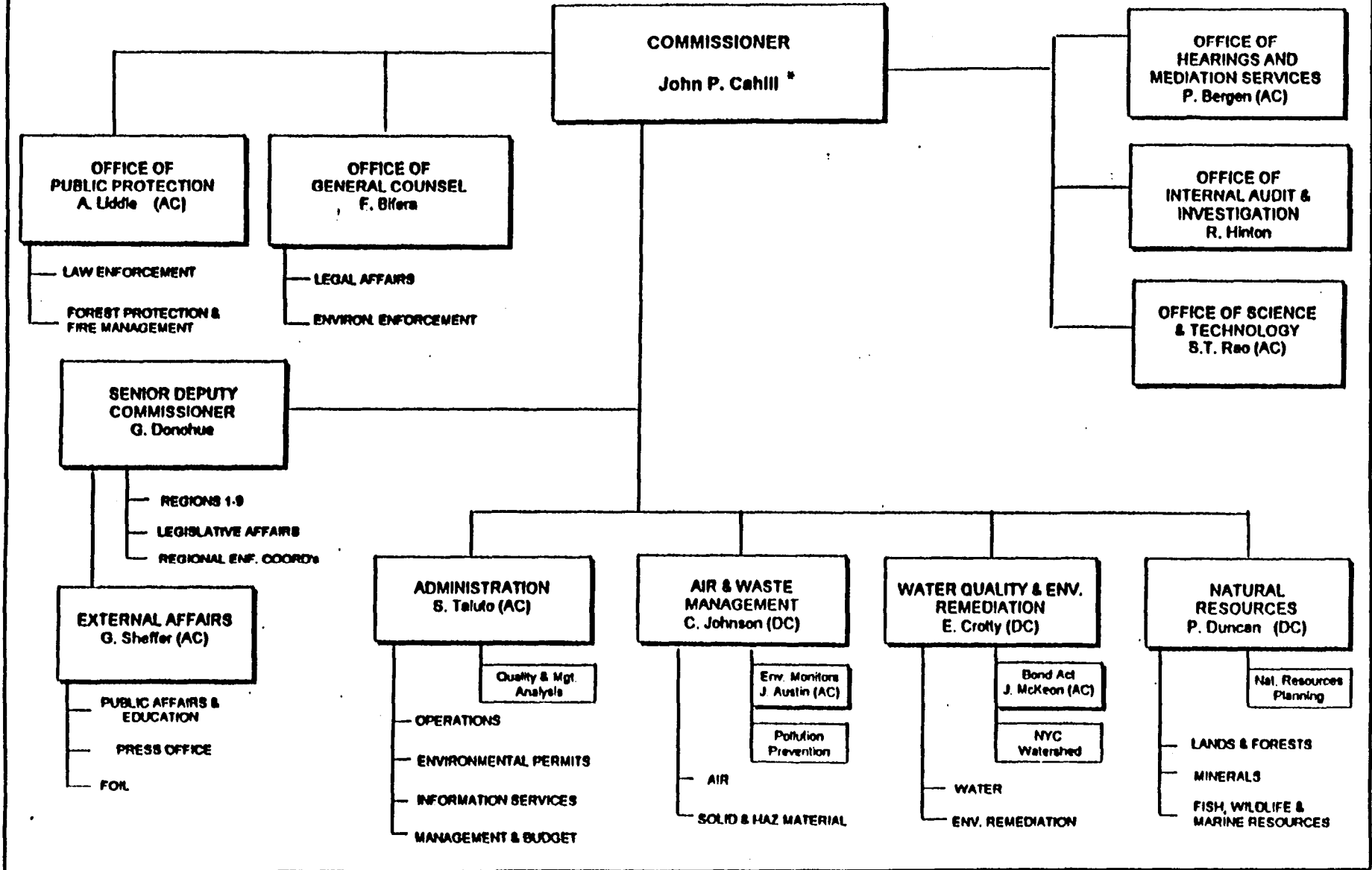
APPENDIX B-4

New York State

Department of Environmental Conservation, Bureau of Pesticides and Radiation (NYDEC)

ORGANIZATION CHARTS

New York State Department of Environmental Conservation
ORGANIZATION CHART (January 1998)



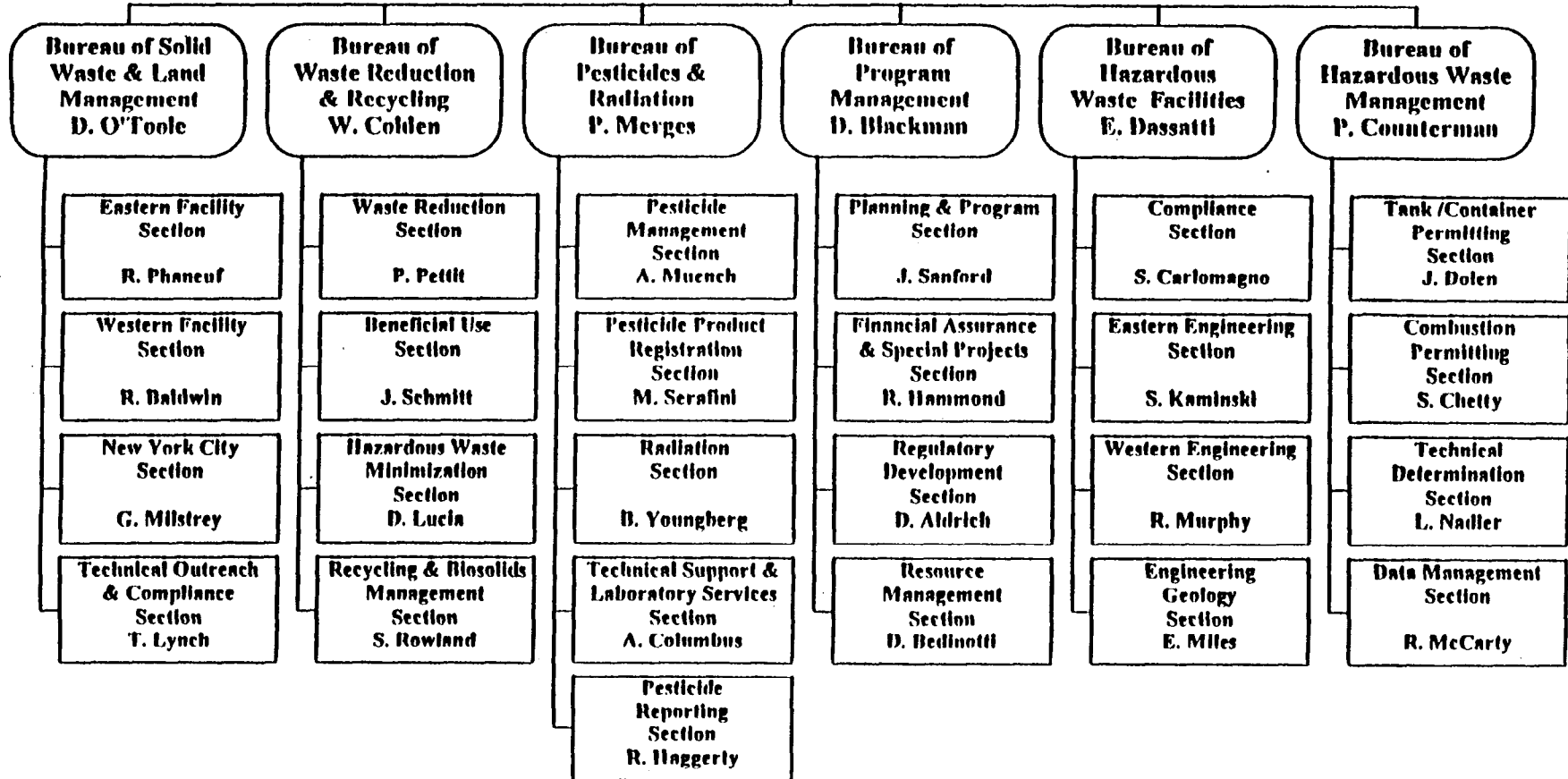
* Commissioner Cahill reports to Governor George Pataki

NEW YORK STATE DEPARTMENT OF ENVIRONMENTAL CONSERVATION
DIVISION OF SOLID & HAZARDOUS MATERIALS

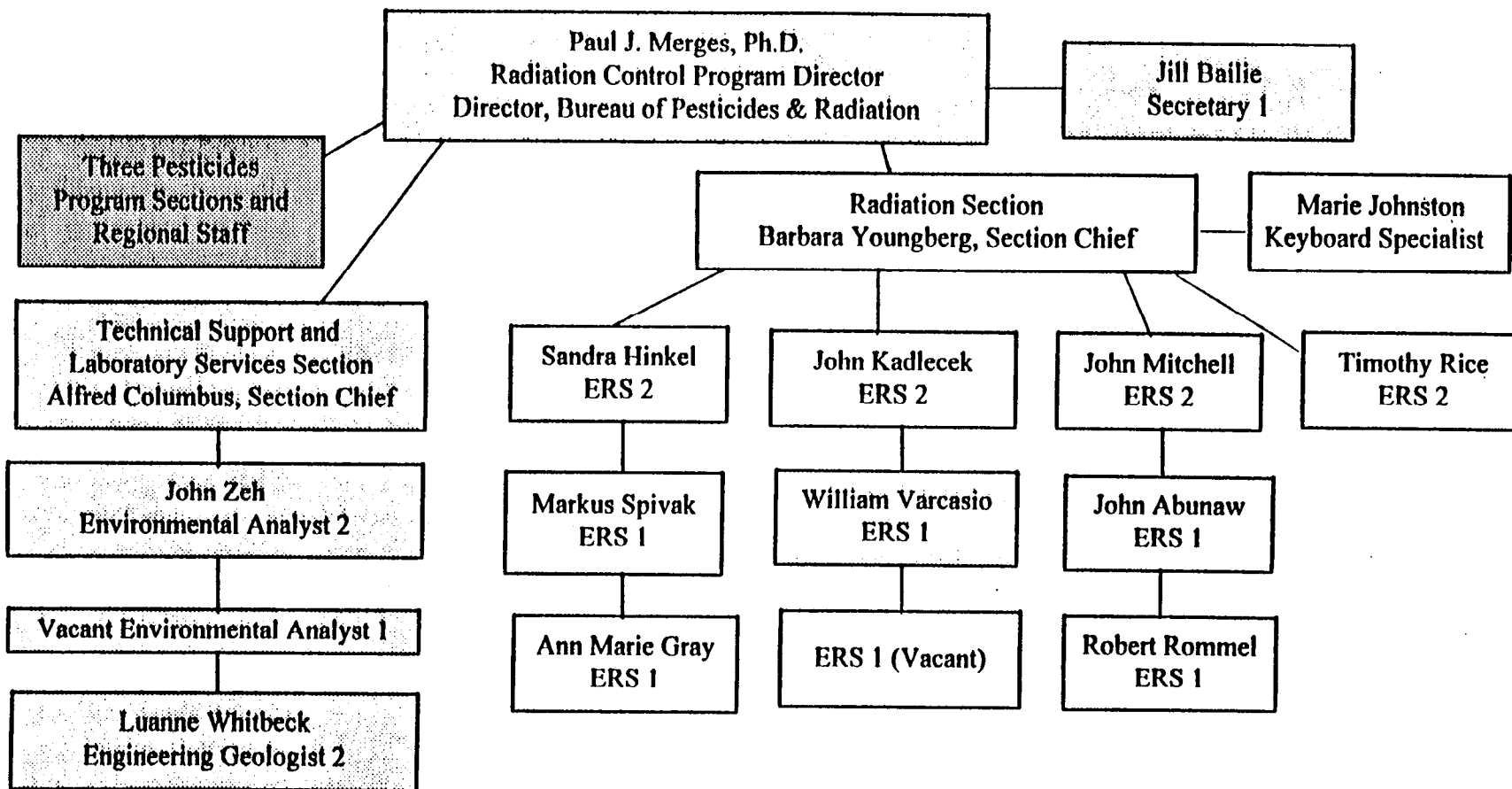
March 2, 1998

ACTING DIRECTOR
S. Hammond
ASST. DIRECTOR
J. Willson

DEC
REGIONS
1-9



Location of Radiation Program Staff in Bureau of Pesticides & Radiation



Radiation Program Staff

Less than full time in Radiation Program

Other than Radiation Program

Attachment 2

New York Programs' Comments on the Draft IMPEP Report

(Section 3.3.1)

5. The Bureau has had documentation of overall policy and minimum training requirements for its professional staff since the inception of the scientist titles. (See enclosure)
6. The Bureau maintains an ongoing Training Log for each Assistant Scientist, Scientist and Senior Scientist. This log includes all NRC courses, DOT courses, FEMA courses, seminars and in-house training these individuals participated in.

Please note that there is an error on page 16 of the draft team report in section 3.3.1, first paragraph. The compliance section supervisor is the senior scientist and the field supervisor is a scientist.

(Section 3.5.1)

7. The Bureau is unaware of any instance when a significant event occurring within New York City was not reported to NRC within 24 hours. Follow up documentation has been provided to Region 1 and/or Headquarters as appropriate. The NMED software has been installed in the Bureau's stand-alone PC connected to the Internet.

(Section 4.1 .I -2)

8. Bureau management and NYCDOH Office of General Counsel have been meeting to discuss upcoming rule-making requirements so that the three year time limits for adoption can be met.

We appreciate the effort that went into issuing this complicated draft team report in such a timely manner. If you or the review team members have any questions, please contact Mr. Kenneth Daniel, Deputy Director, at 212/676-1558.

Sincerely,



Neal 1. Cohen, M.D.
Commissioner

enc. "Assistant Scientist (Radiation Control) Notice of Examination 11124i82"

c c : B. Mojica, M.D,
A. Goldberg
G. Miskin
R. Borri

ASSISTANT SCIENTIST (RADIATION CONTROL)

EXAM. NO. 2046

NOTICE OF EXAMINATION
AMENDED NOTICE (11/24/82)

The Notice of Examination has been amended to delete the qualifying written multiple-choice test.

THE GENERAL PROVISIONS OF THE NOTICE OF EXAMINATION AND THE GENERAL EXAMINATION REGULATIONS OF THE DEPARTMENT OF PERSONNEL APPLY TO THIS EXAMINATION AND ARE PART OF THIS NOTICE OF EXAMINATION. THE GENERAL PROVISIONS AND THE GENERAL EXAMINATION REGULATIONS ARE POSTED AND COPIES ARE AVAILABLE IN THE APPLICATION SECTION OF THE DEPARTMENT OF PERSONNEL AT 49 THOMAS STREET, NEW YORK, N.Y.

The City of New York is an Equal Opportunity Employer.

FILING DATES: From October 6, 1982 through October 26, 1982. Application Forms may be filed in person or by mail. Either way, properly completed Application Forms **MUST BE RECEIVED BY THE LAST DATE FOR FILING.** Date of receipt, rather than date of postmark, will be controlling.

Experience Paper Form A must be filled out completely and in detail and filed with your Application.

TEST: There will be no competitive test other than an evaluation of your education and/or experience.

SALARY AND VACANCIES: The appointment rate for this position is \$20,903 per annum. There are vacancies in the Department of Health.

PROMOTION OPPORTUNITIES: Employees in the title of Assistant Scientist (Radiation Control) are accorded promotion opportunities, when eligible, to the title of Scientist (Radiation Control).

FILING FEE: \$15.00; payable when you submit your application. Checks or money orders should be made payable to the New York City Department of Personnel.

REQUIREMENTS

MINIMUM REQUIREMENTS: (a) A baccalaureate degree from an accredited college including or supplemented by 24 credits in physics, chemistry, biology, engineering or a related field plus one year of full-time paid professional experience in the field of health physics, radiological health, radiation physics or radiation hygiene; or (b) a master's degree in radiological health; or (c) education and/or experience which is equivalent to (a) and/or (b).

To verify course credits you will later be required to have your college send us an official transcript.

The minimum requirements must be met by the last date for filing of applications.

Candidates who were educated in countries other than the United States must file form DP-404 for evaluation of foreign education. Foreign education will be evaluated by the Department of Personnel to determine comparability to education received in domestic accredited educational institutions.

If, at the time of appointment interview, in the judgment of the appointing officer the candidate has not demonstrated sufficient ability to understand and be understood in English, the candidate, prior to appointment, must pass a qualifying English oral test conducted by the Department of Personnel. A candidate who fails the English oral test conducted by the Department of Personnel shall not be qualified for appointment.

JOB DESCRIPTION

DUTIES AND RESPONSIBILITIES: Under supervision, performs scientific work of moderate professional responsibility with respect to measurements associated with radiation hygiene and safety; performs related work.



STATE OF NEW YORK
DEPARTMENT OF LABOR
DIVISION OF SAFETY AND HEALTH
Radiological Health Unit
Building # 12, Room 134-A
State Office Building Campus
Albany, NY 12240

SS

July 27, 1998

Richard L. Bangart
U.S. Nuclear Regulatory Commission
11555 Rockville Pike
Rockville, Maryland 20852-2738

Dear Mr. Bangart,

We have received the June 24, 1998 draft report on the recent NRC evaluation of our program and have reviewed it for factual correctness, as requested.

Our comments regarding the factual accuracy of specific sections of the report are attached. However, we feel that it is also both appropriate and necessary to comment on a procedural problem that was evident during the evaluation, and which figures prominently in the draft report.

We found the Team Leader, Dennis Sollenberger, and his associate, Duncan White, to be highly professional in their conduct of our evaluation. They related to myself and my staff on a peer basis, and seemed quite comfortable with the concept that our policies and procedures need not be the same as NRC's in order for us to achieve equivalent or better performance outcomes: i.e., they placed primary emphasis on performance, in keeping with the new IMPEP process philosophy.

However, there was one area of the evaluation where this philosophy was conspicuously lacking, and this was in the review of our sealed source and device (SS&D) evaluation program by a member of NRC's SS&D evaluation unit. For some reason, this part of the review was not only not performance-based; it seemed to deliberately ignore performance. To begin with, we were told at all three levels of exit meetings for this review that the SS&D registration certificate for the only SS&D evaluation performed during the review period by our program was satisfactory, that applicable health and safety issues had been properly addressed and that our staff are capable, but could use more experience. In other words, our actual performance in this area during the review period had been satisfactory. However, we were also told that the NRC reviewer for this "performance" indicator who had spent the entire week analyzing

how our staff had approached this one evaluation, their first, wanted to find us unsatisfactory!

The reasons for his findings were incomprehensible to us at the time and remain incomprehensible. Although the draft report modifies his findings, as a result of the team leader's overriding opinion, it still asserts deficiencies in our SS&D program which are not supported by the facts or by the specific guidelines in Management Directive (MD) 5.6, and which are inconsistent with our actual performance.

For example: the draft report posits as an "issue" that neither of our SS&D reviewers "has a strong background, through formal training and prior experience, in the area of engineering design analysis." However, nowhere in MD 5.6 is this criterion given as a requirement or even as a guideline. MD 5.6 states only that evaluation of SS&D review staffing and training should be conducted in the same manner and as part of the Common Performance Indicator 3, except with a focus on training commensurate with the conduct of the SS&D reviews. It then goes on to state that staff should have a bachelor's degree or equivalent training in the physical and/or life sciences; should be able to understand and interpret prototype tests and results, to read and understand blueprints and drawings, and to understand and utilize basic knowledge of engineering materials and their properties - training and abilities which both of our reviewers have. MD 5.6 does not specify the means by which these abilities should be acquired, nor should it, and it most certainly does not require "formal training and prior experience, in the area of engineering design analysis." It is evident to us that a person who has had such specific "formal training and prior experience" will almost certainly be a graduate of an engineering program. It was equally evident during our IMPEP review that the NRC reviewer was using this criterion as his personal standard for judging our staffs technical training and experience. However, such personal preferences have no place in an objective evaluation of a program's performance. Nothing in the draft report supports a factual finding that our staff do not meet the criteria listed in MD 5.6 for SS&D review staffing and training, and we also note that our performance with regard to Common Performance Indicator 3 was found to be satisfactory.

We are also at a loss to understand the statement made in the draft report that "NYDL management has not put forth the effort to bring the SS&D program in line with the specific guidelines in management Directive (MD) 5.6." We meet every single one of the indicators for satisfactory performance that are listed in MD 5.6, as evidenced by our actual satisfactory performance, and this is a result of significant effort on our part.

We also disagree wholeheartedly with the report's statements that "The NYDL management does not feel that it is an efficient use of its resources to qualify and maintain qualification for staff in a discipline that is infrequently needed", and that "Neither staff member has any previous experience performing safety evaluations of products or similar types of evaluations, nor has worked in a related field." As stated above, our staff are "qualified" to perform the reviews in question, and they need not be engineers in order to competently perform such reviews. Also, radioactive materials

licensing, and health physics in general, is most definitely a "related field." Both reviewers are experienced licensing staff who have attended NRC's training on the conduct of SS&D evaluations, and who frequently review and critique SS&D certificates in the process of licensing companies to use sources and devices. Contrary to NRC's concept of these certificates as "approvals", we consider them simply to be sources of information, and can and do require additional safeguards during licensing if we consider it appropriate, as do the other NYS radioactive materials licensing agencies. In one case, the three NYS agencies required a device to be retrofitted with an additional safety feature before we even allowed NYS licensees to acquire and use it. Evaluating radioactive sources and devices is not a separate and unique discipline; it is, and has always been, a part of radioactive materials licensing and should not be a separate and "non-common" performance indicator for IMPEP reviews.

The current IMPEP approach fails to recognize that all states and, we assume, NRC regional offices perform "custom" SS&D evaluations, and they all respond to incidents and accidents involving source and device product failures. Yet only state programs that conduct non-custom SS&D evaluations have their "custom" evaluations reviewed under IMPEP, and only they are required to evaluate the root causes of defects and incidents regarding SS&D's under IMPEP (including SS&D's that they didn't evaluate). This is true regardless of the relative numbers of custom or non-custom evaluations performed by a state or region, or the number of product failures involving SS&D's that they may have investigated. Therefore, a state or region that may have performed a large number of custom SS&D evaluations (but no non-custom evaluations), and may have responded to a number of incidents involving SS&D product failures, during the IMPEP review period will not have its performance in these areas reviewed. However, the NYDL which performed one custom and one non-custom SS&D evaluation and responded to one SS&D product failure incident during the review period, had each of these three actions reviewed in exhaustive detail. This is neither fair nor equitable, and it does not promote the kind of uniform evaluation of state and regional programs, which is one of the stated purposes of the IMPEP process.

In summary, it appears that the SS&D portion of our program evaluation was conducted under the "old" rules for NRC evaluations, not the IMPEP approach; and that conclusions were based on how closely our way of achieving satisfactory performance paralleled NRC's way, rather than on the satisfactory performance outcome itself. It also appears that the current IMPEP approach of treating a program's competence to perform source and device evaluations as a non-common performance indicator is invalid, and unfairly fails to hold all programs to the same standards.

The attachment to this letter contains our specific factual objections to statements made in the draft report. However, we strongly urge that NRC management review the manner in which the SS&D component of IMPEP evaluations is being addressed by NRC staff; and especially whether staff are placing "primary emphasis on performance" as directed. Conversations with other Agreements State programs indicate that our experience is not unique, and that the approach being used for this one performance

July 27, 1998

indicator during IMPEP reviews is not performance-based. NRC management should also review and reevaluate the practice of treating evaluations of radioactive sources and devices, and investigation of source and device product failures as a performance indicator only for states that perform non-custom SS&D evaluations. This performance indicator clearly should apply to all Agreement States and NRC regional offices.

Sincerely,

A handwritten signature in black ink that reads "Rita Aldrich". The signature is written in a cursive style with a distinct loop at the end of the last name.

Rita Aldrich
Principal Radiophysicist

W f d h
Enc.

cc: Peter Chiefari

**NYDL Comments on June 24,1998
Draft IMPEP Report**

Section 3.1.2:

This section discusses the reciprocity inspections performed by the NYDL, and it states that we do not schedule reciprocity inspections consistent with any priority schedule, and goes on to say that we are focusing resources on inspection of our own licensees.

However, we should have brought to the reviewers' attention the fact that in June, 1994 we reduced our reciprocity limit to thirty days in a calendar year. As a result, the companies that performed work in NYS with any frequency were required to apply for and receive a license from NYS. This resulted in the issuance of 47 out-of-state licenses, and these licensees are scheduled for inspection at the same priority interval as our in-state licensees. Therefore, the companies we would be most concerned about, due to the scope of their operations in NYS, no longer operate under reciprocity and are inspected by this agency on a regular basis.

We would also like to make a comment on the draft report's statement that "reciprocity licensees should be inspected to assure the health and safety of both radiation workers as well as the public." Since any member of the public reading this statement might find it alarming, the statement should be deleted or appropriately qualified. "Reciprocity licensees" are inspected -by the agency that issued their license. We give reciprocity based on the understanding that such licensees are regulated by their licensing authorities as stringently as we regulate our licensees, including regular inspections by those authorities to assure that these companies operate in a manner that assures the health and safety of radiation workers and the public. Indeed, one of the purposes of the Agreement State Program is to provide a basis for confidence in granting reciprocity. We require advance notification by companies wishing to enter the state under reciprocity, to afford us the opportunity to inspect their operations if we so choose. This is a matter of discretion on our part - not a responsibility. Our first obligation is the inspection of companies licensed by this agency.

NRC should also consider the resource implications of their position on inspection of reciprocity licensees. If an industrial radiography licensee is inspected annually by a state that issued their license, and in the course of a year does work under reciprocity in three other Agreement States and in NRC jurisdiction, is it an intelligent use of limited resources to have them inspected four additional times in that year? The performance of reciprocity inspections is a matter that must be left to the judgment of the authority that grants reciprocity, and each authority must have the latitude to make its judgements based on its own priorities and the availability of resources.

Section 3.3.2:

This section states that our staffing and training will be impacted by recommendations made further on in the draft report for "significant additional training" of our SS&D staff. Since, as stated in our cover letter, our staff are already appropriately trained, we do not expect routine ongoing training in this area to impact on staffing resources.

The section also states that to be considered for a position in this program, an individual must have a bachelor's degree in science and at least one year of experience. This is incorrect in that a candidate must have three years of specific qualifying professional experience. Also, twenty-four graduate credit hours in radiological science may be substituted for up to one year of the experience.

The section also states that there is no written training policy although the program had committed in a memo to upper management to follow the recommendations of the NRUOAS Training Working Group Report, and goes on to state that one staff member should attend an industrial radiography course and that other staff desired additional training in internal dosimetry and the conduct of decommissioning surveys.

The program is located in the NYDL's Division of Occupational Safety and Health, and all programs in the Division prepare overall training plans, annual training plans and annual training and conference timelines. The report of the NRCIOAS Working Group was submitted to Division management as our program's overall training plan, and we have also submitted annual plans and timelines which are specific to the training planned for a particular year and also contain topical meetings and conferences we plan to attend. All formal training completed by program staff is documented in a computer database. On-the-job training is documented in signature cards signed by the mentoring staff person. These documents constitute our written training policies and plans.

Section 3.4.2:

This section comments on an NRC review of financial assurance documents submitted by licensees, especially one case in which a document was a copy rather than the original. We have since been advised by our finance office and by counsel, that we do not need original documents but do need original signatures and that a standby trust is not required by the State of New York for surety bonds. We are continuing our review of financial assurance documents on file, but our policy on licensees that no longer need financial assurance, due to changes in operations or changes made in our regulations in 1994, is to advise them of this during license renewals.

Section 3.5.2:

This section discusses our reporting of incidents requiring immediate or 24-hour reporting to us by licensees, to NRC. It also states that during the review period we made only one “summary report” of incidents to NRC, and describes our reporting as “inconsistent.”

However, of the thirteen incident files reviewed by NRC during this IMPEP, only four required immediate or 24-hour notification to our program by licensees under current regulations. In spite of this, five of the thirteen incidents were reported to NRC, and four of the thirteen were reported to other Agreement States having a regulatory involvement. We consider that quite consistent.

The “summary report” referred to was not a report of “immediate or 24-hour incidents”, it was simply a printout of our computer database for all of the incidents (reportable or not) that occurred during a one year period. Periodically we receive a request from NRC for this data and are happy to provide it.

We will continue to share information on incidents of concern to NRC and the states to these agencies.

Section 4.1.2:

This section discusses regulations that NRC desires the state to adopt or to enforce by alternate legally binding requirements. However, it focuses on a rulemaking package that had been under review by counsel at the time of the IMPEP as the only means to accomplish this. The package has since been approved by counsel’s office, which had been otherwise tied up with the review of a number of emergency rulemakings.

This section should be modified to acknowledge that the NYDL is effectively implementing the requirements in question, during the licensing and inspection of relevant facilities through the use of licensing guides, license conditions and inspection reports and checklists. This would also make the draft report internally consistent, since Section 2.0 closes out a recommendation from the previous review through a finding that we are implementing one of the regulations in question through licensing and inspection protocols.

Section 4.2:

This section is a four-page discussion of our SS&D evaluation program and the one SS&D evaluation performed since the current program manager took over the program in 1993. The staff member who had previously performed these evaluations retired early in 1994, and this unit began petitioning NRC to provide training in the conduct of these evaluations since NRC was the sole arbiter of what a satisfactory evaluation was. In September 1995, NRC did hold a training workshop on the evaluation

of SS&D's and two of our staff attended. In a follow-up letter to our Commissioner dated October 27, 1995, the Director of the Office of State Programs, Richard Bangart, stated that as a result of the workshop "we believe that sufficient instruction and reference information was provided to Agreement State staff to enable them to conduct adequate SS&D evaluations." This was a reasonable statement, especially if the staff in question had good health physics backgrounds and solid radioactive materials licensing experience, which our staff did. Therefore, this combination of training, knowledge and experience constituted our qualification program for staff who would perform SS&D evaluations.

We are now being told that we must establish an elaborate program for "signature authority" for these evaluations, in a qualification program in which reviewers are to "complete a sufficient number of cases which are critiqued by a qualified SS&D reviewer."

We have already commented in our cover letter that the NRC reviewer for this indicator seemed to be comparing our program to his personal preferences rather than to something reasonably approximating the contents of MD 5.6 for this and similar indicators. We have never been asked for a similar elaborate program for "signature authority" for licensing in general (and SS&D evaluations are a part of licensing), or for inspection correspondence; nor does the phrase "signature authority" have any meaning in our program. The NYDL is responsible for the actions of all Department staff while they are acting in their official capacities. It is the responsibility of the program manager to authorize staff to perform specific functions, and at what level of independence they may operate. For example: all current inspection staff are authorized to sign final inspection letters, only myself and one staff member are authorized to sign licenses and only two staff members are authorized to perform SS&D evaluations. Licensing actions and SS&D evaluations also require a concurrence review and sign off by designated staff. These concurrence reviews include an independent technical review of the materials submitted by the applicant, and the documents prepared by the initial reviewer (but not to the same level of detail as the initial review and do not involve a review of every page of the applicant's submittal) and address each area addressed in the initial review. Concurrent reviewers must make an independent determination that the documents prepared by the initial reviewer address all relevant health and safety issues, are well-supported by the material submitted by the applicant, that all regulatory requirements are met, that the draft documents are clear and complete and that it is safe and appropriate to issue them in final form. Typically, a checklist is used to assist in ensuring that all necessary topics are covered and to document the consistency of reviews. However, we have no prohibition against collaboration between the initial and concurrence reviewers, and this is true for both licensing and SS&D actions. In the case of unusual or infrequent actions I encourage as much dialogue and collaboration as possible since we find that this helps to surface issues and improve our final product, as well as to provide maximum experience benefit to the reviewers. In the case of this first SS&D evaluation, the two reviewers approached it as a team effort, with the concurrence reviewer fully involved as the work progressed. However, a full concurrence review was performed; the reviewer

evaluated each area addressed during the initial review, following the same checklist and referring back to the applicant's submittal; the reviewer focused on ensuring that the SS&D met all requirements, would not pose health or safety concerns and that the draft registration certificate provided an adequate basis for licensing. This meets all the criteria in MD 5.6.

Appendix F of the draft report contains specific comments by the review team on the one non-custom SS&D evaluation reviewed. Our response to each of these comments is contained in the attached memo from Clayton Bradt to myself, which itself includes attachments.

There are also three particular items raised in the draft report that are based on an hours-long question and answer session conducted separately with each of our two reviewers by the NRC SS&D team member. One item faults the reviewers for not reviewing our draft regulations for GL manufacture and distribution during the SS&D evaluation, although it is also stated that the reviewers were aware of the relevant requirements and no specific deficiency is alleged to have resulted. Another item faults the concurrence reviewer because he "was not aware of the policy to review QA/QC programs during the licensing review, and assumed that the first reviewer adequately reviewed the QA/QC program." This was a matter of memory. The concurrence review was conducted several months before this interview and the reviewer did not recall that it was noted on the review checklist that the QA/QC program review was done as part of the license renewal, and he himself had not done a renewal of one of our three manufacturing licenses. The third item faults both reviewers because they "relied heavily on the checklist in NUREG- 1550 to identify specific items that should be reviewed.. rather than using it as a guide to help identify areas that should be evaluated", and goes on to say that additional guidance documents and regulations should have been consulted "to identify specific items that must be evaluated" or addressed. We disagree with the NRC reviewer's concept of a checklist and can find no items or areas that we failed to evaluate as a result of its use. We like the checklist, believe that it served our needs and are working on modifying it to make it even more useful. As stated earlier, we use checklists in all of our licensing activities, including SS&D evaluations, and find them very useful. We would also quote from the third paragraph of Section 4.2 of the draft report, which states "Staff uses the checklist from NUREG- 1550 to assist in the review of SS&D's, and help ensure that all pertinent issues are addressed." That is correct.

OSP

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THE CITY OF NEW YORK
DEPARTMENT OF HEALTH
OFFICE OF THE COMMISSIONER



125 WORTH STREET
NEW YORK, NY 10013

July 15, 1998

NITTI & COHEN, tlo.
COMMISSIONER
TEL (2 12) 766.626 1
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Richard L. Bangart, Director
Office of State Programs
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Mr. Bangart:

The following responses are being made by the New York City Bureau of Radiological Health to the IMPEP draft team report dated June 24, 1998.

(Section 3,1 .I)

1. The software anomalies of our RAD database have been cleared up. Management can now call up inspections due on a weekly, monthly and yearly basis, in addition to being able to ascertain which licenses have been inspected for these periods.
2. The initial inspection is now being scheduled when the new license is mailed out. This is accomplished through the RAD database with a "Need Inspection" activation button or code. The new license is then included in the inspections due list that is reviewed on a monthly basis by the radioactive materials field supervisor in charge of scheduling.

(Section 32.1)

3. As pointed out, the procedures for properly documenting violations are included in our inspection procedure manual. In-services, in addition to supervisory review, are being stepped up to ensure that inspectors are fully aware of these procedures. A radioactive materials inspection log has been developed as an addition to the inspection forms that includes NOV # and date of hearing and results of the hearing.
4. The in-services mentioned above will include emphasis on performance-based rather than compliance-based inspections. The Bureau has obtained the "Inspecting for Performance Materials" student manual from NRC which will be used as a classroom resource for the in-services. The Bureau is also pursuing the feasibility of incorporating projected training fund requirements for professional staff in upcoming fee schedule revisions.



STATE OF NEW YORK
DEPARTMENT OF HEALTH

11 University Place

Albany, New York X2203-3399

Barbara A. DeBuono, M.D., M.P.H.
Commissioner

Dennis P. Whalen
Executive Deputy Commissioner

Dennis Sollenberger, Ph.D.
Mail Stop 0-3-H-20
Office of State Programs
US Nuclear Regulatory Commission
Washington, DC. 20555

July 20, 1998

Dear Dr. Sollenberger:

Enclosed are our comments on the draft report "Integrated Materials Performance Evaluation Program, Review of New York Agreement State Program, January 26-April 24, 1998." These comments address editorial changes that we feel should be made to the report. We also plan to submit a separate response to the recommendations made by the team in the report.

I would like to emphasize the point that is included in the attached comments, on the need to maintain confidentiality of facilities reporting medical misadministrations to our department. This confidentiality is required by New York State Public Health Law, and therefore, we ask that all identifiers to licensees that reported such misadministrations to us be removed from the IMPEP report, as well as from all other NRC reports or documents available to the public.

If you have any questions, or need additional information, contact Steve Gavitt at 518/458-6485.

Sincerely,

Karim Rimawi, Ph.D., Director
Bureau of Environmental Radiation Protection

cc: Stephen Gavin

NYS Department of Health
Comments on draft IMPEP report

The following comments concern only those portions of the draft IMPEP report relating to New York State Health Department program:

Page 8 The report indicates that there are 24 overdue inspections of new licensees (out of 34 reviewed), however there is no mention of the significance of these findings. For example, seven of these overdue inspections are former General Licensees (which are not inspected by NRC) which we decided **to** convert to specific licensees for tracking purposes; one is a depleted uranium licensee; three licensees where not overdue since the facilities did not **have materials** on-site until sometime after the license issuance date (this information is contained in the license file); and two licenses were inspected previously but a change in ownership initiated a new license to the new owners but the facilities and equipment remained unchanged.

Page 24 The report notes that certain standard conditions are in some licenses but not others. It then goes on to indicate a potential problem - "a license reviewer informed the team that this standard condition should be put on all licenses." But it is then resolved - "As this issue was pursued, the team was then informed that this standard condition is now in the regulations." It is unclear as to the significance of the above. When a standard license condition is made into a regulation it is taken off the licenses as they are renewed. Therefore licenses that have not been renewed will have the condition until their renewal. We do not believe this is a problem.

In the same paragraph there is a focus on our "list of standard license conditions." This list is just a compilation of all various license conditions. We do not use this list to generate licenses. Licenses are not created from a blank document. Each category of license has its own "boilerplate" that is kept up **to date with** all applicable license conditions. When a **new** license condition is created, it is added to the appropriate "boilerplate" and to our list of standard license conditions. When a license condition becomes obsolete it is deleted from the boilerplate but not from the "list". So while it is true our list of standard license conditions contains outdated conditions - this does not affect our licensing process and has no significance.

Page 36 We did adopt the "Criteria for Release of Individuals Administered Radioactive Materials" see section 16.123 of Part 16.

Appendix E-3 Please note that NYS law prohibits the disclosure of the name of any facility that

provides reports pursuant to Part 405. Therefore you cannot print the name, location and license # for files nos. 6,7,8, and 9 in Appendix E-3 and we ask that these be removed from all copies of the reports and any other public documents NRC issues or maintains. File no. 1 is allowed since we took an enforcement action against this licensee and that information is available for public review.

Page 18 There are 4 field offices (Buffalo, Rochester, Syracuse and New Rochelle) and the main office.

Page 19 We do have a written training policy which was provided to the IMPEP team (copy attached).

Page 19 We only have one CHP in the program. Six others passed Part I of the certification exam last year, four of whom were eligible and took Part II this year.

BERP INSPECTOR QUALIFICATION PROCEDURE

-01 PURPOSE

01.01 To provide training guidelines for personnel to achieve initial qualification as an inspector through local, formal classroom and on-the-job training.

01.02 To identify mandatory and optional requirements for inspectors after achieving initial inspector qualification status.

01.03 To provide additional training opportunities for the experienced inspector in identified specialty areas.

-02 OBJECTIVES

02.01 To ensure that inspectors meet minimum knowledge and qualification standard.

02.02 To provide a standardized methodology for determining that an inspector has met the minimum training requirements.

-03 POLICY

Inspector personnel must understand the facilities, processes, and activities for those areas they inspect in addition to the criteria, techniques, and mechanics of inspection. They must also be keenly aware of the potential for negative impact on safety if the inspection process is allowed to become overly intrusive in areas of operation where problems are not occurring. In addition, the inspector must be sensitized to the potential for negative regulatory impact. Newly hired personnel seldom possess all of these required qualifications. Therefore, formal classroom self-study, and on-the-job training are needed to ensure that the newly hired inspector obtains the required knowledge and understanding necessary to be considered qualified to implement the inspection program

Each inspector must complete the appropriate required training outlined in Appendix A of this procedure or verify, through successful completion of a written equivalency examination, that the desired level of knowledge in a particular specialty area has been obtained. Training requirements for new inspectors will be documented by the Bureau of Environmental Radiation Protection in a Qualification Journal which is identified in Appendix B of this chapter. Completion of the Training and Qualification Journal constitutes the minimum inspector qualification requirements, and encompasses regulatory, administrative, and technical practices pertinent to each area of inspection. Other requirements such as

Page 2

local training may be used to supplement or enhance training. The passing grade for each course examination or equivalency examination is 70%

Once an inspector has completed the training identified in Appendix A, that inspector will be evaluated by the appropriate Section Chief or Field Supervisor to determine that the minimum requirements are met.

In a situation where qualification is delayed as a result of an inspector not being able to schedule certain formal training courses, or for other time restraint consideration, the appropriate Section Chief, the BERP Field Supervisor or Bureau Director (or his delegate) may provide interim qualification for those areas where the inspector is considered qualified.

Inspectors who are receiving on-the-job training in preparation for meeting qualification requirements, can perform inspection activities under the direction of an inspector. With the exception of inspectors who are receiving on-the-job training, an inspector is expected to be qualified for the area being inspected. In some cases where an inspector has taken most but not all of the required training, this may require the issuance of interim qualification. An inspector who changes disciplines or is assigned to perform inspections in additional areas of discipline, must meet the training and qualifications requirements for the new discipline. It is expected that similar training requirements between disciplines will not have to be repeated, and credit for the previous similar training will be indicated in the current qualification journal.

This procedure and qualification journal are periodically revised to reflect the training needs of inspectors as determined by changes to the inspection procedures. An inspector that is qualified prior to the time any revisions are made to this procedure will continue to remain qualified. The supervisor of a qualified inspector will determine whether or not the inspector should take new courses added to this procedure as they are offered. This determination is based on the inspector's prior work experience and current inspection activities.

Special circumstances (e.g., training opportunities) may make it impossible to provide employees with required formal classroom training within the time frames specified in Appendix A. When this occurs, the appropriate Section Chief will issue a memorandum indicating the affected training courses, circumstances involved, and reinstatement dates. If a new or proposed course listed in the procedure is not available at the time an inspector has satisfied all other requirements, and the course is not critical to performing inspections as a qualified inspector, certification

may be given with the condition that the remaining course requirement be satisfied when the course is "next available. "

Temporary instructions (TIs) that focus on specific "Area of Emphasis" may require special training requirements for Inspectors prior to their performing the inspection. These special training requirements will be identified by the appropriate Section Chief. The schedule for preparation of any special training should allow enough lead time to prepare the required training course and implement it prior to inspection being performed using the TI.

- 04 DEFINITIONS

COURSE SERIES. A progressive sequence of courses in a particular technology.

Equivalency Examination. An Examination administered in lieu of specific course attendance.

On-Site Training. Required training for inspectors designed to thoroughly acquaint the inspector with specific site systems, structures, and management organization.

Required Training. Formal classroom and on-the-job training representing the minimum acceptable level of knowledge in a given field.

Supplemental Training. Additional training courses beyond those identified for "Required Training." The additional courses will be determined by the inspector's supervisor and will depend on the inspector's previous work experience and planned inspection activities in specific area.

Refresher Training. Required training designed to update and maintain qualification.

Training and Qualification Journal. A document that establishes the minimum training requirements for formal classroom instruction, on-the-job training, local training sessions, and self-study. This document establishes the basic generic training requirements for inspector types identified in Appendix A, and lists the qualification journals in Appendix B.

Interim Qualification. Qualification of an inspector by the Bureau Director or Section Chief or Field Supervisor (or his delegate) to conduct independent inspections in specified areas of the inspection program before that inspector completes all required training.

-05 RESPONSIBILITIES AND AUTHORITIES

05.01 Director, Bureau of Environmental Radiation Protection establishes the training requirements for inspector positions listed in Appendix A.

05.02 Section Chiefs/Field Supervisor, Bureau of Environmental Radiation Protection, ensure that inspectors achieve and maintain qualifications in accordance with the guidelines provided in this procedures.

-06 TRAINING ACTIVITIES

06.01 All staff whose principal job assignment is to perform inspections in their assigned areas of expertise, must successfully complete the training requirements for their individual inspection areas as listed in Appendix A.

- a. Written examinations may be used to determine whether inspectors have obtained the 70% level of knowledge and understanding.**
- b. Inspectors who fail courses may be given the opportunity to acquire the knowledge level required through self-study and re-examination or to repeat the course.**
- c. Program management assumes that inspectors possess the necessary motivation and ability to achieve such a level of knowledge and understanding. In the rare situation where such is not the case, program management will decide what action to take on an individual basis.**

06.02 classroom and simulator training are designed to supplement the inspector's education, experience, and on-the-job training by providing basic theory and knowledge as well as job related techniques.

-07 BERP TRAINING AND QUALIFICATION JOURNAL

07.01 The BERP is responsible for developing and maintaining the Training Qualification Journal. The use of the Journal is described in Appendix B of this chapter.

07.02 The BERP Journal provides the minimum training requirements to develop Training and Qualification Journals. Newly hired inspectors, except those in the intern program will have a detailed series of activities and study areas to be completed in a specific period, usually within the first 2 years of employment.

Page 5

The journals cover self-study and seminars or group discussions in the following areas:

- a. Code of Federal Regulations.
- b. NYSDOH regulations.
- c. Pertinent inspection and environmental health manual procedures.
- d. Technical areas of inspection, methods, and knowledge.
- e. Schedule of orientation and required training as delineated in Appendix A.

07.03 Development, maintenance, and periodic review of these journals will be provided by the BERP.

-09 MANAGEMENT CERTIFICATION OF INSPECTOR QUALIFICATION

DOH management may, in certain circumstances, certify that an inspector is qualified to perform inspections without regard to the requirements of this procedure. The Director, Bureau of Environmental Radiation Protection will ensure the completion of the Qualification Journal including technical training and/or equivalent training.

PAGE 6

- 10 INTERIM INSPECTOR QUALIFICATION

In general, only those inspectors who have successfully completed the required training will be allowed to independently perform inspections. However, if responsible management evaluates the background and performance of an individual inspector and concludes that the inspector has demonstrated an ability to perform inspections in specific areas, even though the required training has not been completed, the Section Chief, the BERP Field Supervisor or Bureau Director, or designee as appropriate, can authorize the individual to perform inspections in those areas. When this approach is used, the successful completion of the training is still required to be completed within the time limits specified.

It is not the intent of this procedure to require persons to participate in each of the defined training activities if they already possess the type and level of knowledge that would be achieved by completing the prescribed training. If inspectors, when hired, through previous work experience and training, are deemed to possess the appropriate knowledge level for a prescribed training area, then equivalency examination(s) may be taken and thereby satisfy the training requirements. However, if work experience or previous training is determined to be equivalent to a given course, that course may be waived by appropriate management (Section Chief or Bureau Director) and a justification entered in the trainee's qualification journal.

10.01 An inspector who has not completed all requirements for final certification in one of the areas listed in A may obtain interim qualification to independently perform inspections in specified areas for which prescribed training has been completed.

10.02 To establish an interim certification, the inspector's supervisor will evaluate the inspector's qualifications and identify the portions of the inspection program for which interim qualification is appropriate.

30.03 Interim qualification will be approved by the the BERP Field Supervisor, the appropriate Section Chief or the Bureau Director, or his designee for interim qualification in the identified areas.

10.04 Approval of the interim qualification will be documented and record kept in the individual's training file.

-11 EXCEPTIONS

11.01 Inspectors, who through prior experience and education, possess sufficient knowledge to meet minimum requirements, may validate a course through satisfactory completion of an equivalency examination.

11.02 At the discretion of the Section Chief or Field Supervisor, inspectors may be qualified for certain types of inspections before they complete all of the training requirements for certification. For example, an inspector may be qualified to perform inspections of academic materials licensees before completing the specialized courses and becoming qualified for inspecting medical licenses.

11.03 The Bureau Director has the authority to waive any requirement listed for an inspector in this procedure. Justification for the waiver will be documented, and entered into the inspector's training file.

1245-12 POST QUALIFICATION TRAINING

This procedure identifies training requirements beyond those that are required for initial qualification for the experienced inspector. For the inspector who has received certification of initial qualification, mandatory and optional training requirements are identified in the sections entitled "Training Required Within Two Years of Certification," "Supplemental Training Courses," and "Refresher Training." These sections are listed for purpose in Appendix A to this procedure. The purpose of this additional training is to recognize that inspector training does not stop with initial qualification; that training should be made available for the experienced inspector on the basis of need, special circumstances, and to keep current with the inspection program. In particular, the Fundamentals of Inspection Refresher Course (G-102) provides the inspector current views on regulatory policy and philosophy as it relates to the inspection program and the Principles of Good Regulation.

END

Appendices

Appendix A, Training Activities

:: Appendix 8, NRC Training and Qualification Journals

APPENDIX A

TRAINING ACTIVITIES

A. PURPOSE

To ensure that inspectors are qualified to:

1. **Know their role and mission.**
2. **Understand the responsibilities and legal authority of an inspector.**
3. **Know inspection techniques and procedures and are capable of performing the inspector function.**
4. **Have the type and level of technical knowledge needed to adequately perform inspection activities.**
5. **Understand the inspection program**

B. TRAINING REQUIREMENTS

Each section of this appendix provides the inspector training requirements for a particular inspection activity as indicated below.

Section	Area of inspection
I-A	Radiation Producing Equipment Inspector
I-B	HCFA Mammography Inspector
I-C	Radioactive Materials Inspector
II-A	Next Inspector
II-B	FDA Compliance Testing Inspector

SECTION I-A
TRAINING REQUIREMENTS FOR
RADIATION PRODUCING EQUIPMENT INSPECTOR

A. APPLICABILITY

The training described below is required for all radiation producing equipment inspectors assigned to perform radiological safety inspection activities at radiation equipment registrant facilities.

B. TRAINING

1. Required initial training. This training is required for initial certification of the radiation equipment inspector.

a. Required local on-the-job training.

- (1) Orientation
- (2) Code of Federal Regulations (21 CFR 1000)
- (3) NYSDGH Regulations (10 NYCRR 16, 76, 89)
- (4) NY Public Health Law
- (5) NCRP Reports No. 66, 85, 99, 100, 102, 104, 105, 107
- (6) DOH Memorandums
- (7) NYS Guides on Radiation Safety/Quality Assurance Programs
- (8) FDA Inspection Manual
- (9) Industry Codes and NIST Standards
- (10) Radiological Safety Inspection Accompaniments.
These include at a minimum accompaniment inspections at least two hospitals including or supplemented by at least four surveys of each of the following units: fluoroscopic, mammographic, radiographic, dental, Computerized Tomographic (CT), and non-human use other than veterinary.
- (11) NYSDOH Inspection Procedures

b. Required Formal Training Courses. This training is provided in formal classroom or workshop environments and is conducted by the BERP or FDA staff or contractors.

- (1) Basic Radiation Protection/Health Physics
- (2) Medical X-ray Protection

2. Training Required Within Two Years of Certification. This training is required within two years of initial formal certification and is conducted by Eastman Kodak Corporation.

a. Kodak More 2

3. Supplemental Training Courses. Depending on the inspector's previous work experience and planned inspection activities, these additional courses may be required in order to gain knowledge necessary for specialized inspection activities. Program management will make this determination on an individual basis.

- a. Accelerator Health Physics
- b. Radiological Emergency Response Course
- c. Radiological Accident Assessment Course
- d. Enforcement Procedures

4. Refresher Training. Refresher training will be conducted as needed and as determined by management.

SECTION I-B
TRAINING REQUIREMENTS FOR
HCFA MAMMOGRAPHY SURVEYOR

A. APPLICABILITY

The training described below is required for all HCFA mammography program inspectors assigned to perform radiological safety inspection activities at HCFA mammographic facilities.

B. TRAINING

1. **Required initial training.** This training is required for initial certification of the radiation equipment inspector.

a. **Required local on-the-job training.**

- (1) **Orientation** -
- (2) **Code of Federal Regulations (42 CFR 494.50 to 494.64)**
- (3) **NYSDOH Regulations (10 NYCRR 16, 76, 89)**
- (4) **NY Public Health Law**
- (5) **NCRP Reports No. 66, 85, 99, 100, 102, 104, 105, 107**
- (6) **DOH Memorandums**
- (7) **NYS Guides on Radiation Safety/Quality Assurance Programs**
- (8) **HCFA Inspection Manual**
- (9) **Industry Codes and NIST Standards**
- (10) **HCFA Mammographic Survey Accompaniments. These must include at a minimum accompaniment inspections at least five HCFA mammographic surveys.**
- (11) **NYSDOH Inspection Procedures**
- (12) **ASPEN**

b. **Required Formal Training Courses.** This training is provided in formal classroom or workshop environments and is conducted by the BERP or FDA staff or contractors.

- (1) **HCFA Mammography Certification Course**

2. **Training Required Within Two Years of Certification.** This training is required within two years of initial formal certification and is conducted by Eastman Kodak Corporation.

a. **Kodak More 2**

3. **Supplemental Training Courses.** Depending on the inspector's previous work experience and planned inspection activities, additional courses may be required in order to gain knowledge necessary for specialized inspection activities. Program management will make this determination on an individual basis.

4. Refresher Training. Refresher training will be conducted as *needed* and as determined by management.

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SECTION I-C

TRAINING REQUIREMENTS FOR RADIOACTIVE MATERIALS INSPECTOR

A. APPLICABILITY

The training described below is required for all radioactive materials inspectors assigned to perform radiological safety inspection activities at material licensee facilities.

B. TRAINING

1. REQUIRED INITIAL TRAINING. This training is required for initial certification of the materials inspector.

a. Required Local Training. - This training is conducted in the local office using the appropriate Training and Qualification Journal.

- (1) Orientation**
- (2) Code of Federal Regulations**
- (3) NYSDOH Regulations**
- (4) NY Public Health Law**
- (5) NYS DEC Regulations**
- (6) Updated Safety Analysis Report (if applicable)**
- (7) Regulatory Guidance**
- (8) NRC Inspection Manual**
- (9) Industry Codes and Standards**
- (10) Radiological Safety Inspection Accompaniments**
- (11) NRC Manual**
- (12) NYSDOH Inspection Procedures**

b. Required Formal Training Courses. This training is provided in formal classroom or workshop environments and is conducted by USNRC staff and USNRC contractors.

- (1) Health Physics (&NRC)**
- (2) Medical use of Radionuclides Nuclear Medicine Course (USNRC)**
- (3) Teletherapy (USNRC) for teletherapy inspections**
- (4) Inspection Procedures Course (GPA/SP) or Fundamentals of Inspection Course (G-101)**

2. Training Required Within Two Years of Certification. This training is required within two years of initial formal certification and is conducted or arranged by NRC staff.

- a. OSHA Orientation Course**
- b. Transportation of Radioactive Materials Course (H-308)**
- c. Internal Dosimetry & Whole Body Counting Course'**
- d. Effective Communications for NRC Inspectors**

3. Supplemental Training Courses. Depending on the inspector's previous work experience and planned inspection activities, these additional courses may be required in order to gain knowledge necessary for specialized inspection activities. Regional management will make this determination on an individual basis.

- a. In-Place Filter Testing (H-105)
- b. Radiological Emergency Response Course (H-303)
- c. Radiological Accident Assessment Course (H-307)
- d. Health Physics in Radiation Accidents Course (H-309)
- e. MORT - Accident Incident Investigations Workshop (G-200)
- f. MORT - Management Oversight and Risk Tree Analysis Seminar (G-201)
- g. Air Sampling for Radioactive Materials (ORAU) Engineering
- h. Licensing Practices and Procedures (G-109)
- i. Safety Aspects of Well Logging (H-314)
- j. Irradiator Technology course (H-315)
- k. Environmental Sampling and Analysis Course (H-310)
- l. Health Physics topical Review Course (H-401)
- j. Inspecting for Performance Course (G-303)

4. Refresher Training. Refresher training will be conducted every three years following initial certification and will be determined by Regional management. Refresher training will also include the following course:

- a. Fundamentals of Inspection Course (G-102)

**SECTION II-A
TRAINING REQUIREMENTS FOR
NEXT SURVEYOR**

A. APPLICABILITY

The training described below is required for all NEXT program inspectors assigned to perform radiological safety inspection activities at NEXT facilities.

B. TRAINING

1. **Required initial training.** This training is required for initial certification of the NEXT surveyor.

a. **Required local training.**

- (1) **Orientation**
- (2) **Code of Federal Regulations (21 CFR 1000)**
- (3) **NYSDQH Regulations (10 NYCRR 16, 76, 89)**
- (4) **NY Public Health Law**
- (5) **NCRP Reports No. 66, 85, 99, 100, 102, 104, 105, 107**
- (6) **DOH Memorandums**
- (7) **NYS Guides on Radiation Safety/Quality Assurance Programs**
- (8) **NEXT Survey Procedures Manual**
- (9) **Industry Codes and NIST Standards**
- (10) **BERP Inspection Procedures**

b. **Required Formal Training Courses.** This training is provided in formal classroom or workshop environments and is conducted by the BERP or FDA staff or contractors.

- (1) **NEXT Surveyor Training Course**

2. **Training Required Within Two Years of Certification.** Not applicable.

3. **Supplemental Training Courses.** Each year, NEXT surveyors are expected to complete the Next Surveyor Training Course for that year since changes in inspection procedures and areas of coverage usually occur.

4. **Refresher Training.** Refresher training will be conducted each year as needed.

APPENDIX B**EERP INSPECTOR TRAINING AND QUALIFICATION JOURNAL****A. PURPOSE**

To establish a method of conducting and documenting successful completion of the training requirements set forth in this procedure.

6. BACKGROUND

The BERP Training and Qualification Journal is designed to ensure that a uniform method of conducting and documenting training is being followed for all inspectors.

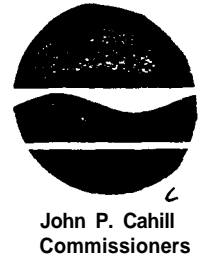
The Journal establishes the minimum training requirements that must be met for all required general and formal training courses listed in Appendix A and serves as a guide for development of other training and qualification journals (i.e., local and vendor journals).

C. BASIC REQUIREMENTS

The BERP Journal must be used to conduct and document training activities for all inspectors.

The BERP is responsible for developing and maintaining the Training and Qualification Journals. The Training and Qualification Journals included as part of this Appendix 6 establish the minimum requirements for a Training and Qualification Journal that must be completed for each inspector type listed in this and defined in Appendix A.

New York State Department of Environmental Conservation
Division of Solid & Hazardous Materials
Bureau of Pesticides & Radiation
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518-485-8981 FAX 518-485-8390



July 24,1998

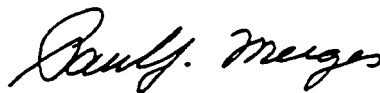
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We have reviewed the Draft Report of the Integrated Materials Performance Evaluation Program Review of the New York Agreement State Program (January 26- April 24,1998), which was transmitted to this Department by a June 24,1998 letter from Richard Bangart. For the most part, we found the sections of the report addressing this Department's radiation control program to be factually correct. Our suggested corrections are enclosed.

We appreciate the suggestions and recommendations offered by IMPEP team, both during their visit and in the draft report. We are reviewing them, and will respond when the final report is issued.

Thank you for the opportunity to review the draft report. If you have any questions, please contact me or Barbara Youngberg.

Sincerely,



Paul J. Merges, Ph.D.
Director, Bureau of Pesticides & Radiation
Division of Solid & Hazardous Materials

Enc.

cc: D. White, USNRC, Region 1
R. Aldrich, NYSDOL
G. Miskin, NYCDOH
K. Rimawi, NYSDOH
J. Spath NYSERDA

New York State Department of Environmental Conservation
Division of Solid & Hazardous Materials
Bureau of Pesticides & Radiation

Comments on Draft Report
Integrated Materials Performance Evaluation Program
Review of New York Agreement State Program
January 26 - April 24, 1998

1. Page 9, Section 3.1.4 Status of Materials Inspection Program

The draft report notes that although initial inspections are usually performed within six months of permit issuance, our inspection policy memorandum called for initial inspections to be performed with one year of the date the permit is issued. This was inconsistent with IMC 2800, which requires initial inspections within six months. The draft report also states that the Program Director committed to revising the policy memorandum accordingly. This has been done.

2. Page 19, Section 3.3.4 NYDEC - Technical Staffing and Training

The two vacancies noted in the draft report have been filled.

3. Pages 42 - 43, Section 4.3 Low-Level Radioactive Waste (LLRW) Disposal Program

The draft report states, "NYDL is responsible for the occupational exposure of individuals and control of radioactive material up to the point of placement in the disposal unit or release from the site." This is not completely accurate. The Department of Labor does have responsibility for occupational exposures and therefore, has authority over the radioactive material as it affects occupational exposures; however, DEC has authority, under Articles 17 and 29 of the Environmental Conservation Law, over most aspects of the design, construction, and operation of the disposal facility. This includes waste package receipt and inspection and temporary storage of waste prior to emplacement in waste disposal units. DEC's authority is reflected in our regulations for LLRW Disposal Facilities, 6 NYCRR Parts 382 and 383.

In the second paragraph of this section, the last sentence would be more consistent with commonly used acronyms if it read, "The State does have two former radioactive waste disposal sites: the State Licensed Disposal Area (SDA) at West Valley, and the Radiation Disposal Site (RDS) at Cornell University."

We suggest changing the first sentence of the third paragraph of this section to read, "The SDA is a portion of the West Valley Nuclear Services Center site and was operated as a commercial radioactive waste disposal site." The operation of the SDA predates the adoption of the radioactive waste classification system. Some of the waste placed in the SDA would vary

from the criteria for classification as LLRW pursuant to 10 CFR Part 61. The reference to LLRW in the fourth sentence should also be deleted.

In the first complete paragraph on page 43, the second sentence should be changed to read, "The NYDL has no responsibility at this site since it was not a commercial disposal site. Cornell holds a radioactive materials license from the NYS Department of Health."

4. Appendix D-4 NYDEC License File Reviews, Page D-4.1, File No. 2

We suggest revising the comment to read, "Since emissions at two release points exceed the effluent concentration values in Table II, permit limits were set to limit the potential dose to the maximally exposed member of the public."

5. Appendix D-4 NYDEC License File Reviews, Page D-4.3, File No. 13

The comment states that the termination application and licensee's closeout survey were not in the file. This is true, and as was explained to the IMPEP reviewer at the time, it was due to the fact that the documents were large and therefore not stored in the file drawer. At that time, only the SPL project manager, who was not in the office when the question was posed, knew where the documents were. The documents were always in the office. We have since made room in the file drawer for them, and they are stored with the rest of the SPL file.

Attachment 3

New York Department of Labor Comment Letter
on Revised SS&D Section and
NRC Comment Analysis



STATE OF NEW YORK
DEPARTMENT OF LABOR
DIVISION OF SAFETY AND HEALTH
Radiological Health Unit
Building #12, Room 134-A
State Office Building Campus
Albany, NY 12240

October 13, 1998

TO: Hugh Thompson, USNRC
Richard Bangart, USNRC
Karen Cyr, USNRC
Carl Paperiello, USNRC
Thomas Martin, USNRC
Roland Fletcher, State of Maryland

FROM: Rita Aldrich

We have received and reviewed Richard Bangart's letter of October 2, 1998, and the enclosed revision of the Sealed Source & Device (SS&D) section of the New York IMPEP report on our February, 1998 review. We note that although some of the language has been modified the findings are unchanged.

We have also polled other Agreement States on what SS&D reviewer's checklist(s) they were using, if any. Responses indicate that they are under the impression that NRC wants them to use the checklist in NUREG 1550 (or 1556), as is, since this is what was used in the NRC SS&D workshops. One state reported that conversations with NRC staff had convinced them that NRC had "no tolerance for customized or improved checklists."

We have also obtained a copy of the "IMPEP Regulatory Review Sealed Source & Device Reviewer Guidance." Strangely enough the guidance includes a checklist that parallels the NUREG checklist, indicating clearly that the NUREG checklist is the model expected to be in use by the states during IMPEPS.

Yet we continue to be criticized for placing "primary emphasis on the use of the checklist . . . as an all inclusive review document," even though it was used for the review of an ultimately simple device and nothing was overlooked as a result of its use. Curious.

We have also reviewed the Texas (June, 1997) and Illinois (March, 1997) IMPEP report sections on their SS&D evaluation programs. Based on the issues raised, criticisms made and responses accepted by their IMPEP teams, and the fact that both programs were found to be satisfactory, our program should clearly be found satisfactory. We would be happy to present a point-by-point comparison between what was accepted by the Texas and Illinois IMPEP teams as justifying a finding of fully "satisfactory" for those states, versus what was found insufficient to support such a finding for our program. However, in the interest of brevity, I would like to point out the following inconsistencies:

1. We were criticized for perceived shortcomings in our concurrence review for the one SS&D evaluation performed (which criticism we categorically disagree with).

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Texas was judged to have overlooked a serious discrepancy in an applicant's submission that would probably have been caught by a concurrence review. The product involved was a radiographic exposure device. The IMPEP team recommended that "the state review the issue of concurrence reviews for SS&D safety evaluations and implement procedures that require an independent review for all future evaluations."

Conclusion:

Texas did not perform a concurrence review of a high hazard device evaluation in which the IMPEP team reported a significant discrepancy in the applicant's submission.

We did perform a concurrence review of a low hazard device evaluation in which no significant discrepancies were found, but were criticized for not having "a clear policy for what constitutes a concurrence review."

Texas was found satisfactory but we need improvement.

2. We were criticized because staff did not refer to draft regulations before allowing use of a leak test interval of 13 months, even though the rationale for the 13 month interval was explained to the reviewer during the IMPEP.

Illinois allowed a 36 month leak test interval for a device based on a comparison with similar model devices. The IMPEP report merely "suggested" that the basis for the decision be documented in the registry file.

Conclusion:

We allowed a 13 month leak test interval for a device because the source used was approved for a 13 month interval, and were criticized for staffs not being "aware of the specific requirements contained in the draft regulations" and not consulting them during the review.

Illinois allowed a 36 month interval, has the same regulations in place that we have in draft, and was not criticized for not consulting them.

The two programs made decisions based on very similar reasoning. It was acceptable in one case but not in the other. Illinois was found satisfactory but we need improvement.

3. The Illinois SS&D staff have college and graduate school degrees similar to our staffs , and a statement is made in their report that "all members are trained in health physics principles and have attended at least one SS&D workshop." It is also stated that if needed, the program can obtain engineering assistance from professional engineers who work in other programs. It is also stated that the head reviewer demonstrated to the IMPEP team "an ability to understand and interpret the information submitted by applicants as described in the performance criteria, including engineering-related issues." (emphasis added)

Everything stated above concerning the Illinois staff is true of our staff. The section could have been used verbatim in our report, but it was not. Instead we were criticized for our staff not having “formal training or prior design analysis experience in all areas listed in MD5.6,” and were told that we should develop an elaborate training program.

Conclusion:

Illinois staff were evaluated against the criteria in MD5.6 and found satisfactory.

We were not evaluated against the criteria in MD5.6, which is limited to staff having specified basic “abilities,” but apparently against the IMPEP reviewer’s personal criteria which require “formal training or prior design analysis experience.” We have qualifications identical to those of Illinois program staff, who are satisfactory, but we are being told that we need improvement.

4. Neither the Texas nor the Illinois report used the term “signature authority,” nor made any reference to a “formal qualification program” for granting such authority. This is not surprising, however, because the terminology does not appear in MD5.6, although reference is made to states having a program for training and qualification of personnel. Yet our IMPEP report contains a discussion of our need for an elaborate “qualification program” and “formal written process” for “signature authority” to ensure that “reviewers meet the qualifications listed in MD5.6.”

Our program has adopted the recommendations of the Nuclear Regulatory Commission OAS Training Working Group on Training requirements, and all of our staff have had the “basic” training specified on page 3 of the report (I mis-referenced this as “core” training during our MRB discussion), as well as extensive additional training. All of this training is documented in our consolidated computer training file which was shown to the IMPEP team.

In addition to this training, our two SS&D reviewers have attended the Nuclear Regulatory Commission’s workshop on the performance of SS&D evaluations. Following this, I authorized them to perform and sign SS&D evaluations; one as the lead reviewer and the other as the concurrence reviewer. These constitute our qualifying procedures for the staff who perform SS&D evaluations. I would draw your attention to page 1 of the Training Working Group Report, which states that “the number of inspector or license reviewer positions in an individual Agreement State may not warrant the development of extremely detailed qualifying procedures.”

The report goes on to recommend that states develop lists of positions and basic training requirements for them, and have some method to sign off on completed areas of training, although some of the requirements may be included in hiring requirements. We believe we have done that, as I explained during the MRB meeting.

Conclusion:

The Texas and Illinois programs were found satisfactory by their IMPEP teams under the direction of Richard Woodruff, with no discussion of formal qualification programs for signature authority.

Neither MD5.6 nor the Nuclear Regulatory Commission OAS Working Group Report requires such a program.

We conduct our program in the same manner as Texas and Illinois; our staff have similar qualifications; their training is documented; and I have authorized them to perform and sign SS&D evaluations. Texas and Illinois were found satisfactory but we are being told that we need improvement.

We have also reviewed the SS&D section of the proposed IMPEP Report for Rhode Island; a program very similar to our own in size and scope.

For example, Rhode Island performed one SS&D evaluation during the review period, and has two staff involved in the program - neither of which has an engineering background or other formal training, other than attendance at an NRC SS&D workshop.

The SS&D section of the Rhode Island report is one page in length, which is remarkable to begin with, compared to four pages for our report. Comments included in the Rhode Island report include the following:

- "The SS&D review checklist received at the NRC SS&D workshop was used to assure all relevant materials had been submitted and reviewed," and "The team determined that the staff will use the guidance in NUREG-1556, Vol. 3, for any future reviews."
- "The team found that the two reviewers work together closely when conducting a review and discuss issues and concerns they have identified in an application."
- "The ORH also indicated that they would draw upon resources outside of their office if necessary. Outside resources could include State engineers or the local University engineering department, the NRC SS&D Section or another Agreement State," and that the ORH "would, if necessary, send their reviewers for additional training."

Rhode Island's SS&D Program was found satisfactory. If the members of the MRB will review the comparable paragraphs in the New York State report, we believe that the inconsistencies with the approach used in Rhode Island's review will be quite obvious.

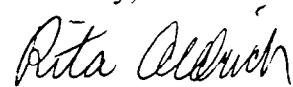
The situation that New York finds itself in defies logic. If we had not adopted all of NRC's guidance documents in the SS&D area; had not used a reviewer's checklist or used one very different from the NUREG model; had not performed a concurrence review; had not sent our SS&D reviewers to NRC's SS&D workshop; did not have additional engineering expertise at our disposal; and had not produced a satisfactory SS&D evaluation sheet, we could make some sense out of the criticisms in this report. However, having done all of the above, and having demonstrated in our previous comments on this section of the IMPEP report that we meet all of the criteria in MD5.6 for a finding of satisfactory, we do not intend to waste any more of our program's time and resources on this issue.

NRC did not follow its own procedures in the review of our SS&D program, and did not apply the criteria in MD5.6. State programs that were reviewed against those criteria, such as Texas, Illinois and Rhode Island, and were found satisfactory, were not criticized for a lack of formal training in engineering, or for using NRC's checklist (uncustomized) and following the review process taught at NRC's SS&D workshop, or for working closely and jointly on evaluations, or for not having a formal qualification program for "signature authority."

We do not see how any unbiased person could read the IMPEP reports of the Texas, Illinois, Rhode Island and New York State Department Of Labor SS&D programs and conclude that we are being treated fairly. I am personally shocked at the disparities which we found when we reviewed the other states' reports.

Based on the criteria used for the Texas, Illinois and Rhode Island programs we must be found fully satisfactory or this process has no credibility.

Sincerely,



Rita Aldrich
Principal Radiophysicist

RA:jmp

cc: Karim Rimawi
Gene Miskin
Paul Merges
Jack Spath
Richard Cucolo
Shirley Jackson

NRC Staff Analysis of the New York State Department of Labor Comments on Revised Draft Section 4.2, Sealed Source and Device Evaluation Program

The IMPEP review team evaluation of the NYDL comments on the revised SS&D Section of the 1998 program review and the recommendations to the MRB follow:

General Comment:

The recommendations in the SS&D Section are programmatic issues that should be addressed regardless of the number of case reviews conducted during the review period. Comment No. 2 below is a case-specific comment that demonstrates that additional experience conducting reviews would enhance the thoroughness of the NYDL reviews.

Specific Comments:

1. Concurrency review: As stated in the report, the team identified inconsistent understanding of what constitutes a concurrence review. The team's recommendation is that this be corrected through the program establishing a definition, in writing, for concurrence review. The team continues to support this recommendation.
2. Leak test frequency extension: The staff reviewed NYDL's comment about the source SS&D registration sheet allowing a 13 month leak test frequency. The source SS&D sheet does allow extension of the frequency to up to 13 months when it is justified based on the device in which the source is being placed. Since the case-specific review did not discuss a rationale for this extension, the team made the case-specific comment that such a rationale should have been documented in the device evaluation file. The team continues to support the case-specific comment.
3. Qualifications of NYDL staff to perform SS&D reviews: The comparisons to other programs is not an accurate comparison. The NYDL staff are not as well qualified, based mainly on experience conducting SS&D reviews, as the other programs mentioned in the NYDL response. In addition, the TX and IL programs have staff conducting SS&D reviews that have had formal engineering training and have other engineering resources within the RCP that are consulted on a regular basis. The RI primary reviewer has been conducting SS&D reviews for 18 years although at a similarly low frequency of reviews per year. The review team continues to support its recommendation for experience based training for the SS&D reviewers prior to conducting an SS&D review of a more complex device.
4. Signature authority or formal qualification program: NYDL stated that they have adopted the recommendations of the NRC/OAS Training Working Group report, however, on page 3 of the report it states, "The Agreement States should document a training program that, at a minimum, contains a statement of policy, minimum qualifications for staff training, and supervisory responsibility for ensuring this policy is implemented...." The sample policy statement in Appendix D of the report also states, "When an individual has demonstrated competency in a particular training area to management, the training chart will be completed by that member of management." The review team was reflecting these statements when it made the recommendation that NYDL clearly define its requirements for staff to independently perform SS&D evaluation including a demonstration of competency and for management to "grant signature authority" or what ever term the state wants to use to signify that the individual has made such a demonstration to management. This process is what is expected for the licensing and inspection programs also and is not

something unique to the SS&D evaluation program. The review team continues to support its recommendation that the training requirements and management approval (signature authority) to conduct independent work in the SS&D evaluation area be documented.

The NYDL response referred frequently to other program review reports and there were comparisons made to each of the other programs as they may compare to the NYDL. The TX and IL programs are significantly larger than the NYDL program and similar issues were raised in the IL and TX reviews but were limited to case-specific and individual reviewer issues.

The objective of the review team's recommendations was to improve the documentation of the NYDL program that would, at a minimum, have procedures that would address the sources and devices that are manufactured in the State. The response from NYDL appears to state that they do not wish to define the scope of their program by developing procedures specific to the sources and devices currently manufacture in the State. Such documentation would focus future SS&D casework reviews and IMPEP reviews of the program. The review team continues to support clarification in the NYDL program and continues to support is recommendations in this area.

Conclusion:

The review team concluded, after consideration of the comments presented at the September 1, 1998 MRB meeting and in the October 13, 1998 letter, that the NYDL SS&D program did not fully meet the criteria in MD 5.6 for a satisfactory rating. Therefore, the review team recommends that NYDL's performance with respect to the SS&D evaluation program be found satisfactory with recommendations for improvement based on the criteria in MD 5.6.