DATED: JULY 29, 1999 SIGNED BY: FRANK J. MIRAGLIA

Neal L. Cohen, M.D.
Commissioner
New York City Department of Health
125 Worth Street, Room 329
New York, NY 10013

Dear Dr. Cohen:

Enclosed is the final report of the follow-up Integrated Materials Performance Evaluation Program (IMPEP) review of the New York City Department of Health (NYCH) radiation control program. The review of the NYCH program was conducted by an interoffice team during the period April 26-28, 1999. The areas of concern (Status of Materials Inspection Program and Technical Quality of Inspections) were reviewed in detail as well as response to, and resolution of, eight recommendations made during the January 25-30, 1998 IMPEP review.

The review team found the City's performance in responding to and resolving the eight recommendations to be satisfactory with the exception of Recommendations 3, 5 and 6. Recommendation 3 discussed the need for the documentation for violations presented to licensees. Recommendations 5 and 6 discussed the need to develop training requirements and evaluate current and future staff so they will have the necessary skills for their specific work assignments. The team found that the database for the inspection and licensing program was working well and management had the needed information to plan and schedule inspection assignments. The follow-up team concluded that the program has improved and the significant issue of the status of the materials inspection program has been resolved.

Based on the follow-up IMPEP review, the Management Review Board finds that there is no change to the finding resulting from the January-May 1998 IMPEP review, that the New York program is adequate to protect public health and safety, and compatible with NRC's program.

Section 5 on page 8 of the enclosed final report presents the follow-up IMPEP team's recommendations. We request your evaluation and response to the three recommendations in this section within 30 days from the receipt of this letter.

Based on the results of the follow-up IMPEP review, the next IMPEP review will be scheduled in approximately 3 years to correspond with the IMPEP reviews of the other New York radiation control agencies.

I appreciate the courtesy and cooperation extended to the IMPEP team during the follow-up review and your support of the radiation control program. I look forward to our agencies continuing to work cooperatively in the future.

Sincerely, ***/RA/***

Frank J. Miraglia, Jr.
Deputy Executive Director
for Regulatory Programs

Enclosure:
As stated

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

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

Rita Aldrich, Principal Radiophysicist
Radiological Health Unit, NYDL

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

Paul J. Merges, Ph.D., Director
Bureau of Radiation and Hazardous Site Management

I appreciate the courtesy and cooperation extended to the IMPEP team during the follow-up review and your support of the radiation control program. I look forward to our agencies continuing to work cooperatively in the future.

Sincerely,

Frank J. Miraglia, Jr.
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Bureau of Radiation and Hazardous Site Management

bcc: Chairman Dicus
Commissioner McGaffigan
Commissioner Diaz
Commissioner Merrifield

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM (IMPEP) FOLLOW-UP REVIEW OF THE NEW YORK CITY RADIATION CONTROL PROGRAM

April 26-28, 1999

FINAL REPORT

U. S. Nuclear Regulatory Commission

1.0 INTRODUCTION

This report presents the results of the follow-up review of the New York City Department of Health, Bureau of Radiological Health (NYCH), radiation control program conducted April 26-28, 1999. The follow-up review was conducted by a review team comprised of technical staff members from the Nuclear Regulatory Commission (NRC). Team members are identified in Appendix A. The follow-up review was conducted in accordance with the "Policy Statement on Adequacy and Compatibility of Agreement State Programs," published in the *Federal Register* on September 3, 1997 (62 FR 46517), and the November 25, 1998, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)."

A draft of this report was issued to NYCH for factual comment on May 26, 1999. The NYCH responded in a letter dated June 17, 1999, from Neal L. Cohen, M.D., Commissioner of Health (Attachment 1). A copy of the final report was provided to the Management Review Board (MRB). The MRB considered and concurred in the team's overall recommendation and found the New York radiation control program remains adequate to protect public health and safety and compatible with NRC's program.

The New York Agreement State program is administered by: (1) the 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. At the time of the review, the combined New York programs regulated approximately 1400 specific licenses, including all types of major licensees except for uranium mill tailings. NYCH regulated approximately 440 of these licenses.

The follow-up 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 and administered, in part, by the NYCH. The follow-up review covered the NYCH's response to, and resolution of, eight recommendations made during the January 26 - 30, 1998 IMPEP review. The team's general approach for conduct of the follow-up review included: (1) evaluation of NYCH's implementation of their responses to the recommendations, (2) the status of the program indicators, Status of Materials Inspection Program and Technical Quality of Inspections, for the period of January 30, 1998 - April 28, 1999, (3) review of quantitative information from the radiation control program inspection database, (4) technical review of selected inspection program documentation for response to issues identified during the previous review, (5) interviews with staff and management to answer questions or clarify issues and (6) inspection accompaniments. The team evaluated the information that it gathered against the IMPEP performance criteria for each of the common performance indicators reviewed and made a preliminary assessment of the radiation control program's performance for activities conducted during the period of January 30, 1998 - April 28, 1999. Preliminary results were discussed with New York City management on April 28, 1999.

Section 2 below discusses the results of the previous IMPEP review of the New York program. Results of the follow-up review of the NYCH program for the IMPEP common performance indicators are presented in Section 3. Section 4 discusses the results of the applicable non-common performance indicators. Section 5 summarizes the review team's findings and recommendations during the follow-up review.

2.0 RESULTS OF THE PREVIOUS REVIEW

The previous routine IMPEP review for the New York programs was conducted between January and May 1998, with the New York City program portion conducted on January 26-30, 1998. This review resulted in an overall finding that the New York radiation control programs were “adequate to protect public health and safety and compatible with NRC’s program.” Due to the significance of the findings in the inspection portion of the New York City program, which included findings of satisfactory with recommendations for improvement in two performance indicators, the review team recommended, and the Management Review Board agreed, a follow-up review should be performed after a year of operation with identified corrective actions being taken.

During the follow-up review, the team discussed the five suggestions from the previous review which included: (1) policy on placement of Tribunal results in the inspection files, (2) documentation on how SS&D conditions are addressed in licensing, (3) dating of the issuance of new licenses, (4) investigated incidents to be documented in the notes at the next inspection, and (5) documentation that the alleger has been contacted regarding the results of NYCH’s findings into the alleger’s concerns. All suggestions were considered and actions taken by NYCH except the fourth one. NYCH staff indicated that they would consider this issue in the future. The actions taken on the four suggestions were acceptable to the team.

3.0 COMMON PERFORMANCE INDICATORS

The IMPEP process uses five common performance indicators 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. The 1998 review team’s recommendation was that the follow-up review focus on the two indicators that were found satisfactory with recommendations for improvement (i.e., Status of Materials Inspection Program and Technical Quality of Inspections). The discussion of the recommendations for the other indicators are presented in the respective indicator sections.

3.1 Status of Materials Inspection Program

During the April 1999 follow-up review, the team focused on NYCH’s database for inspection information and its impact on overdue inspections, initial inspections of new licenses, and the timely management of the inspection program. To evaluate these issues, the team interviewed program management and staff, reviewed automated data, and examined the State’s responses to the recommendations in the final report of the 1998 IMPEP review, which resulted in a finding of satisfactory with recommendations for improvement. The final report contained two recommendations for this indicator. The team’s evaluation of the NYCH’s response to the two recommendations are presented below:

Recommendation 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 of the 1998 report)

Current Status

NYCH responded to this recommendation stating that they had corrected the database and could accurately plan and implement their inspection priorities. During the follow-up review, the team evaluated the computer tracking system and found that the system had been corrected and greatly improved the oversight capabilities of the inspection process. The team evaluated how NYCH uses the database and discussed clarifying issues with the Bureau Director. The team found that the Bureau Director and Inspection Supervisor can now identify overdue and past due inspections, and take the necessary actions to address the needs of the inspection program in a timely manner. The team found that NYCH had completed 170 inspections in 1998. Following the review of the database and list of inspections completed since January 1998, the team examined the inspection histories of 18 licenses. Sixteen licenses were inspected on schedule and two inspections were overdue at the time of the follow-up review. One broadscope licensee (one month overdue) was scheduled for inspection the week following the review. One Gamma Stereotactic Radiosurgery licensee was identified as being entered into the database under the incorrect license type code, and, therefore, was not identified as due. The Inspection Supervisor assigned this overdue inspection for the week following the follow-up review. These were the only two inspections that were identified as overdue at the time of the review. The Inspection Supervisor files a monthly report with the Deputy Director who tracks the inspections completed. The team identified a few errors in the database which will be corrected by NYCH staff. The team found the database system in NYCH to be acceptable and that it provides the information needed to effectively manage the materials inspection program.

Based on the follow-up review, the team considers this recommendation to be closed.

Recommendation 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 of the 1998 report)

Current Status

During 1998, NYCH issued 12 new licenses. Initial inspections were completed for nine of these licenses, two were overdue about one month, and one is due in May 1999. The Bureau Chief demonstrated how the database was changed upon issuance of a new license and the automatic assignment of the initial inspection due date in the database. The team found the performance of the database in providing information on initial inspections and the subsequent conduct of initial inspections to be acceptable.

Based on the follow-up review, the team considers this recommendation to be closed.

The timeliness of the issuance of inspection findings was also evaluated during the inspection file review. Of the 16 inspections files examined, NYCH issued compliance letters within 30 days for all but two. One letter (51 days late) was delayed due to negotiations with the Food and Drug Administration on the experimental use of the labeled compound. The other letter (22 days late) had no specific reason for its being late.

Based on the team's review of the Status of Materials Inspection Program, the issues identified during the 1998 review regarding tracking of inspections, conduct of initial and routine inspections, and timeliness of issuance of inspection findings have been addressed by NYCH and the team considers this recommendation to be closed.

3.2 Technical Quality of Inspections

During the April 1999 follow-up review, the team focused on the quality of inspections as reflected in the performance during inspection accompaniments and documentation in inspection files. To evaluate these issues, the team interviewed program management and staff, reviewed inspection files, performed inspection accompaniments, and examined the State's responses to the recommendations in the final report of the 1998 IMPEP review, which resulted in a finding of satisfactory with recommendations for improvement. The final report contained two recommendations for this indicator.

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 inspection files selected for review included at least one inspection for each of the NYCH's inspectors. The inspections included four medical broad scope licenses, three academic broad scope licenses, two teletherapy licenses, two limited medical use licenses, and five private practice physicians. One of the limited medical use license inspections included a review of a high-dose-rate afterloader program. Appendix B lists the inspection files reviewed in depth with case-specific comments.

The team's evaluation of the State's response to the two recommendations are presented below:

Recommendation 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 of the 1998 report)

Current Status

Of the 16 inspections reviewed, six resulted in no violations being identified. For the remaining ten, a majority of the violations identified in the transmittal letters to the licensees were not sufficiently described in the field notes documenting the inspection. The team continues to recommend that NYCH inspectors follow the guidance in the NYCH inspection procedure manual which specifies that supporting information documenting the basis for violations be in the file. During discussions with management, they stated that the requirement for documentation in support of violations as stated in their procedures manual referred to the violation citations that

result in civil penalties. The team indicated that supporting documentation for all cited violations, whether it results in a civil penalty or not, should be available in the inspection file.

Based on the follow-up review, the team considers this recommendation to be open, in part, until management addresses the issue of interpretation/revision of the inspection procedure manual to clarify the policy on supporting documentation needs prior to issuing letters identifying violations of the regulations.

Recommendation 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 of the 1998 report)

Current Status

In response to this recommendation, NYCH used the NRC training manual for the "Inspecting for Performance" course and presented an in-house course. The instructor emphasized the need to do performance based inspections. During the week of April 12, 1999, a team member performed accompaniments of two NYCH inspectors on separate inspections of two medical private practice physician licensees. Appendix B lists the accompaniments performed with specific comments.

During the accompaniments, inspectors demonstrated appropriate inspection skills and knowledge of the regulations. The inspectors were prepared and thorough in their reviews of licensee programs. Inspection techniques were observed to be performance-oriented and the technical performance of both inspectors was good. The inspections were adequate to assess the radiological health and safety of the licensed activities.

Based on the follow-up review, the team considers this recommendation to be closed.

Based on the team's review of the Technical Quality of Inspection indicator, the issues identified in the 1998 IMPEP review have not been fully addressed. The team continues to recommend that NYCH inspectors follow the guidance in the NYCH inspection procedure manual which includes the information necessary for properly documenting violations or that NYCH clarify the policy in their inspection manual for supporting documentation of violations noted during an inspection.

3.3 Technical Staffing and Training

During this follow-up review, the team reviewed the response to the two recommendations for this indicator presented in the revised final report for the 1998 IMPEP review. The results of the discussions with management on the two recommendations are presented below:

Recommendation 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 of the 1998 report)

Current Status

The discussions with the Bureau Director and Deputy Director clarified the recommendation. They stated that they had collected documentation for the training of the materials staff and that they considered them adequately trained. The least experienced person has been with the program for at least five years. The documentation of the training requirements for materials inspectors and licensing staff will be assigned to the person hired to fill the Chief of the materials section position (formerly the Licensing Supervisor). As program documentation is revised, the training requirements may be incorporated prior to filling the position.

The team considers this recommendation to be open until the training requirements are documented in the NYCH procedures manual. The above approach discussed during this review was acceptable to the team.

Recommendation 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 of the 1998 report)

Current Status

As discussed above, the documentation for the training requirements has not been completed. The Bureau Director stated that he considers the current staff adequately trained. Since the 1998 IMPEP review, one assistant scientist left the program and the licensing supervisor was selected for the Bureau Director position. NYCH has posted an assistant scientist position and modified the licensing supervisor position description to be the Chief of the materials section which includes the responsibility for the duties of the Licensing Supervisor. Given the new potential staff for the program, the need for training requirement documentation is emphasized.

The team considers this recommendation to remain open until the training requirements are documented and the evaluation completed.

3.4 Technical Quality of Licensing Actions

During the 1998 IMPEP review, the NYCH was found to be satisfactory for this indicator with no recommendations. This indicator was not reviewed during this follow-up review and no issues were identified during discussions to warrant additional review.

3.5 Response to Incidents and Allegations

During the 1998 IMPEP review, the NYCH program was found to be satisfactory for this indicator. The final report contained one recommendation for this indicator. The team reviewed NYCH's response to the recommendation the current status is presented below:

Recommendation 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 of the 1998 report)

Current Status

The team found that the Inspection Supervisor attended the recent Nuclear Materials Event Database (NMED) training course in Region I and is prepared to begin using the NMED system to manage their events including reporting to NRC. They identified that they did report one event and that they were not aware of any other reportable events.

The team considers this recommendation to be closed.

4.0 NON-COMMON PERFORMANCE INDICATORS

The team reviewed one non-common performance indicator that applied to the New York City program, Legislation and Program Elements Required for Compatibility.

4.1 Legislation and Program Elements Required for Compatibility

During the April 1999 follow-up review, the team discussed the status of NYCH's adoption of regulations needed for compatibility. The final report had one recommendation.

Recommendation 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 of the 1998 report)

Current Status

NYCH has promulgated the transportation regulation which was the major regulation in need of adoption. They are reviewing the list of regulations needed for compatibility and will add them to their regulatory agenda. The team discussed the need to continue promulgation of amendments to maintain a compatible regulatory basis for the program. The team demonstrated the use of the OSP Home Page, how the NYCH can access NRC's list of regulations, and the process for NRC review of draft and final regulations (OSP Procedures SA-200 and SA-201).

The team considers this recommendation to be closed based on the action taken and future actions discussed.

5.0 SUMMARY

The team found the NYCH's performance in responding to and resolving the eight recommendations to be satisfactory with the exception of Recommendations 3, 5 and 6. Recommendation 3 discussed the need for the documentation for violations presented to licensees. Recommendations 5 and 6 discussed the need to develop training requirements and evaluate current and future staff so that they will have the necessary skills for their specific work. The team found that the database for the inspection and licensing programs was working well and management had the needed information to plan and schedule the inspection work.

The team concluded that the program has improved and the significant issue of status of the inspection program has been resolved. The team recommended, and the MRB concurred, that the New York program remains adequate to protect public health and safety, and compatible with NRC's program. The team recommended that the NYCH portion of the New York agreement program be reviewed along with the other three implementing programs at the next scheduled IMPEP review. The MRB considered and concurred with the review team's recommendation.

Below is a summary list of open and modified recommendations from the 1998 report.

Recommendations:

1. The review team continues to recommend that NYCH inspectors follow the guidance in the NYCH inspection procedure manual which includes the information necessary for properly documenting violations (Recommendation 3, Section 3.2.1 of the 1998 report), or that NYCH clarify the policy in their inspection manual for supporting documentation of violations noted during an inspection (Section 3.2).

2. 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. (Recommendation 5, Section 3.3.1 of the 1998 report, Section 3.3)

3. 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. (Recommendation 6, Section 3.3.1 of the 1998 report, Section 3.3)

LIST OF APPENDICES

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
Dennis M. Sollenberger, OSP	Team Leader Status of Materials Inspection Program
Duncan White, RI	Technical Quality of Inspections Inspection Accompaniments
Jamnes Cameron, RIII	Status of Materials Inspection Program Technical Quality of Inspections

THE CITY OF NEW YORK
DEPARTMENT OF HEALTH

Rudolph W. Giuliani
Mayor

Neal L. Cohen, M.D.
Commissioner

June 17, 1999

Paul H. Lohaus, Director
Office of State Programs
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Mr. Lohaus:

The following responses are being made by the New York City.Bureau of Radiological Health addressing the draft IMPEP Follow-up Review Report.

The Bureau reviewed the draft report and found it to be accurate and reflective of the preliminary discussions held at the end of the follow-up review on April 28, 1999.The Bureau staff is pleased with the follow-up team's conclusion that the program has improved and that the significant issue of the status of the inspection program has been resolved. Bureau management is committed to resolving the three open recommendations and is confident that by the next program review, these too will be closed.

Since the Bureau agrees with the draft follow-up review report, I recommend that it be issued to the MRB for concurrence as a final report. The Bureau staff and I feel that the entire IMPEP process has been a positive experience and has enhanced this program's ability to oversee the safe and effective use of radioactive materials in this city. Please pass along our compliments to Dennis Sollenberger and his IMPEP team members.

Sincerely,

Neal L. Cohen, M.D.
Commissioner of Health

NLC/ih
cc: B. Mojica, M.D.
H. Stirling
A. Goldberg

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