



**UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION I**  
2100 RENAISSANCE BOULEVARD, SUITE 100  
KING OF PRUSSIA, PENNSYLVANIA 19406-2713

November 20, 2012

Gene Miskin, Director  
Office of Radiological Health  
Division of Environmental Remediation  
New York City Department of Health and Mental Hygiene  
22 Cortlandt Street, 34<sup>th</sup> Floor  
New York, NY 10007

Dear Mr. Miskin:

A periodic meeting was held with you and your staff on September 27, 2012. The purpose of the meeting was to review and discuss the status of the New York City Department of Health and Mental Hygiene's Agreement State Program. The NRC was represented by Raymond Lorson, Michelle Beardsley and me.

I have completed and enclosed a general meeting summary, including any specific actions that will be taken as a result of this meeting. If you feel that our conclusions do not accurately summarize the meeting discussion, or have any additional remarks about the meeting in general, please contact me at (610) 337-5371, or email to [Donna.Janda@nrc.gov](mailto:Donna.Janda@nrc.gov) to discuss your comments.

Sincerely,

***/RA/***

Donna M. Janda  
Regional State Agreements Officer  
Division of Nuclear Materials Safety

Enclosure: As stated

AGREEMENT STATE PERIODIC MEETING SUMMARY FOR NEW YORK CITY  
DEPARTMENT OF HEALTH AND MENTAL HYGIENE (NYC)

DATE OF MEETING: September 27, 2012

NRC Attendees	New York City Department of Health and Mental Hygiene Attendees
Donna Janda, RSAO, Region I	Gene Miskin, Director, Office of Radiological Health
Michelle Beardsley, FSME	Tobias Lickerman, Unit Chief, Materials Program
Raymond Lorson, Director, DNMS, Region I	

DISCUSSION:

The Integrated Materials Performance Evaluation Program (IMPEP) review of the New York Agreement State Program (the Program) was conducted on June 6-16, 2011. On October 11, 2011, the Management Review Board (MRB) met to consider the proposed final IMPEP report on the Program and found the Program adequate, but needs improvement, to protect public health and safety, and not compatible with the U.S. Nuclear Regulatory Commission's (NRC) program. The agencies which comprise the New York Agreement State program are the New York State Department of Health (NYS DOH), New York State Department of Environmental Conservation (NYS DEC), and New York City Department of Health and Mental Hygiene (NYC). Because of the significance of the findings, the MRB determined that the Program should continue the period of heightened oversight, which was initiated in November 2005. The MRB also directed each of the agencies that comprise the Agreement State program to revise their Program Improvement Plans (PIP) as part of their response to the final IMPEP report. The NRC reviewed the agencies' initial PIPs and concluded that each PIP contained a reasonable and realistic approach to addressing the recommendations made in the final IMPEP report. The MRB also directed that bimonthly calls be conducted between the New York and NRC staffs. As part of the heightened oversight process, each agency submits an updated PIP prior to each bimonthly call. In addition, the MRB determined that a periodic meeting should be held within one year of the MRB to assess the State's progress in addressing the open recommendations. This summary describes the periodic meeting with the NYC.

The status of NYC's actions to address the open recommendation from the 2006 IMPEP review follows:

**Recommendation 1:** The 2006 IMPEP review team recommended that NYC develop and implement an action plan to adopt NRC regulations in accordance with the current NRC policy on adequacy and compatibility.

**Status:** Since the June 2011 IMPEP, NYC has updated their PIP to address their overdue regulation amendments. The adoption process for the eight overdue amendments has slipped six to nine months due to managing other Program priorities, including amending the regulations to address a new proton beam facility being built in New York City.

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The status of NYC's actions to address the open recommendations from the 2011 IMPEP review follows:

**Recommendation 2:** The review team recommended that NYC respond to each incident received in accordance with its established Incident Response Procedure.

**Status:** Since the 2011 IMPEP review, NYC revised its Incident Response Procedure and has trained the staff on the contents of the revised procedure. Program managers reminded the staff to follow the established protocol for medical events reported to NYC and to follow the proper sequence of events to close out all incidents reported to NYC.

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

**Status:** The Office Director stated that program staff was made aware of and instructed to review the reporting requirements as listed in SA-300. The Incident Response Procedure was modified to add the requirement for timely notifications.

**Recommendation 4:** The review team recommended that NYC evaluate all incident statistical information received from licensees, both retrospectively and prospectively, and follow up in a manner to ensure that each incident is properly evaluated for health, safety, and security implications.

**Status:** The Office Director stated that this evaluation continues to be the standard practice of NYC. The inspection staff has been reminded to follow the medical event protocol for all events received (whether voluntarily reported or identified through an Order.) The inspection staff was also reminded to review the quality assurance records during inspections at licensee facilities to determine if any reportable events occurred which were not reported to NYC.

OTHER TOPICS COVERED DURING THE MEETING INCLUDED:

Program Strengths and Weaknesses

The Office Director stated that having a well-trained, experienced staff is a major strength of NYC's radioactive materials program. In addition, the Office Director stated that he has good management support. He meets with the Assistant Commissioner on a weekly basis to discuss the status of the radioactive materials program. NYC has adequate equipment to support the program.

The Office Director noted that training needs are being addressed and will continue to be addressed as they are identified. Several staff members are approaching retirement age so the Office Director is evaluating potential areas for addressing knowledge management issues.

### Feedback on the NRC's Program

The Office Director offered his opinion that recently the IMPEP process has become more subjective and is not as helpful as previous IMPEP reviews. This opinion is consistent with concerns previously raised by the New York Agreement State program related to the IMPEP process. NYC is appreciative of NRC-funded qualification training courses.

### Agreement State Program Staffing and Training

Since the 2011 IMPEP review, NYC has lost one technical staff member due to retirement. According to the Office Director, this position is being posted. Currently the NYC program is allotted 4.7 full-time equivalents (FTE) which is adequate to implement the radioactive materials program.

Support for staff training exists in NYC. Staff members have attended NRC-funded training courses as part of their training process. Staff members need a 30-day lead time for approval for out-of-state travel.

### Inspection and Licensing Programs

The Office Director and Unit Chief noted that since the 2011 IMPEP review, there have been no backlogs in either licensing or inspection activities. NYC currently has approximately 350 radioactive materials licenses. License reviewers are using the pre-licensing guidance. Three pre-licensing visits have been completed since the 2011 IMPEP review.

### Regulations

During the 2011 IMPEP review, the review team identified eight NRC amendments that were overdue for adoption by NYC. Since the IMPEP review and prior to submission of the updated PIP, NYC submitted two final amendments to NRC for review. In addition, NRC determined that one amendment which was listed as overdue in the 2011 IMPEP report was not applicable to NYC's program. The NYC submitted the latest version of their PIP to the NRC in August 2012 (ML12235A438). Since the 2011 IMPEP review, one additional amendment has become overdue and will need to be addressed by NYC.

The following six NRC amendments are overdue for adoption by NYC:

- "Minor Corrections, Clarifying Changes, and a Minor Policy Change," 10 CFR Parts 20, 30, 40, and 70 amendments (63 FR 39477, 63 FR 45393), that became effective on October 26, 1998, and was due for Agreement State adoption by October 26, 2001. (RATS ID 1998-5)
- "Transfer for Disposal and Manifests: Minor Technical Conforming Amendment," 10 CFR Part 20 amendment (63 FR 50127), that became effective on November 20, 1998, and was due for Agreement State adoption by November 20, 2001. (RATS ID 1998-6)
- "Exemptions from Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements," 10 CFR Parts 30, 31, 32, and 150 amendments (72 FR 58473), that became effective on December 17, 2007, and were due for Agreement State adoption by December 17, 2010. (RATS ID 2007-2)

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- “Requirements for Expanded Definition of Byproduct Material,” 10 CFR Parts 20, 30, 31, 32, 35, 61, and 150 amendments (72 FR 55864), that became effective on November 30, 2007, and were due for Agreement State adoption by November 30, 2012. (RATS ID 2007-3)
- “Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent,” 10 CFR Parts 19 and 20 amendments (72 FR 68043), that became effective on February 15, 2008, and were due for Agreement State adoption by February 15, 2011. (RATS ID 2008-1)
- “Medical Use of Byproduct Material – Authorized user Clarification,” 10 CFR Part 35 amendment (74 FR 33901), that became effective on September 28, 2009, and was due for Agreement State adoption by September 28, 2012. (RATS ID 2009-1)

### Organization

The radioactive materials program is administered by the Materials Unit in the Office of Radiological Health. The Office is located in the Department of Health and Mental Hygiene (Department). The Office Director stated that NYC has had no legislative changes or organization changes to their program since the 2011 IMPEP review.

### Program Budget/Funding

The Office Director stated that there have been across-the-board reductions in funding within the Department. License fees are placed into a general fund and have not been changed in the last 18 years. The program is not experiencing any problems with travel for inspections or for out-of-state activities.

### Event Reporting

NYC has reported two events to NRC since the 2011 IMPEP review. NYC inspectors responded to both events in a timely manner.

### Response to Incidents and Allegations

NYC continues to be sensitive to notifications of incidents and allegations. The Office Director stated that there have been no significant events or events with generic implications in NYC’s jurisdiction since the 2011 IMPEP review. One misdirected call was referred to NYC from NRC since the IMPEP.

### Current NYC Initiatives

NYC has received an application for a proton therapy facility. Significant effort has been utilized to ensure regulations and guidance documents are in place prior to this facility being operational.

Large, Complicated, or Unusual Authorizations for Use of Radioactive Materials

NYC received a request for authorization of radium-223 for medical use. The Office Director and Unit Chief are interested in guidance on licensing this type of material and use. After this meeting, Ms. Beardsley was informed by the FSME Team Leader, Medical Radiation Safety Team, an update on this topic will be provided at the November 2012 NRC/OAS/CRCPD conference call.

State's Mechanisms to Evaluate Performance

Supervisors accompany all inspectors on an annual basis. All inspection and licensing work receive supervisory reviews. License reviewers conduct peer reviews of licensing actions. Periodic staff meetings are held to discuss issues.

SUMMARY:

NYC has experienced some delay in moving regulation amendments through the adoption process due to other Office priorities. NYC does not have a backlog in either licensing or inspections. NYC is addressing the recommendations made in the 2011 IMPEP review.

NRC staff recommends that the next IMPEP review should be conducted as scheduled in FY 2013 (tentatively September 2013).