February 19, 2013

MEMORANDUM TO: Michael F. Weber
Deputy Executive Director for Materials, Waste,
Research, State, Tribal, and Compliance Programs
Office of the Executive Director for Operations

Bradley W. Jones, Assistant General Counsel
for Reactor and Materials Rulemaking
Office of the General Counsel

Brian E. Holian, Deputy Director
Office of Federal and State Materials
and Environmental Management Programs

Cynthia D. Pederson, Deputy Administrator
Region III

FROM: Michelle R. Beardsley, Health Physicist ***/RA K. Meyer for/***
Division of Materials Safety and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

SUBJECT: MARCH 5, 2013 SPECIAL MRB MEETING

A Special Management Review Board (MRB) meeting, to discuss the results of the periodic meetings held with the New York Agreement State Program which is comprised of the New York State Department of Health, the New York State Department of Environmental Conservation and the New York City Department of Health and Mental Hygiene, has been scheduled for **Tuesday, March 5, 2013 from 1:00 p.m. to 4:00 p.m. ET, in One White Flint North, Room 4-B6**. The summaries for each of the meetings are enclosed (Enclosures 1, 2 and 3).

In accordance with Management Directive 5.6, the meeting is open to the public. The agenda for this meeting is enclosed (Enclosure 4).

If you have any questions or need additional information, please feel free to contact me at (610) 337-6942 or Michelle.Beardsley@nrc.gov.

Enclosures:
As stated

cc w/ encl.: James McNees, AL
Organization of Agreement States
Liaison to the MRB

MRB Members

Distribution: DCD (SP01)
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AGREEMENT STATE PERIODIC MEETING SUMMARY FOR NEW YORK STATE DEPARTMENT OF HEALTH (DOH)

DATE OF MEETING: September 25, 2012

NRC Attendees	New York State Department of Health Attendees
Pamela Henderson, Deputy Director, DMSSA, FSME	Adela Salame-Alfie, PhD, Assistant Director, Division of Environmental Health Investigations
Michelle Beardsley, FSME	Stephen Gavitt, CHP, Director, Bureau of Environmental Radiation Protection (Bureau)
Donna Janda, Region I RSAO	Robert Dansereau, Assistant Bureau Director
	Charles Burns, Radioactive Materials Section
	Robert Snyder, Chief, Field Operations Section

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 meeting to assess the State's progress in addressing the open recommendations. This summary describes the periodic meeting with the NYS DOH.

The status of NYS DOH's actions to address the open recommendations follows:

> **Recommendation 1**: The review team recommended that DOH develop and implement a process to track reciprocity inspections to ensure at least 20 percent of candidate licensees for reciprocity are inspected.
>
> **Status**: Since the June 2011 IMPEP, NYS DOH has implemented the use of a tracking system which allows for tracking and completion of reciprocity inspections. According to the Bureau Director, the Bureau has completed inspections of greater than 20 percent of the candidate licensees since the 2011 IMPEP review.

During a discussion on the 2011 IMPEP Self-Assessment report, the Bureau Director commented that one of the recommendations in the report was to remove the 20% requirement for reciprocity inspections from the IMPEP program. Mr. Gavitt stated that NRC needs to address this recommendation in a timely manner in order to relieve states of unnecessary burden on their already limited resources.

Recommendation 2: The review team recommended that NYS DOH develop comprehensive incident response and allegation procedures, and ensure that reportable incidents are reported to the NRC Operations Center in accordance with the timelines identified in FSME Procedure SA-300.

Status: Since the 2011 IMPEP review, NYS DOH has created two policy manuals, one for incident response and one for allegations. After the manuals were completed, the Bureau staff was trained on the new policies.

OTHER TOPICS COVERED DURING THE MEETING INCLUDED:

Program Strengths and Weaknesses

The Bureau Director stated that having a well-trained, experienced staff is a major strength of the radioactive materials program. One challenge for the DOH is filling vacancies within the Bureau. When a staff member leaves the Bureau, the position is eliminated and the Bureau must request a new position be filled on a case-by-case basis.

Feedback on the NRC's Program

The Bureau managers stated that NYS DOH is appreciative of NRC-funded training courses. During this meeting, the Bureau had requests for information from NRC on several topics, including information on the process for technical assistance requests from Agreement States; additional information related to a facility that may possess tritium watches without a license; the process for returning an SS&D program to NRC; and a question on the 2002 IMPEP assessment recommendation regarding reviews of complex programs.

Since the periodic meeting, FSME has provided responses to the requests for information on technical assistance requests and the process for returning an SS&D program to NRC. NRC staff is addressing the remaining requests and will provide information to the Bureau on each of the open items once a response is received.

Agreement State Program Staffing and Training

Since the 2011 IMPEP review, the Bureau has lost three materials staff members and hired three new staff members. One new staff member is being qualified in materials inspections and two new staff members are being trained in x-ray inspections. The Bureau currently has approximately 10.0 full-time equivalents (FTE) in the radioactive materials area, which is down from approximately 11.5 FTE at the time of the 2011 IMPEP review. The Bureau Director is currently focusing his efforts on receiving approval to fill the recently vacated Radioactive Materials Section Chief position. Support for staff training exists in the Bureau. DOH radioactive

materials program staff members have attended NRC-funded training courses as part of their qualification process. The Bureau also uses other means (i.e., in-house training and inspector accompaniments) to train current staff. State staff members need approval from the Governor's office for out-of-state travel which at times impacts State employees' attendance at the NRC-funded training courses.

Organization

The radioactive materials program is administered by the Bureau's Radioactive Materials Section. The Bureau is part of the Division of Environmental Health Investigations in the New York State Department of Health. The Bureau is also responsible for radiation-producing machines, radiological emergency response and environmental radiation/radon. There have been no organizational changes since the 2011 IMPEP review.

Program Budget/Funding

The Bureau Director stated that the program is adequately funded. Program fees are placed into a dedicated fund. Upper management approval is needed to spend from the account. The last fee update for the Bureau occurred in 2001.

Inspection and Licensing Programs

The Bureau's inspection frequencies are at least as frequent as NRC's. Since the 2011 IMPEP review, one inspection was completed overdue and one inspection is currently overdue with respect to NRC inspection priorities.

The Bureau has approximately 1100 radioactive materials specific licenses. The 2011 IMPEP review team noted that the Bureau had a total of 73 licenses that were under timely renewal for more than one year. The Bureau has been actively working on this backlog of renewal actions, with priority given to the oldest renewals. Mr. Gavitt stated that the DOH is in the process of converting licenses which transferred from the Department of Labor (DOL), which had a three-year renewal term, to the DOH, which has a ten-year renewal period. According to Mr. Gavitt, they have not identified any health and safety or security issues associated with the overdue renewals.

Regulations

During the 2011 IMPEP review, the review team identified 16 NRC amendments that were overdue for adoption by DOH. Since the IMPEP, one additional regulation has become overdue. The Bureau submitted the latest version of their PIP to the NRC in June 2012 (ML12235A411). The Bureau is addressing the overdue regulations in two packages.

The following six overdue regulations are being addressed in Regulatory Package #1:

- "Quality Management Program and Misadministrations," 10 CFR Part 35 amendment (56 FR 34104), that became effective on January 27, 1992, and was due for Agreement State adoption on January 27, 1995. (RATS ID 1992-1)

- "Medical Administration of Radiation and Radioactive Materials," 10 CFR Parts 20 and 35 amendments (60 FR 48623), that became effective on October 20, 1995, and were due for Agreement State adoption by October 20, 1998. (RATS ID 1995-7)

- "Medical Use of Byproduct Material," Parts 20, 32 and 35 amendments (67 FR 20249), that became effective on October 24, 2002, and were due for Agreement State adoption on October 24, 2005. (RATS ID 2002-2)

- "Medical Use of Byproduct Material - Recognition of Specialty Boards," 10 CFR Part 35 amendment (70 FR 16336; 71 FR 1926), that became effective on April 29, 2005, and was due for Agreement State adoption on April 29, 2008. (RATS ID 2005-2)

- "Medical Use of Byproduct Material – Minor Corrections and Clarifications," 10 CFR Parts 32 and 35 amendments (72 FR 45147; 72 FR 54207), that became effective on October 29, 2007 and were due for Agreement State adoption on October 29, 2010. (RATS ID 2007-1)

- "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 on September 28, 2012. (RATS ID 2009-1)

According to the Bureau Director, this final regulation package was approved by the Governor's Office and was expected to be published in the State Register for a 45-day public comment period on October 3, 2012.

The following 11 overdue regulations are being addressed in Regulatory Package #2:

- "Termination or Transfer of Licensed Activities: Recordkeeping Requirements," 10 CFR Parts 20, 30, 40, 61, and 70 amendments (61 FR 24669), that became effective on June 17, 1996, and were due for Agreement State adoption on June 17, 1999. (RATS ID 1996-3)

- "Radiological Criteria for License Termination," 10 CFR Parts 20, 30, 40, and 70 amendments (62 FR 39057), that became effective on August 20, 1997, and were due for Agreement State adoption on August 20, 2000. (RATS ID 1997-6)

- "Deliberate Misconduct by Unlicensed Persons," Parts 30, 40, 61, 70, 71 and 150 amendments (63 FR 1890, 63 FR 13773), that became effective on February 12, 1998, and were due for Agreement State adoption on February 12, 2001. (RATS ID 1998-1)

- "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 were due for Agreement State adoption on October 26, 2001. (RATS ID 1998-5)

- "Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material," 10 CFR Parts 30, 31 and 32 (65 FR 79162), that became effective on February 16, 2001, and were due for Agreement State adoption on February 16, 2004. (RATS ID 2001-1)

- "Revision of the Skin Dose Limit," 10 CFR Part 20 amendment (67 FR 16298), that became effective on April 5, 2002, and was due for Agreement State adoption on April 5, 2005. (RATS ID 2002-1)

- "Financial Assurance for Materials Licensees," 10 CFR Parts 30, 40, and 70 (68 FR 57327), that became effective on December 3, 2003, and were due for Agreement State adoption on December 3, 2006. (RATS ID 2003-1)

- "Minor Amendments," 10 CFR Parts 20, 30, 32, 35, 40, and 70 (71 FR 15005), that became effective on March 27, 2006, and were due for Agreement State adoption on March 27, 2009. (RATS ID 2006-1)

- "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 on December 17, 2010. (RATS ID 2007-2)

- "Requirements for Expanded Definition of Byproduct Material," 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, and 150 amendments (72 FR 55864), that became effective on November 30, 2007, and were due for Agreement State adoption on November 30, 2010. (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 on February 15, 2011. (RATS ID 2008-1)

Event Reporting

During the 2011 IMPEP review, the review team identified that 23 of 26 incidents were not reported to NRC in a timely manner. Since the IMPEP, the Bureau created two policy manuals, one for incident response and one for allegations. After the manuals were completed, the Program staff was trained on the new policies. The Bureau has reported three events to NRC since the 2011 IMPEP review, all of which were reported to NRC in a timely manner.

During a discussion on the importance of timeliness reporting of events in order to identify generic issues, among other reasons, DOH commented that, if the NRC expects states to provide timely and complete event notification then it is reasonable for the states to expect NRC to analyze events for generic implication in a timely manner and to disseminate such information to the states. DOH was particularly interested in the status of NRC's evaluation of microsphere brachytherapy events. After this meeting, Ms. Beardsley was informed by the FSME Team Leader, Medical Radiation Safety Team, that an update on this topic will be provided during the November 2012 NRC/OAS/CRCPD conference call.

Response to Incidents and Allegations

DOH continues to be sensitive to notifications of incidents and allegations. The Bureau Director stated that there have been no significant events or events with generic implications in New York since the 2011 IMPEP review. Three allegations were referred to the Bureau since the IMPEP.

Sealed Source and Device (SS&D) Evaluation Program

The Bureau reported that several new SS&D sheets were approved for a company in New York that purchased a Massachusetts company who distributed chemical detector kits.

Current State Initiatives

The Bureau will be conducting training for its staff during an annual meeting in October 2012. The main focus of this training is to emphasize the importance of being as efficient as possible using in-house resources.

Emerging Technologies

The Bureau is interested in being provided current guidance from NRC related to licensing and use of radium-223 for medical purposes.

The Bureau has received inquiries from a company interested in the manufacture and distribution of beta voltaic batteries. No license application has been received at this time.

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

The Bureau sent inspection staff to an irradiator facility during the construction phase for a new irradiator. Source loading is expected in Spring 2013. In addition, the Bureau licensed a new cyclotron pharmacy.

State's Mechanisms to Evaluate Performance

Supervisors accompany all inspectors on an annual basis. The Bureau conducts biweekly conference calls with the inspection staff and the Field Supervisor. The Bureau uses a computer application to track licensing and inspection activities and holds monthly staff meetings to discuss Bureau activities. All licensing actions are reviewed by the Section Chief.

All inspection reports are reviewed by the Field Supervisor.

SUMMARY:

The Bureau has made progress in addressing IMPEP recommendations on tracking reciprocity inspections and timely reporting of events to NRC. DOH has also made progress on moving one of two regulation packages. The program is adequately funded.

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

AGREEMENT STATE PERIODIC MEETING SUMMARY FOR NEW YORK STATE DEPARTMENT OF ENVIRONMENTAL CONSERVATION (DEC)

DATE OF MEETING: September 26, 2012

NRC Attendees	**New York State Department of Environmental Conservation Attendees**
Donna Janda, Region I RSAO	Robert Schick, Director, Division of Environmental Remediation
Michelle Beardsley, FSME	Jim Harrington, Director, Remedial Bureau A
	Sandra Hinkel, Chief, Radiation Control Permit Section (RCPS)
	Timothy Rice, Chief, Radiological Sites Section (RSS)
	Jessie Owens, Radiological Sites Section

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 meeting to assess the State's progress in addressing the open recommendations. This summary describes the periodic meeting with the NYS DEC.

The status of NYS DEC's actions to address the open recommendation follows:

> **Recommendation**: The 2006 IMPEP review team recommended that DEC develop and implement an action plan to adopt NRC regulations in accordance with the current NRC policy on adequacy and compatibility. (Open recommendation from the 2006 IMPEP review)
>
> **Status**: Since the June 2011 IMPEP, NYS DEC 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 (e.g., Marcellus Shale issues).

OTHER TOPICS COVERED DURING THE MEETING INCLUDED:

Program Strengths

The Section Chiefs stated that having a well-trained, experienced staff is a major strength of the DEC's radioactive materials program.

Feedback on the NRC's Program

The Section Chiefs are appreciative of NRC-funded training courses. The Section Chiefs noted that it is more difficult for staff to attend NRC-sponsored training courses, particularly the new health physics course series, due to the increased demand for the courses now that there are more Agreement States.

Agreement State Program Staffing and Training

Since the 2011 IMPEP review, the DEC has filled one of their two vacant technical staff positions. This position has been moved to the DEC's Region 9 office in Buffalo. The RCPS Chief does not anticipate any impacts to the Program due to the position being moved from the Albany office to Buffalo. Currently there are 6.75 full-time equivalents (FTE) between both Sections to administer the Program.

Support for staff training exists in the DEC. Staff members have attended NRC-funded training courses as part of their training process. The Sections also use other means (i.e., in-house training and inspector accompaniments) to train current staff. State staff members need approval from the Governor's office for out-of-state travel which at times impacts State employees' attendance at the NRC-funded training courses.

Inspection and Licensing Programs

The Section Chiefs noted that since the 2011 IMPEP review, there have been no backlogs in either permit applications or inspections.

Regulations and Legislative Changes

During the 2011 IMPEP review, the review team identified eight NRC amendments that were overdue for adoption by DEC. The DEC submitted the latest version of their PIP to the NRC in June 2012 (ML12235A447). The DEC is addressing the overdue regulations in two packages.

The following two overdue regulations are being addressed in Part 384:

- "Timeliness in Decommissioning Materials Facilities," 10 CFR Parts 30, 40, and 70 amendments (59 FR 36026), that became effective on August 15, 1994 and were due for Agreement State adoption by August 15, 1994. (RATS ID 1994-3)

- "Radiological Criteria for License Termination," 10 CFR Parts 20, 30, 40, and 70 amendments (62 FR 39057), that became effective on August 20, 1997, and were due for Agreement State adoption by August 20, 2000. (RATS ID 1997-6)

The following six overdue regulations are being addressed in Part 380:

- "Notification of Incidents," 10 CFR Parts 20, 30, 31, 34, 39, 40, and 70 amendments (58 FR 64980), that became effective on October 15, 1991, and were due for Agreement State adoption by August 15, 1994. (RATS ID 1991-4)

- "Radiation Protection Requirements: Amended Definitions and Criteria," 10 CFR Parts 19 and 20 amendments (60 FR 36038), that became effective on August 14, 1995, and were due for Agreement State adoption by August 14, 1998. (RATS ID 1995-5)

- "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 were due for Agreement State adoption by October 26, 2001. (RATS ID 1998-5)

- "Revision of the Skin Dose Limit," 10 CFR Part 20 amendment (67 FR 16298), that became effective on April 5, 2002, and was due for Agreement State adoption by April 5, 2005. (RATS ID 2002-1)

- "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)

Since the 2011 IMPEP, one step in the legislative review process has been eliminated. The regulation packages no longer require review by the Environmental Board.

Organization

The radioactive materials program is administered by two Sections, the Radiation Control Permits Sections and the Radiological Sites Section. The Sections are administered by the Remedial Bureau A (Bureau) of the Division of Environmental Remediation (Division). The

Division is located in the New York State Department of Environmental Conservation. One organizational change, a new permanent Division Director, has occurred since the 2011 IMPEP review. The DEC has had no changes to their enabling legislation since the IMPEP.

Program Budget/Funding

The Section Chiefs do not anticipate an increase in the program budget. They noted that it can be a challenge in their ability to spend money for the Program. The DEC Radiological Laboratory was closed within the last six months. Samples now get sent out for contract analysis. Travel approval, both in-state and out-of-state, can be challenging as noted above.

Event Reporting

The DEC has had no reported events since the 2011 IMPEP review.

Response to Incidents and Allegations

DEC continues to be sensitive to notifications of incidents and allegations. The Section Chiefs stated that there have been no significant events or events with generic implications in DEC's jurisdiction since the 2011 IMPEP review. No allegations were referred to the DEC from NRC since the IMPEP.

Low-Level Radioactive Waste Disposal Program

DEC maintains regulatory oversight of two former radioactive waste disposal sites in the State of New York. These sites are inspected on an annual basis and are due to be inspected in the last quarter of 2012.

Current State Initiatives

The RCPS is planning to revisit veterinary facilities that handle unsealed I-131 that did not previously need discharge permits (within the last 10 years) to determine if any of them now require a permit. The RCPS is also addressing new permits from cyclotron facilities. One new permit has been issued this year and the Section expects to receive another permit application in the near future.

To address issues with Marcellus Shale waste, the RSS is working with the Solid Waste Program to issue guidance on how to handle these new waste streams. The Solid Waste Program will make a requirement to have radiation monitors at all solid waste facilities.

State's Mechanisms to Evaluate Performance

Supervisors accompany all inspectors on an annual basis. All inspection and permitting work receive supervisory reviews. Periodic staff meetings are held to discuss issues.

SUMMARY:

The DEC has experienced some delay in moving regulation amendments through the adoption process; however, the removal of one step in the process may help offset some of the delay being experienced. The DEC does not have a backlog in either permitting or inspections and has hired an inspector to fill one of the two vacant positions.

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

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. 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)

- "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).

Agenda for Management Review Board Meeting
March 5, 2013 1:00 p.m. – 4:00 p.m. ET, O-4B6

1. Announcement of Public Meeting to all attendees and request for identification of any members of the public participating in this meeting.

2. MRB Chair convenes meeting. Introduction of MRB members, NRC staff members, State representatives, and other participants.

3. Discussion of Periodic Meetings:

   a. New York Department of Health
      (September 25, 2012) – ML12328A051 – Janda / Beardsley / Henderson

   b. New York Department of Environmental Conservation
      (September 26, 2012) – ML12342A325 – Janda / Beardsley

   c. New York Department of Health & Mental Hygiene
      (September 27, 2012) – ML12328A050 – Janda / Beardsley / Lorson

4. Adjournment

Invitees:

Michael Weber, DEDMRT
Bradley Jones, OGC
Brian Holian, FSME
Cynthia Pederson, RIII
James McNees, AL
Donna Janda, RSAO/RI
Michelle Beardsley, FSME
Raymond Lorson, RI
Daniel Collins, RI
Brian McDermott, FSME
Pamela Henderson, FSME
Duncan White, FSME
Lisa Dimmick, FSME
Karen Meyer, FSME
Jack Foster, OEDO
Stephen Gavitt, NY DOH
Sandra Hinkle, NY DEC
Gene Miskin, NY DHMH

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