# NEW YORK HEIGHTENED OVERSIGHT CONFERENCE CALL January 26, 2012

NRC Attendees	New York Attendees
Dan Collins, Region I	Adela Salame-Alfie, Division Director (NYSDOH)
Monica Orendi, Region I	Stephen Gavitt, Bureau Director (NYSDOH)
Donna Janda, Region I	Robert Dansereau, Assistant Bureau Director (NYSDOH)
Pam Henderson, FSME	Charles Burns, Section Chief, (NYSDOH)
Duncan White, FSME	Robert Snyder, Section Chief (NYSDOH)
Lisa Dimmick, FSME	Jim Harrington, Bureau Director (NYSDEC)
Michelle Beardsley, FSME	Jesse Owens (NYSDEC)
	Sandra Hinkel, Section Chief (NYSDEC)
	Timothy Rice, Section Chief (NYSDEC)
	Christopher Boyd, Assistant Commissionner (NYC)
	Gene Miskin, Office Director (NYC)
	Tobias Lickerman, Unit Chief (NYC)

#### SUMMARY

On February 8, 2007, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the New York Agreement State Program. The MRB directed that each of the New York agencies revise and resubmit their Program Improvement Plan (PIP) as part of the response to the IMPEP. Also it was directed that bimonthly conference calls be conducted between the appropriate New York and NRC staffs to discuss each agency's revised PIP regarding their performance with compatibility requirements. In November 2007 Periodic Meetings were held with the agencies that comprise the New York Agreement State Program. Subsequent to these Periodic Meetings, the MRB met on March 24, 2008, to consider the findings. The MRB directed that calls between New York and NRC staffs continue to be conducted quarterly to discuss the revised PIPs. In July 2009 another set of Periodic Meetings were held. The MRB met on January 7, 2010 to consider the findings of the July 2009 Periodic Meetings. The MRB directed that calls between the New York and NRC staffs continue to be conducted quarterly. In June 2011 an IMPEP review of the New York Agreement State Program was conducted. On October 11, 2011, the MRB met to consider the proposed final IMPEP report. The MRB determined that the New York Agreement State Program should remain on heightened oversight and directed each agency to revise their PIP as part of their response to the final IMPEP report. The MRB also directed that bimonthly calls be conducted between the New York and NRC staffs. This is the first bimonthly call since the October 2011 MRB. The revised PIPs for each agency were submitted on December 28, 2011, January 24, 2012, and January 25, 2012 and can be found in ADAMs (ML120090058, ML120250356, and ML120250353).

NRC has reviewed the NYSDEC PIP and concluded that it contains a reasonable and realistic approach to addressing the recommendations made in the final IMPEP report. The PIP has subsequently been approved by letter dated January 20, 2012 (ML120100402). NRC is still in the process of reviewing both the NYSDOH PIP and the NYC PIP and will be making a determination of approval in the near future.

The next New York Agreement State bimonthly call will take place in March 2012.

#### **DISCUSSION OF PROGRAM STATUS**

## Technical Staffing and Training (IMPEP finding: Satisfactory but Needs Improvement)

At the time of the IMPEP review both NYSDOH and NYSDEC had staff vacancies. Since then, NYSDOH has been given permission and is working on hiring three new employees. Two of the positions are for entry level employees and one is for a senior level staff member. These three positions will help to negate the 6.2 full time equivalent (FTE) loss that NYSDOH has experienced. As of this call NYSDEC has not been given permission to fill either of the two vacant staff positions. NYSDOH and NYSDEC have not lost any additional staff since the IMPEP and NYC is still fully staffed. All three agencies are taking advantage of NRC funded training as well as using other means (i.e.: in house training and inspector accompaniments) to train current staff.

## Status of the Materials Inspection Program (IMPEP finding: Satisfactory)

All three agencies are on track with their inspections and have had no issues since the June 2011 IMPEP. All three agencies are issuing inspection findings timely. In order to better track timeliness of inspection finding issuance, NYSDOH has added this item to the database that was created to track reciprocity inspections. The 2011 IMPEP team generated one recommendation for NYSDOH for this performance indicator. This recommendation is listed below along with its status.

**Recommendation 1:** The review team recommends 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:** Mr. Gavitt stated that NYSDOH has implemented a tracking system which allows for tracking and completion of reciprocity inspections. Mr. Gavitt stated that NYSDOH completed 23 percent of the reciprocity inspections for candidate licensees in calendar year 2011.

### Technical Quality of Inspections (IMPEP finding: Satisfactory)

All three agencies continue to do well in this area and have had no issues arise since the June 2011 IMPEP. NYSDEC mentioned that they have had no relief with regards to travel restrictions. If the dollar amount of a trip (including inspection trips) is above a certain amount then they need to get approval for the travel. Annual inspector accompaniments are ongoing

### Technical Quality of Licensing (IMPEP finding: Satisfactory but Needs Improvement)

During the June 2011 IMPEP the review team found that NYC had not implemented the prelicensing guidance. The team also noted that NYC did not review past enforcement history during the license renewal process as a means of performing quality assurance on the license file. The review team found follow-up questions to licensing actions are often performed via undocumented telephone calls and email. Mr. Miskin stated that NYC is using the NUREG 1556 series and Pre-licensing Guidance when doing licensing actions. NYC is also documenting any interactions with the licensee/ potential licensee that occur during the processing of the licensing application.

During the June 2011 IMPEP, the review team found that NYSDOH had 73 licenses under timely renewal for more than one year and ten licenses under timely renewal for more than 5

years. Mr. Gavitt stated that NYSDOH is actively working on the renewal backlog in an attempt to bring it up to date.

During the June 2011 IMPEP, the review team found no issues with NYSDEC in this indicator. Ms. Hinkel stated that as of this call NYSDEC had no backlog with regards to licensing actions.

## Technical Quality of Incidents and Allegations (IMPEP finding: Unsatisfactory)

The 2011 IMPEP review team generated four recommendations for this performance indicator. These recommendations are listed below along with their status.

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

**Status:** Mr. Miskin stated that this recommendation had been implemented. Staff was reminded to follow the established protocol for medical events reported to NYC. Staff was also reminded of the proper sequence of events to be followed to close out all incidents reported.

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

**Status:** Mr. Miskin stated that staff was made aware of and told to review the reporting requirements as listed in SA-300.

**Recommendation 4:** The review team recommends 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:** Mr. Miskin stated that this continues to be the standard practice of NYC. Staff has been reminded to follow the medical event protocol for all events received (whether voluntary or through an Order).

**Recommendation 5:** The review team recommends that 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 SA-300.

**Status:** Mr. Gavitt stated that NYSDOH has created two policy manuals, 1 for incident response and 1 for allegations. After the manuals were completed staff was trained on the policy.

New York is aware of the need to maintain an effective response to incidents and allegations. During the June 2011 IMPEP the review team found no issues with NYSDEC under the indicator Technical Quality of Incidents and Allegations. Since the IMPEP NYSDEC stated that they have received no new incidents or allegations. NYSDOH has received no allegations since the June 2011 IMPEP. NYC has received one allegation since the June 2011 IMPEP and has followed their procedures for the handling and follow-up of this allegation.

### Compatibility Requirements (IMPEP finding: Unsatisfactory)

New York continues to work on addressing this indicator. All three agencies are continuing to

focus attention on bringing New York up to date with compatible regulations.

NYC has the following six NRC amendments overdue for adoption:

- "Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use," 10 CFR Parts 30, 32, and 35 amendments (59 FR 61767; 59 FR 65243; 60 FR 322), that became effective on January 1, 1995 and was due for Agreement State adoption by January 1, 1998.
- "Minor Corrections, Clarifying Changes, and a Minor Policy Change," 10 CFR Parts 20, 35, and 36 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.
- "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.
- "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 was due for Agreement State adoption by December 17, 2010.
- "Requirements for Expanded Definition of Byproduct Material," Parts 20, 30, 31, 32, 33, 35, 61, and 150 amendments (72 FR 55864), that became effective on November 30, 2007 and was due for Agreement State adoption by November 30, 2010.
- "Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent," 10 CFR Parts 19 and 20 amendments (72 FR 68043), that became effective February 15, 2008 and was due for Agreement State adoption by February 15, 2011.

NYC has included as part of their submitted PIP a plan to adopt not only those regulations that are currently overdue but also future regulation amendments that are coming due. In reviewing the NYC PIP, NRC noted that NYC omitted a plan for adoption of RATS ID 1995- 1 (see first bullet above). NYC should include a plan for adoption of this overdue regulation when they send in their revised PIP before the next bi-monthly Heightened Oversight call.

NYSDOH has the following 16 NRC amendments overdue for adoption:

- "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 by January 27, 1995.
- "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 was due for Agreement State adoption by October 20, 1998.
- "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 was due for Agreement State adoption by June 17, 1999.

- "Radiological Criteria for License Termination," 10 CFR Parts 20, 30, 40, and 70 amendments (62 FR 39057), that became effective August 20, 1997 and was due for Agreement State adoption on August 20, 2000.
- "Deliberate Misconduct by Unlicensed Persons," 10 CFR Parts 30, 40, and 70 amendments (63 FR 1890, 63 FR 13773), that became effective on February 12, 1998, and was due for Agreement State adoption by February 12, 2001.
- "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.
- "Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material," 10 CFR Parts 30, 31, and 32 amendments (65 FR 79162), that became effective on February 16, 2001 and was due for Agreement State adoption on February 16, 2004.
- "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.
- "Medical Use of Byproduct Material," 10 CFR Parts 20, 32, and 35 amendments (67 FR 20249), that became effective on April 24, 2002, and was due for Agreement State adoption by October 24, 2005.
- "Financial Assurance for Materials Licensees," 10 CFR Parts 30, 40, and 70 amendments (68 FR 57327), that became effective on December 3, 2003, and was due for Agreement State adoption by December 3, 2006.
- "Medical Use of Byproduct Material," 10 CFR Parts 20, 32, and 35 amendments (67 FR 20249), that became effective on April 24, 2002, and was due for Agreement State adoption by April 24, 2005.
- "Minor Amendments," 10 CFR Parts 20, 30, 32, 35, 40, and 70 amendments (71 FR 15005), that became effective on March 27, 2006, and is due for Agreement State adoption by March 27, 2009.
- "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.
- "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 was due for Agreement State adoption by December 17, 2010.
- "Requirements for Expanded Definition of Byproduct Material," Parts 20, 30, 31, 32, 33, 35, 61, and 150 amendments (72 FR 55864), that became effective on November 30, 2007 and was due for Agreement State adoption by November 30, 2010.

• "Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent," 10 CFR Parts 19 and 20 amendments (72 FR 68043), that became effective February 15, 2008 and was due for Agreement State adoption by February 15, 2011.

NYSDOH has included as part of their submitted PIP a plan to adopt currently overdue regulation amendments.

NYSDEC has the following eight NRC amendments overdue for adoption:

- "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 was due for Agreement State adoption by August 15, 1994.
- "Timeliness in Decommissioning Material Facilities," 10 CFR Parts 30, 40, and 70 amendments (59 FR 36026), that became effective on August 15, 1994 and was due for Agreement State adoption by August 15, 1997.
- "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 was due for Agreement State adoption by August 14, 1998.
- "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 was due for Agreement State adoption by August 20, 2000.
- "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.
- "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.
- "Requirements for Expanded Definition of Byproduct Material," Parts 20, 30, 31, 32, 33, 35, 61, and 150 amendments (72 FR 55864), that became effective on November 30, 2007 and was due for Agreement State adoption by November 30, 2010.
- "Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent," 10 CFR Parts 19 and 20 amendments (72 FR 68043), that became effective February 15, 2008 and was due for Agreement State adoption by February 15, 2011.

NYSDEC has included as part of their submitted PIP a plan to adopt currently overdue regulation amendments.

Sealed Source and Device (SS&D) Evaluation Program (IMPEP finding: Satisfactory)

There have been no changes in the SS&D program since the June 2011 IMPEP. New York currently has two qualified SS&D reviewers and one individual serving as a backup. Both reviewers are considered by NYSDOH to be fully qualified. During the June 2011 IMPEP review the review team found that SS&D reviews performed by NYSDOH adequately addressed health and safety issues and were of sufficient technical quality.

## Low-Level Radioactive Waste Disposal (LLRW) Program (IMPEP finding: Satisfactory)

There have been no changes in the LLRW Program since the June 2011 IMPEP. During the 2011 IMPEP, the review team found that the oversight of the two former radioactive waste disposal sites was suitable and thorough.

## Conclusion

The three agencies that make up the New York Agreement State Program have submitted their respective PIPs to NRC for approval. Each agency is working on and has been responsive to the recommendations that were made during the 2011 IMPEP review. The next bi-monthly Heightened Oversight call will be held in March 2012.