NEW YORK HEIGHTENED OVERSIGHT
CONFERENCE CALL
March 29, 2012

NRC Attendees	New York Attendees
Raymond Lorson, 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)
Duncan White, FSME	Jim Harrington, Bureau Director (NYSDEC)
Lisa Dimmick, FSME	Jesse Owens (NYSDEC)
Sara Mroz, FSME	Sandra Hinkel, Section Chief (NYSDEC)
	Timothy Rice, Section Chief (NYSDEC)
	Gene Miskin, Office Director (NYC)

SUMMARY

In June 2011 an Integrated Materials Performance Evaluation Program (IMPEP) review of the New York Agreement State Program was conducted. On October 11, 2011, the Management Review Board (MRB) met to consider the proposed final IMPEP report. The MRB determined that the New York Agreement State Program should remain on 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 Plan (PIP) as part of their response to the final IMPEP report. The agencies which comprise the Agreement State program are the New York State Department of Health (NYSDOH), New York State Department of Environmental Conservation (NYSDEC), and New York City Health Department (NYC). The MRB also directed that bimonthly calls be conducted between the New York and NRC staffs. This is the second bimonthly call since the October 2011 MRB. The revised PIPs for each agency were submitted on March 21, 2012 and March 26, 2012.

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 PIPs were subsequently approved by letter dated January 20, 2012 (ML120100402) to NYSDEC, by letter dated February 21, 2012 (ML1200440093) to NYSDOH, and by letter dated February 21, 2012 (ML1204490112) to NYC.

DISCUSSION OF PROGRAM STATUS

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

At the time of the 2011 IMPEP review both NYSDOH and NYSDEC had staff vacancies. Since the January 2012 conference call, NYSDOH has hired two new staff members into entry level positions and are in the process of hiring a senior level staff member. These three positions will help to negate the 6.2 full time equivalent (FTE) loss that NYSDOH has experienced. One senior level attorney who is involved in regulation development activities will be leaving the department. The NYSDOH Program managers are reviewing the possible impact of this staff member's departure on the development of regulations and plan to address any impacts identified as part of their review.

As of this call NYSDEC has two vacant staff positions. Funding for one of these vacant positions has been transferred from the main office in Albany to the NYS Region 9 office in Buffalo. The Program managers had no knowledge at the time of the conference call of possible impacts to the Program due to the position being moved. 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. 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 no update for this recommendation since the previous conference call. NYSDOH continues to use their recently developed tracking system which allows for tracking and completion of reciprocity inspections.

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. 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 pre-licensing 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 were often performed via undocumented telephone calls and email. During the conference call in January 2012, Mr. Miskin stated that NYC is using the NUREG-1556 guidance series and pre-licensing guidance when completing licensing actions. NYC is also documenting any interactions with the licensee/ potential licensee that occur during the processing of the licensing application. There have been no changes/issues associated with this indicator since the previous conference call.

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 five years. Mr. Gavitt stated that NYSDOH is actively working on the renewal backlog in an attempt to bring it up to date. There have no changes/issues associated with this indicator since the previous conference call.

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. The Program held a pre-permitting meeting with a new cyclotron applicant.

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 NYC has updated their Policies and Procedures Manual to include the NRC definition of a medical event.

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 NYC has updated their Incident Response Procedure to add timely notifications to the NRC Operations Center in accordance with the timelines identified 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: During the conference call in January 2012, Mr. Miskin stated that this continued to be the standard practice of NYC. NYC had no updates for this recommendation.

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 this recommendation was addressed prior to the conference call in January 2012. NYSDOH had no updates for this recommendation.

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 review, 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.

The following NRC amendment was not applicable to the NYC portion of the Agreement and was removed from the NYC PIP prior to this conference call:

- "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.

NYC has the following five NRC amendments overdue for adoption:

- "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 updated 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 dated March 26, 2012, NRC noted that NYC omitted a plan for adoption of RATS ID 1998-5 and RATS ID 1998-6 (see first two bullets listed as overdue amendments above). NYC should include a plan for adoption of these overdue regulations 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 updated PIP a plan to adopt currently overdue regulation amendments. Mr. Gavitt noted that the medical regulations have been submitted to the Governor's Office. Once they are approved by the Governor's Office, the regulations will be published for a 45-day comment period, submitted to the Public Health Council for final review and approval, then the final rule will be published and submitted to NRC for review.

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 updated PIP a plan to adopt currently overdue regulation amendments. NYSDEC is making progress on Parts 380 and 384 amendments; however, the schedule for adopting these amendments has slipped approximately two to three months due to managing other priorities.

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, 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. Program managers are still evaluating the possible impacts from moving one of the open positions to the Region 9 office. This position was associated with regulation development and the West Valley Project.

Conclusion

The three agencies that make up the New York Agreement State Program have received NRC approval for their respective PIPs. Each agency is addressing the recommendations that were made during the 2011 IMPEP review. The next bimonthly Heightened Oversight call will be held in May or June 2012.