UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
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KING OF PRUSSIA, PENNSYLVANIA 19406-2713

November 20, 2012

Stephen Gavitt, CHP, Director
Bureau of Environmental Radiation Protection
Division of Environmental Health Investigations
New York State Department of Health
Empire State Plaza - Corning Tower, 12th Floor
Albany, NY 12237

Dear Mr. Gavitt:

A periodic meeting was held with you and your staff on September 25, 2012. The purpose of the meeting was to review and discuss the status of the New York State Department of Health's Agreement State Program. The NRC was represented by Pamela Henderson, 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 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 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.

Enclosure

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).

Enclosure