

**Comment Resolution for the August 4, 2011, E-Mail from the
New York Department of Environmental Conservation (ML11216A261)
Regarding the July 15, 2011, Draft IMPEP Report**

- **Comment 1: Page 13**

The first paragraph states, "Prior to the inspection, a full briefing is held between the inspectors, the Permit Unit Supervisor and the Section Chief to discuss the inspection." There is no "Permit Unit Supervisor" position at DEC; reference to that position should be deleted. Briefings are held between inspectors and the Section Chief.

Response 1:

Thank you for the clarification. The paragraph has been changed to delete reference to the Permit Unit Supervisor.

- **Comment 2: Page 16**

The last paragraph states, "The permit unit supervisor monitors the status of permits..." As explained above, the words "permit unit supervisor" should be replaced with "Section Chief."

Response 2:

Thank you for the clarification. The paragraph has been changed to delete reference to the Permit Unit Supervisor.

- **Comment 3: Page 22**

The first paragraph states, "DEC Law Articles 1, 3, 17, 19, 29 and 37 are the basis to create DEC..." DEC's enabling legislation (law) should be referenced as: "Articles 1, 3, 17, 19, 29 and 37 of the Environmental Conservation Law."

Response 3:

Thank you for the clarification. The paragraph has been changed to reflect the term "Environmental Conservation Law."

- **Comment 4: Page 25**

The fourth paragraph states, "DEC regulations are found in 6 NYCRR, Chapter IV, Subchapter C, Parts 380, 381, 382, 383, and 384 and apply..." Because the new Part 384 has not yet been issued, it should be deleted from this sentence. (We are currently working on development of the new Part 384 regulations to implement DEC's portion of the license termination rule.)

Response 4:

Thank you for the clarification. The paragraph has been changed to delete reference to Part 384.

- **Comment 5: Page 29**

The third paragraph states, "In 2007 DEC hired an inspector who has the responsibility of carrying out inspections at the West Valley disposal site and Cornell disposal site." That statement mischaracterizes the situation, as it implies that the inspector was hired in 2007 with the intent of being made responsible for those former disposal sites. When that inspector was hired in 2007, the West Valley environmental monitor position was still occupied (the environmental monitor was also responsible for the Cornell site). The new inspector, hired in 2007, was not assigned to assist the West Valley environmental monitor until 2008. In 2009, the West Valley monitor position became vacant. Since that time, the new inspector has continued to work on the West Valley and Cornell sites, because the West Valley environmental monitor position has not yet been filled.

Response 5:

Thank you for the clarification. We have edited the wording of the report to read as follows: *"In 2007, DEC hired an additional inspector who, in 2008, was assigned to assist the West Valley environmental monitor. In 2009, the West Valley monitor position became vacant and since that time, the inspector hired in 2007 has continued to work both the West Valley and Cornell sites until the West Valley position is filled."*

- **Comment 6: Page 29**

The last paragraph states, "DEC conducts environmental monitoring at the burial sites, which includes gamma radiation measurements using thermoluminescent dosimeters (TLDs), as well as surface water and sediment sampling." DEC discontinued deployment of TLDs at the West Valley site in 2005; since that time, the site operator, NYSERDA, has deployed TLDs. The TLDs at the Cornell site have always been deployed by Cornell, rather than DEC.

Response 6:

Thank you for the clarification. We have edited the wording of the report to read as follows: *"DEC conducts environmental monitoring at the burial sites, including surface water and sediment sampling. In 2005 DEC discontinued deployment of thermoluminescent dosimeters (TLDs) at the West Valley site. Since that time, the site operator NYSERDA has deployed TLDs at West Valley. They are placed along the boundary fence line, at each of the three off-site creeks, the nearest residence, Sardinia and Rock Spring Road. Surface water and sediment samples are collected from the three creeks. Cornell University has always deployed TLDs at the Cornell site."*

- **Comment 7:**

Appendix C, Page C.8: Accompaniment No. 10 is listed under NYSDOH, when in fact the accompaniment was of an inspection conducted by NYSDEC. Please move this entry from DOH to DEC, and identify the facility as a "permitee" rather than a "licensee." The DEC permit No. is 4-0101-00036/00006.

Response 7:

Thank you for your comment. We agree that this inspector accompaniment was inadvertently placed under the NYSDOH accompaniments and identified the licensee rather than the permit holder. This has been corrected in the report.

- **Comment 8:**

In Appendix D, under NYSDEC, "License reviewers" should instead be described as "Permit reviewers." Also, several permit reviewers were misidentified: for file No. 40, the permit reviewer was TF, and for File Nos. 45, 47, and 48 the permit reviewer was AG.

Response 8:

Thank you for your comment. We agree that under NYSDEC, the term "License reviewers" should be described as "Permit reviewers" as you suggest. We have made this correction for all the affected Appendix D entries. We have also corrected the reviewer identifications for files 40, 45, 47 and 48.

**Comment Resolution for the August 8, 2011, Supplemental E-Mail from the
New York Department of Environmental Conservation (ML112201338)
Regarding the July 15, 2011, Draft IMPEP Report.**

- **Comment 9: Page 6, Section 3.3, Paragraph 4, Sentence 3:**

On page 22: The sentence that talks about the "DEC law" should be replaced with the following: "Articles 1, 3, 17, 19, 29, and 37 of the Environmental Conservation Law provides DEC with the authority to implement its radiation program."

Response 9:

Thank you for the clarification. We have edited the wording of the report to read as follows: "*Articles 1, 3, 17, 19, 29, and 37 of the Environmental Conservation Law provide DEC with the authority to implement its radiation program.*"

- **Comment 10:**

On page 30, second paragraph - there is a new error that needs fixing. The sentence incorrectly says, "NYSERDA has always deployed TLDs at the Cornell site." To clarify:

NYSERDA is not involved with the Cornell site. The sentence should instead say, "Cornell University has always deployed TLDs at its former land burial site."

Response 10:

Thank you for the clarification. We have edited the wording of the report to read as follows: *"DEC conducts environmental monitoring at the burial sites, including surface water and sediment sampling. In 2005 DEC discontinued deployment of thermoluminescent dosimeters (TLDs) at the West Valley site. Since that time, the site operator NYSERDA has deployed TLDs at West Valley. They are placed along the boundary fence line, at each of the three off-site creeks, the nearest residence, Sardinia and Rock Spring Road. Surface water and sediment samples are collected from the three creeks. Cornell University has always deployed TLDs at the Cornell site."*

**Comment Resolution for the August 10, 2011 E-Mail from the
New York City Department of Health and Mental Hygiene (ML11222A252)
regarding the July 15, 2011 draft IMPEP report.**

- **Comment 11:**

On page 3, 3.1.1. you state "Previously the ERU was responsible for conducting Increased Control (IC) inspections for the Program. However, when the ERU expanded and became a Bureau, responsibility for IC inspections became the sole responsibility of the NYC program. With the advent of the Lower Manhattan Security Initiative, NYC inspectors in conjunction with the New York City Police Department now conduct joint IC inspections." This paragraph is incorrect. The New York City Office of Radiological Health (ORH), as part of the New York State Agreement, has been responsible for conducting IC inspections since the initiative began. Additionally, we have conducted joint IC inspections with NYPD's Bureau of Counterterrorism from the start of the initiative.

Response 11:

Thank you for your clarification. The report was changed to better identify the relationship of the New York City Emergency Response Unit (ERU) and the New York City Office of Radiological Health (ORH).

- **Comment 12:**

On Page 4, the second paragraph states that no member of the staff had attended any technical training courses other than NRC's S-201 in several years. We pointed out to the review team that for the last year and a half, 3 members of the Materials team had been undergoing cross training for x-ray inspections and that our Senior Physicist had conducted numerous in-house and field training sessions on x-ray physics and inspection techniques. In our program, we consider this technical training.

Response 12:

Thank you for your comment. While the review team acknowledges that some basic aspects of X-ray physics are transferrable to materials uses, and that basic inspection techniques may be considered technical training, the team disagrees with NYC's assertion that X-ray training will suffice for materials technical training. The report was changed to reflect that training records provided to the review team did not demonstrate that staff has received specific materials related training.

- **Comment 13:**

On page 4, the third, fifth and sixth paragraphs state that there had been "various", "multiple" and "ongoing" requests for technical training by the two newest inspectors. We frankly do not recall "various", "multiple" and "ongoing requests".

Response 13:

Please see the comment 14 below.

- **Comment 14:**

The review team did not discuss these alleged requests with supervisors or management to verify them. During this period, emergency response training, in-services, and local technical symposia were utilized instead. We sent an inspector, the field supervisor and the Section Chief to the IC training, and were planning to send our newest Licensing Reviewer to the NRC licensing course, but this had to be delayed due to a death in her family. We note that the IMPEP review team encouraged ORH not to take part in this NRC sponsored training because it was "worthless".

Response 14:

Thank you for your comment. Initial and ongoing training is a basic component of a sound program and the review team commends NYC on their efforts to send their staff to emergency response training, in-services, and local technical symposia. The review team acknowledges that while these venues are indeed ways to provide training, they do not always provide the level of specific technical training needed to fully understand the modality being reviewed, and do not always provide the inspector with enough technical knowledge to be able to perform a thorough and comprehensive program review. During the review process, NYC staff came forward to describe their specific unease in performing inspections of some of the highly technical modalities licensed by the NYC program. They further described their requests for technical training, which as they described, had not been acted upon. The fact that NYC staff was concerned enough to ask for training should be commended. When statements regarding training requests were brought forward, the review team listened to the staff and took their concerns seriously. Their concerns arose initially during inspector accompaniments and again during the onsite review. These concerns were brought to the attention of differing levels of NYC management at various times, both verbally and by electronic mail. When asked for specific documents identifying the specific training the staff had attended, the Unit Chief supplied the team with a single page table document identifying individuals and the training they had attended. No other documentation such as training plans or

qualification journals were available. When specifically asked which managers had not followed up on requests to attend technical training, the staff refused to provide the individual's name(s).

Lastly, the review team does not view any technical training as "worthless" as described in NYC's comment. The review team discussed this issue internally and does not understand the basis for the comment or how NYC came to that conclusion.

However, this level of detail was removed from the proposed final report.

- **Comment 15:**

It is critical that IMPEP teams apply an objective and verifiable standard that staff training needs are not being met or that their ability to properly execute their functions are limited due to a lack of training. In this report, the IMPEP team failed to corroborate staff statements with supervisors or managers and failed to determine if supervisors had identified any technical lapses in the inspections performed. Simply repeating the statements of staff as being accurate reflections of the work environment and their skill level is inappropriate and leaves the NRC in the position of being, potentially, used by staff to address their frustration with their promotion history and work assignments.

Response 15:

Thank you for your comment. The review team disagrees with NYC's comment that the review team failed in part, to apply an objective and verifiable standard to the NYC training program. The review team applied the same standard to the NYC training program that is applied to all programs reviewed, both at NRC and in Agreement States. The review team looked for a documented training and qualification program for NYC staff members who perform licensing and inspection duties that is consistent with NRC's Inspection Manual Chapter (IMC) 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area" or the NRC and Organization of Agreement States Training Working Group's Recommendations for Agreement State Training Programs, but was not provided with even the basic components of such a program. Section "C" of the NYC Policy and Procedure Manual requires that new field staff attend the 5-week course or a similar series of courses. This requirement is equivalent to the requirements found in the NRC and Organization of Agreement States Training Working Group's Recommendations for Agreement State Training Programs; however, the team noted that NYC is not following their own training plan as neither the 5-week nor a similar series of courses were attended.

It should be further noted that NYC staff never described or reflected on their work environment, promotion history, or work assignments with the review team. Their only concern appeared to be frustration with NYC management over their inability to attend technical training specific to the modalities they inspecting.

- **Comment 16:**

On page 4, paragraph 5 states "And while NYC managers began to discuss taking advantage of training in recent months, again nothing had been acted upon until a member of the review team documented and forwarded these requests to NYC

Management in May 2011.” This statement is false and can only be seen as a willful disregard of the information provided to the IMPEP team. Prior to the IMPEP team arriving, the Program had discussed in detail training needs and the staff that would be best served by training. Prior to the IMPEP team arriving, the Program had scheduled a staff person to attend the Licensing Procedure course, which was delayed due to a death in the family. Prior to the IMPEP team arriving, staff had been part of routine and thorough in-house training and symposia. Despite the IMPEP team being fully aware of these facts, it falsely claims no actions had been taken prior to the IMPEP team arriving. This statement should state, “NYC managers identified appropriate courses for its staff, scheduled opportunities for staff to take NRC courses and staff participated in training on emergency response, in-service health physics, and local technical symposia.”

Response 16:

Thank you for your comment. The review team disagrees with the NYC comment that statements made in the draft report were false and willfully disregarded training information provided to the IMPEP team. The review team further disagrees with the NYC comment that despite being made aware of the facts as described in the NYC response, that the review team falsely claimed no actions were taken (regarding training) prior to the review team’s arrival. Again, as described previously, the review team commends NYC on their efforts to send their staff to emergency response training, in-services, and local technical symposia. And while those venues are indeed ways to provide training, they do not always provide the level of specific technical training needed to fully understand the modality being reviewed, and do not always provide the inspector with enough technical knowledge to be able to perform a thorough and comprehensive program review.

However, this level of detail was removed from the proposed final report.

- **Comment 17:**

The last paragraph on page 4 states that the two newest inspectors did not have the technical backgrounds sufficient to exempt them from initial technical training and that NYC failed to follow its own training procedures and send them to the 5 week course as required. We would like to point out that this requirement was written when the five week course was offered free by NRC. This hasn’t been the case for many years-in fact the cost for this course to Agreement States is now \$9,995.00 per student. We are therefore removing this item as a requirement from our other training requirements. In-house and on-the-job training have proven to be more than adequate in turning out inspectors that can identify health and safety issues in the field as has been confirmed by the last few IMPEP accompaniments, including this latest one. The Program will be sending technical personnel to the NRC courses, as scheduling and workloads permit.

Response 17:

Thank you for your comment. The review team understands your concerns regarding the cost of attending the 5-week course. The NYC Policy and Procedures manual, last revised in 2004, not only identified attendance at the 5-week course as a requirement, but also allowed for alternative training by attending a similar series of courses. Those

same alternative training avenues were still in place at the time of the review in 2011; however, NYC did not provide documentation to demonstrate their equivalency.

The review team acknowledges NYC's commitment to sending their technical personnel to NRC courses as scheduling and workloads permit.

- **Comment 18:**

On page 5, the first paragraph, last sentence states "While no noteworthy performance issues were identified on this one specific accompaniment, it should be noted that each inspector inspected the specific areas they had the most experience." If no noteworthy performance issues were identified, the last part of the statement should be removed and the sentence should read "No noteworthy performance issues were identified..."

Response 18:

Thank you for your comment. The report should have read, "during accompaniments, no noteworthy performance issues were identified." However, this level of detail was removed from the proposed final report

- **Comment 19:**

On page 5, the second paragraph states "The Team noted that in one case NYC staff reviewed a reported incident of an overdose to a fetus that occurred in 2007." The event reported actually took place in 2006 prior to the start of this IMPEP review cycle. The IMPEP team fails to note that the first record of this incident being reported to the Program was April 2011. This sentence should state "The review team noted that in one case NYC staff reviewed a reported incident of an overdose to a fetus that occurred in 2007(sic), that was reported to the Program in April 2011. The Program determined that this incident was not reportable." The report should note that the event occurred outside the IMPEP review period and that the Program, upon investigation, determined that the incident was not reportable.

Response 19:

Thank you for your comment. This level of detail was removed from the body of the report. The factual comments were noted in Appendix E, Incident Casework Reviews.

Comment 20:

On page 5, the second paragraph states "NYC staff did not review the event when it was received. On June, 13, 2011, during a daily management briefing, the AC stated that NYC had reviewed this event and determined that it was not reportable. The review team questioned the AC about the specific date of the review. The AC stated that they had reviewed it the previous week (June 6, 2011)." The report leaves the inaccurate impression that this incident was not reviewed by the Program until June 6, 2011, which is not accurate.

Response 20:

Thank you for your comment. The report will be modified.

- **Comment 21:**

Despite numerous discussions over the course of the IMPEP review regarding this incident and the evaluation that was performed by the Program, the IMPEP team implies that the first time it was reviewed by the Program was June 6, 2011. When the incident was received in April 2011, the Program discussed the appropriate level of response given the complex circumstances of the incident and its being reported five years after it occurred. In preparation for the IMPEP review, the Program met with the AC to discuss medical event reporting. At this meeting the Program expressed why it believed that the event was not reportable. The IMPEP draft report should properly clarify the context of this meeting or remove this language from the report.

Response 21:

Please see comment 20.

- **Comment 22:**

The statement "...no individual in the Program understood the reporting requirements or how to apply them for this specific event." is unwarranted without mentioning the complexity of the series of events involved.

Response 22:

Thank you for your comment. The review team modified the draft report to move a general description of this issue to Section 3.5.1 of the draft report.

- **Comment 23:**

On page 5, the fourth paragraph notes "Again the review team found that no individual in the Program understood the reporting requirements or how to apply them to this specific event." The Program believes that a more accurate statement would be "The review team found that the Program had failed to report this incident to the NRC as required." The language used by this IMPEP Team borders on the pejorative, is subjective and not consistent with how other IMPEP reviews cited the failure to report medical events meeting the reporting criteria in a timely manner.

Response 23:

Thank you for your comment. The review team modified the draft report to move a general description of this issue to Section 3.5.1 of the draft report.

- **Comment 24:**

On page 5, the fifth paragraph notes that NYC reported a medical event on June 24, 2011 which was not a reportable event. Why is this paragraph included since it occurred outside of the review period?

Response 24:

Thank you for your comment. The report has been modified to remove this incident.

- **Comment 25:**

On page 8, in the first paragraph the statement is made that NYC recently reported “**events**” that did not meet the reporting requirements. In fact, there was one event reported, outside of the review period as stated above, which entailed the injection of the wrong radiopharmaceutical.

Response 25:

Thank you for your comment. The report was modified to reflect one event. This was an oversight during the drafting of the draft report.

- **Comment 26:**

On page 14, 3.4.1, The first paragraph states that licensing actions were reviewed for completeness, consistency, proper radioisotopes and quantities, qualifications of authorized users, adequacy of facilities and equipment, adherence to good health physics practices, financial assurance, security requirements, operating and emergency procedures, appropriateness of license conditions, and overall technical quality. However, there is no mention subsequently in this section about the actual findings of the review team for the categories mentioned above.

Response 26:

Thank you for your comment. The remainder of that paragraph reads, “The casework was also reviewed for use of appropriate correspondence, reference to appropriate regulations, supporting documentation, consideration of enforcement history, pre-licensing visits, peer and supervisory review, and proper signatures.”

Each of the three jurisdictions under the New York Agreement State Program is individually identified in the report. Each Licensing section is written uniquely as each jurisdiction (NYC, DOH and DEC) is operated uniquely. The corresponding documentation takes that into consideration and tailors each section to describe the review of each program.

The report has been modified to add a sentence to address the findings noted in the NYC comment.

- **Comment 27:**

On page 14, paragraph four, the IMPEP team claims that the essential elements of RCPD-08-20 had not been implemented. The purpose of RCPD-08-20 is to enhance the basis for confidence that radioactive materials will be used as specified on a radioactive materials license. The IMPEP team did not identify a single instance where a facility was licensed inappropriately because of not receiving a pre-licensing inspection. Further, the Program documented the basis for its high degree of confidence that radioactive

materials will be used as specified on a radioactive materials license for licensee approval for over one hundred license actions. Based on the findings of IMPEP review team's license review and the documentation provided by the Program, NYC met the essential elements of the RCPD-08-20. The Program has long been aware of the potential for radioactive materials to be used for malicious intent and the need for a high level of confidence that radioactive materials will be used as specified on a radioactive materials license. The Program notes that the IMPEP review team failed to include in its summary that license review staff were given direction by the Director of the Program to implement the intent of RCPR-08-20 and that license review staff was aware of the need for a high degree of confidence that radioactive materials will be used as specified on a radioactive materials license.

Response 27:

Thank you for your comment. Implementation of the pre-licensing guidance is a requirement that NRC and all programs are required to implement within their programs. During the last Periodic Meeting held on July 16, 2009, the NYC Program Director acknowledged he was aware of the requirements for pre-licensing guidance and that staff would be implementing pre-licensing guidance for the NYC program. However, during the review the team found through interviews with the senior licensing staff and a review of documents, that pre-licensing guidance had in fact, not been implemented in the NYC licensing program.

The review team acknowledges that following the onsite review, NYC reviewed all licensing actions and found none to have been issued in error, despite not using the pre-licensing criteria as required. However, the fact that no licensing actions were inappropriately issued, does not exempt NYC from following the guidance.

- **Comment 28:**

The IMPEP team claimed that RCPD-08-20 required the Program to use the reporting forms distributed with RCPD-08-20. The Program believes this is incorrect. RCPD-08-20 directed Agreement States "to implement the essential objectives of the revised guidance", which is to have a high degree of confidence that radioactive materials will be used as specified on a radioactive materials license for licensee approval.

Response 28:

Thank you for your comment. The review team did not require NYC to use the forms distributed with RCPD-08-020. The review team simply informed NYC staff that implementation of the pre-licensing guidance was a requirement.

- **Comment 29:**

The Program notes that the IMPEP team incorrectly applied the guidance of RCPD-08-20 to forcefully claim during daily close out sessions that Sloan Kettering, one of the premier cancer research and treatment institutions in the world, with decades' long regulatory relationship with the Program, required a pre-licensing inspection. Obviously, Sloan Kettering meets the criteria outlined in RCPD-08-20 as not needing a pre-license inspection. Similar claims were made for other recognized institutions with decades' long

regulatory relationships with the Program indicating that no individual on the IMPEP team understood how to apply the guidance in RCPD-08-20 for New York City, and how to apply them to the specific licenses reviewed.

Response 29:

Thank you for your comment. The review team disagrees with the NYC comment that the review team forcefully claimed during daily briefings that any specifically named NYC licensee needed a pre-licensing inspection. The review team continued to bring up the fact that NYC needed to apply the pre-licensing guidance to all applicable licensing actions that occurred during the review period, and if after applying the guidance, should NYC determine that a licensee warranted further action then that action should be performed. Also the team discussed the need to implement the pre-licensing guidance on future applicable licensing actions.

- **Comment 30:**

The Program notes that the IMPEP team claimed that it requested the Program to perform a self-assessment to document that it was meeting the essential elements of RCPD-08-20. The Program initiated this effort on its own so it could address the IMPEP teams' concern that the intent of RCPD-08-20 could not be quickly determined due to a lack of succinct documentation stating why the reviewer had a strong basis of confidence that radioactive materials will be used as specified on a radioactive materials license. The Program is puzzled by the IMPEP teams' claim that this additional effort to document compliance with the intent of RCPD-20-08 was performed at its direction.

Response 30:

Thank you for your comment. The review team acknowledges that NYC did an assessment of all applicable licensing actions during the review period to make sure that no license was incorrectly issued and this was performed after the review team left NYC and was performed at the request of the review team.

- **Comment 31:**

The Program never the less concurred with the IMPEP Team's recommendation that a mechanism to succinctly verify that the intent of RCPD-08-20 was met prior to issuing a license approval because it would be helpful to outside auditors.

Response 31:

Thank you for your comment. Please see comment 30. The review team agrees with NYC that application of the pre-licensing guidance is not only required, but helpful too.

- **Comment 32:**

The Program recommends that this section of the draft report should be modified to correctly apply a performance based standard and correct its statement that the IMPEP team requested the Program to perform a self-assessment to document that it was meeting the essential elements of RCPD-08-20.

Response 32:

Thank you for your comment. Please see comment 30 for the review team's response.

- **Comment 33:**

On page 15, the third paragraph, We are not clear why, after the fact, the review team thought that ORH needed to add a license condition to our IC licensees. While we did submit a license condition to NRC for review, we opted to issue a Commissioner's Order to our IC licensees instead, a document which has the force of law and which was a perfectly acceptable alternative according to NRC at the time. NRC did the same thing with their licensees. Since the Orders are still in effect and are legally binding, and the IC program in New York City is well established and going into its sixth year, the need to immediately add a license condition appears to be solely based on the IMPEP teams deep concern that the program had submitted language for NRC approval and had not acted on it. The IMPEP Team should describe why it directed the Program to immediately add a license condition to all IC licenses as the only mechanism to address its concern.

Response 33:

Thank you for your comment. The review team disagrees with the NYC comment. The review team did not instruct NYC to immediately add a license condition to all IC licenses. The review team presented two options to ORH: 1) to add the originally approved license condition to their IC licenses referencing the Commissioner's Order or 2) to submit the Commissioner's Order to NRC for a Compatibility Review. ORH's original license condition was approved by NRC as being compatible (see letter dated October 20, 2005 ADAMS ML: ML052940009). The review team stated that ORH can choose to implement the IC's through a different means than originally submitted, however in order to be found compatible ORH will need to submit the Commissioner's Order to the NRC for review in accordance with FSME Procedure SA-201.

- **Comment 34:**

On Page 19 paragraph 1, the IMPEP team states "On June 15, 2011, NYC notified the review team that they had not followed up on the statistical information received from their licenses," This statement is not correct. The IMPEP team was repeatedly told of the actions taken by the Program in response to the statistical information from licensees, of which all but 2 events related to radiation producing equipment not subject to NRC reporting. Actions included requests for information, required reporting of events and an assessment of whether reported information met the requirements of the New York City Health Code. The statement should be changed to say, "On June 15, 2011, the Section Chief notified the review team that he had not referred to the Program's Policy and Procedure Manual for Incident Response when responding to the reported medical events."

Response 34:

Thank you for your comment. The review team disagrees with the NYC comment that the review team was repeatedly told of the actions taken by the Program in response to the statistical information from licensees.

However, this level of detail was removed from the proposed final report.

- **Comment 35:**

Page 19 paragraph 1 notes “On June 16, 2011 during the final exit meeting with the State, the AC reversed his position and stated that NYC had followed up on each of the events and did have documentation to demonstrate they had followed up on each of the incidents.” This does not properly characterize the comments made at the final exit meeting. First, the AC did not state that the Program did not follow up on the statistical information submitted by licensees and therefore could not “reverse his position”. At the close out meeting the AC clarified the miss-representation made by the IMPEP team that no actions had been taken by the Program in response to the statistical information received from its licensees. The AC committed to providing the NRC with documentation regarding program follow-up related to NRC reportable events. The Program notes that despite this miss-representation being clarified, repeatedly, during the review and at the exit meeting and further contradicted in the records reviewed by the IMPEP team on-site and provided after it left the Program, it ignored the salient facts to repeat the claim that no actions were taken by the Program in response to statistical information regarding reportable events supplied by its licensees. This sentence should be revised to state “On June 16, 2011 during the final exit meeting with the State, the AC agreed to provide the NRC with documentation regarding the follow-up the program performed for each of the incidents reportable to the NRC.”

Response 35:

Thank you for your comment. The review team disagrees with the NYC comment that the AC did not reverse his position on event reporting issue discussed above.

- **Comment 36:**

On Page 19 the second paragraph notes “For the medical event that occurred October 6, 2009, a follow-up inspection was performed on June 16, 2011.” The IMPEP team leaves the impression that no response to this event took place prior to June 16, 2011, which is incorrect. After receiving a report of this incident, the Program contacted the facility and engaged in a series of written correspondences discussing the event and the proposed solution. This should be revised to state “For the medical event that occurred October 6, 2009, the Program contacted the license by phone and written communications dated October 6 and 7, 2009 discussing the cause and the proposed response. During an inspection on 3/8/10, the actions taken in response to this medical event were reviewed and found satisfactory. A follow-up inspection was performed at the direction of the IMPEP team on June 16, 2011 and re-confirmed that the proposed actions were implemented.”

Response 36:

Thank you for the comment. The review team received no documentation while onsite or subsequent to the review that indicated any additional correspondence with the licensee took place. The statements within the draft report are not intended to make any implication, and simply state the facts of when an event occurred and when a follow up was performed based on the information provided to the review team both during the onsite review and with documentation provided after the review. Additionally, IMPEP review teams do not direct State programs to perform any type of work activity. A review team may ask what the State has been done in response to an activity such as an event, but does not have the authority to “direct” a State to perform any activity.

- **Comment 37:**

On Page 19 the second paragraph notes, “For the non-reportable incident that occurred on June 24, 2009, a follow up inspection was performed on June 24, 2011. This is incorrect. The follow-up inspection was performed on 7/16/09 as recorded by the facility and referenced in its letter to the Program on 4/27/11. The inspection on June 24, 2011 was performed in response to a record of the follow-up inspection not being located in the file. This sentence should be changed to “For the non-reportable incident that occurred on June 24, 2009, a follow up inspection was performed on 7/16/09. A close out inspection was performed on June 24, 2011 when a review of the file could not locate the inspection report from that original date.”

Response 37:

Thank you for the comment. The report has been changed to reflect the changes suggested by the NYC program. In addition, this level of detail was removed from the body of the report and included in Appendix E, Incident Casework Reviews as factual comment.

- **Comment 38:**

On Page 19 paragraph 3, the IMPEP team states “This table showed a total of 14 reported events with 7 of them being subject to reporting. The letter did not contain any information as to whether additional reports will be made to the NRC or if NYC performed any follow-up investigations/inspections in accordance with NYC incident follow-up procedures.” The table provided to the IMPEP Team had a transcription error indicating that a LINAC registrant had reportable events subject to NRC review. Attached is a corrected table that also removes the non-reportable event. This sentence should be changed to “This table showed a total of 13 reportable events of which 2 were subject to NRC oversight.”

Response 38:

Thank you for your comment. The report has been changed to reflect the updated information provided by the NYC program.

**Comment Resolution for the August 15, 2011 E-Mail from the
New York State Department of Health (ML11227A287)
regarding the July 15, 2011 draft IMPEP report.**

- **Comment 39:**

1.0 Introduction, 4th paragraph:

DEC issues permits, not licenses. I suggest the wording be changed to indicate xx specific licenses and yy permits. Also, I believe that all of the permittees are licensees.

Response 39:

Thank you for your comment. The review team agrees that DEC issues permits and not licenses; however, DEC described the relationship as one where each of their permit holders is first a DOH licensee. Permits are then issued to those DOH license holders who make releases to the environment, and are subsequently inspected by DEC inspectors.

- **Comment 40:**

3.1.2. first paragraph, top of page 6:

"...found within the Program were staffing related." I believe it would be more accurate to statefound within the Program were related to a diminished staffing level, or loss of staff during the review period.

Response 40:

Thank you for the comment. The report has been modified to reflect DOH suggested wording.

- **Comment 41:**

3.1.2 Third paragraph, page 6:

"The Assistant Director stated that not all staff need to attend all training courses,...". This statement does not have the full context/rational. As discussed with the IMPEP team, the training needs are based on the program's needs, the individual's prior training and experience, and the person's assignments. I believe he gave examples such as our ABR certified medical physicist not needing the brachytherapy course, and those with nuclear navy training or commercial reactor training did not need to attend the basic health physics course. Also, he indicated that we had hosted the inspection procedures course in Sept 2010 and will be hosting the transportation course during June, 2012. He also indicated that we had little success in getting our staff into the brachytherapy/teletherapy course despite submission of numerous applications for each course announcement. We have taken advantage of numerous NRC courses during the IMPEP review period but that is not indicated in the draft report. I believe this additional information reflects that although we did not have a formal written training plan, we do evaluate training needs and act accordingly. There are no performance issues.

Response 41:

Thank you for your comment. The review team has reexamined this section of the draft report and agrees with DOH that the description of the DOH training program could be described in a more comprehensive manner.

The report has been modified to better reflect the overall context of the DOH training program.

- **Comment 42:**

3.3.2 second paragraph, first sentence:

DOH uses a compliance based inspection approach. It was our understanding that the reviewers observed through inspection accompaniments that inspections included performance based aspects as well as record review elements. Also there is no mention of the escalated enforcement process and actions the program has taken.

Response 42:

Thank you for your comment. The review team acknowledges that DOH inspectors observed during inspections did perform in most, if not all cases, very comprehensive performance based inspections. Some inspectors performed a more thorough review of licensee records while others relied more on interview techniques to obtain information related to licensee performance. All the inspectors accompanied used varying degrees of each of these inspection methods. The report was modified.

- **Comment 43:**

3.4.1: The presentation of casework numbers is presented in an inconsistent manner. In the first paragraph of 3.4.1 it states *....for licensing actions for NYC's 367 specific radioactive materials licensees.....* However in 3.4.2 it is stated *...a random sampling of DOH's 1094 licensing actions.* The report should be consistent; either list the number of licenses or licensing actions, or both for the NYC and DOH sections.

Response 43:

Thank you for your comment. As noted above in response to a NYC comment, the review team noted that each of the three jurisdictions under the New York Agreement State Program is unique and each section of the report is individually drafted to reflect that. The corresponding documentation takes those differences into consideration and tailors each section to accurately describe the review of each program. This indicator was drafted in this manner to demonstrate the large amount of work produced by DOH under a diminished staffing level with permanent loss of staff over the review period.

- **Comment 44:**

3.4.1. page 15, third paragraph, second and third sentences:

"NRC approved the submitted license condition and letter; however, NYC never implemented the change and the license condition was never added to the applicable licenses. Instead, the review team found that NYC issued Commissioner's Order to their licensees requiring them to implement the provisions of the IC Order."

There is no statement here to the effect that NYC Commissioner's orders were not satisfactory, i.e., legally binding. However it appears that the IMPEP team believed that the Orders were inadequate as evidenced by the NRC's request for NYC to add the approved license conditions to the applicable licenses. Please clarify your findings by indicating what the specific deficiency with the order was. Please note that in the previous IMPEP report, dated January 31, 2007, it is stated in section 4.1.2, 4th paragraph that "Since the 2002 IMPEP review, NYC has adopted the Increased Controls license condition and ten NRC amendments." Did the previous team mean orders instead of license condition?

Response 44:

Thank you for your comment. Please see the NYC comment response related to this subject.

- **Comment 45:**

3.4.2. Second paragraph:

"License reviewers have the proper signature authority for the cases they review". That is incorrect or could be incorrectly interpreted. It looks like the term license reviewer is used differently in the report. Appendix D, File Nos. 15-38 has the license reviewers' initials. Those license reviewers are the ones who were assigned the license action, and most do not have signature authority. The Commissioner or Health designates who has signature authority. Currently only the Director, Assistant Director, Radioactive Materials Section Chief and the Radiation Equipment Section Chief have such authority.

Response 45:

Thank you for your comment. The review team would like to clarify the use of the term license reviewer. As related to the licensing section of the draft report, as well as the license reviewers identified in Appendix D, simply put, they are the individuals who write the license. In some programs the license writer has signature authority and in other programs they do not. When an IMPEP reviewer reviews the licensing section, they are not only looking at the technical quality of the licensing work performed by the license reviewers, but also determining, based on the individual program's policies if the license was signed out under the signature of the individual with signature authority.

- **Comment 46:**

3.4.2 Third paragraph: Where in the performance indicator is the criteria for making license documents tamper resistant? DOH had been employing the methodology since the inception of the program and all original license documents contain a raised DOH seal. Please remove the paragraph or reference the specific criteria for this performance indicator and support your contention that it is easier to forge an amendment than it is to forge an entire license document. Moreover, it is inappropriate to put information regarding license document vulnerability in a public document (final report). Such information should be available on a need to know basis.

Response 46:

Thank you for your comment. Nowhere in the draft report does the review team state that documents have to be tamper resistant, nor did they imply that during the review. The review team did not indicate that the DOH practice was vulnerability, but rather asked the program if they considered it a potential security issue. At the time of the review DOH managers did not see this as an issue. The report has been modified to remove the paragraph.

- **Comment 47:**

3.4.5 third paragraph:

"However, the team noted that the licensing was another area within the DOH material program where the lack of staff has begun to erode the efficiency of the Program". The program is efficient, so use of that word is not appropriate or accurate. It would be more accurate to replace "...has begun to erode the efficiency of the Program." to "has affected or diminished the Program's capacity."

Response 47:

Thank you for your comment. The report has been modified to better reflect the diminished capacity of the program rather than its efficiency.

- **Comment 48:**

3.5.1 fifth paragraph:

The review period ended on 6/16. Why is an event (non reportable) that was reported after the review period (6/24) included in the report? DOH also reported an event post review that was non reportable, but was reported based on IMPEP team member's having said that NRC would like to know about all medical events. If you intend to leave this in the report you need to edit the Executive Summary and Introduction to extend the review period to 6/24/11.

Response 48:

Thank you for your comment. Please see the NYC comment response related to this subject.

- **Comment 49:**

3.5.2 first paragraph, third sentence:

The database was in place for the previous IMPEP cycle so it is not new.

Response 49:

Thank you for your comment. The report has been modified to remove references to the database being new.

- **Comment 50:**

3.5.2 second paragraph:

"...nor does DOH have a comprehensive allegation response procedure." I believe it would be more accurate if the word "written" was put between comprehensive and allegation. There were no performance issues related to handling of allegations.

Response 50:

Thank you for your comment. The report has been modified to mirror the previous sentence related to the DOH incident response procedure which indicates that DOH does not have a documented incident response procedure. The report will now indicate that DOH does not have a documented allegation response procedure.

- **Comment 51:**

3.5.5 third paragraph:

The event numbers should be more clearly presented. It looks like there were a total of 400 materials events for the review period, 200 of which were reviewed by the team and 200 for which the team recommends that DOH review with respect to reporting criteria. It needs to be explained that the 200 events include mostly x-ray equipment and technologist events/issues, which are not subject to NRC review. The review team should present the total numbers of reportable materials events for the IMPEP review period. Those are the only events within the scope of the IMPEP review.

Response 51:

Thank you for your comment. The review team believes that this paragraph as written accurately reflects what the team found. The review team simply stated that of the 200 events reviewed onsite; only eight were found to be reportable but had not yet been reported. The report indicated that of the remaining 200 files DOH still had to review, there may or may not be other reportable events.

- **Comment 52:**

4.1.2 page 23:

For DOH it is stated that since the 2006 IMPEP DOH has adopted eleven amendments. Please include in this section the number of overdue amendments for which DOH submitted rule text for NRC's review. Although these others have not yet been adopted, it demonstrates progress toward adoption of overdue amendments.

Response 52:

Thank you for your comment. While the IMPEP team does acknowledge that NYSDOH did submit proposed regulations for 10 of the amendments overdue for adoption, NYSDOH has not yet submitted these regulations in final form to the NRC for review.

Proposed legally binding requirements are not enforceable therefore although the team took this information into account when they were reviewing this indicator the team does not believe it should be incorporated into the report since no programmatic impacts were made. No change to the report has been made.

- **Comment 53:**

4.2.1:

Please note that the former Department of Labor radiation program manager is qualified to perform SS&D reviews. He is with the Department of Health, in the Wadsworth Center, and is available as a reviewer if one of the other two reviewers are unavailable. (We do have a back-up person.)

Response 53:

Thank you for your comment. The report has been modified to indicate that the former DOL program manager is qualified to do SSD reviews and is available if needed.