Erickson, Randy

From: Gene Miskin [GMiskin@health.nyc.gov]
Sent: Wednesday, August 10, 2011 1:27 PM
To: Erickson, Randy
Cc: Christopher Boyd; Tobias Lickerman
Subject: 2011 IMPEP Response Letter August 11.doc
Attachments: 2011 IMPEP Response Letter August 11.doc; Copy of Institutions with Confirmed Incidents Reports 8-5-11.xls

Hi, Randy:
Attached is our response to the Draft IMPEP report and a copy of the corrected Table of confirmed incident reports. I plan on being at the MRB and was wondering when we would hear from NRC about the travel arrangements. Thanks for any help on this.

Gene

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August 10, 2011

Randy Erickson
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Dear Mr. Erickson:

Thank you for giving us the opportunity to respond to the draft IMPEP team report.

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.

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.

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".

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".

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.

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."

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.

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..."

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 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.

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.

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.

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.

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.

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?

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.

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.

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.

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.

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.

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.

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.

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.

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.

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."

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."

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."

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."

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."

Again, we appreciate the opportunity to comment on the draft team report.

Sincerely,

Institutions with Confirmed Incident Reports for NYC 2006-2009

#	Lic. Type	Radio Active Lic.No	Linac Crt.Reg #	Facility Name	# of reported errors	Licenses subject to NRC reporting (Y/N)
1			77-0000043	Bronx-Lebanon Hospital Center	1	N
2			77-0000022	Long Island College Hospital	1	N
3			77-0000015	St. Luke's/Roosevelt Hospital Center	1	N
4			77-0000038	Staten Island University Hospital	2	N
5			77-0000049	Montefiore Medical Center	1	N
6	75	2885		Montefiore Medical Center	1	Y
7			77-0000027	Memorial Sloan-Kettering Cancer Center	5	N
8	75	2968-01		Memorial Sloan-Kettering Cancer Center	1	Y
				Totals	**13**	**2**

Note: Updated table correcting the number of medical events reportable to the NRC.