DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration
National Health Physics Program
2200 Fort Roots Drive
North Little Rock, AR 72114

MAR 29 2010

In Reply Refer To: 598/115HP/NLR

Steven A. Reynolds
Director, Division of Nuclear Materials Safety
Region III, Nuclear Regulatory Commission (NRC)
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

Re: Response to Apparent Violations in Inspection Report No(s). (030-34325/2009-002)
EA -10-023

Dear Mr. Reynolds:

I am responding to subject inspection report regarding a medical event at the VA San Diego Healthcare System, San Diego, California. I am enclosing a written response from the facility that is dated March 23, 2010.

I accept the apparent violations as stated, except for the violation regarding reporting of the medical event. I agree with the facility in disputing that apparent violation.

The apparent violation being contested was for failure to report a medical event to NRC by the next day after discovery under 10 CFR 35.3045. The facility offers a logical argument that the clinical care of the patient was an overriding consideration in the decision-making process such that discovery of the medical event could not have been established until September 25, 2009.

Before September 25, 2009, available evidence indicated an unusual clinical situation with delayed elimination of the radionuclide from the patient. Before that date, the clinical staff was not aware that a large portion of the radionuclide had been injected accidently into the balloon port of the gastrostomy tube and at the time did not make an assumption that some dosage remained in the gastrostomy tube, as there was some evidence of physiologic distribution of the radioiodine. Definitive evidence of a medical event was not clear until the gastrostomy tube was removed on September 25, 2009, and measurements were made of the patient and the gastrostomy tube waste.

The clinical decision not to remove the gastrostomy tube before September 25, 2009, was an attempt to balance the opportunity for a more complete dose distribution in a

severely ill patient with the risk from leaving the tube in place. The replacement of a gastrostomy tube is an invasive procedure that is not without anxiety, discomfort, and medical risk to the patient.

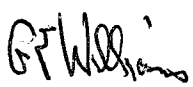
Removal of the gastrostomy tube before September 25, 2009, might have been advisable in retrospect, but would have required the facility to place less emphasis on clinical care. This conclusion is supported in the report by your medical consultant, which states, "There was immediate reporting of the event to the NRC, once the index case was noted." Also, our Director, National Nuclear Medicine Program, a highly experienced and board certified nuclear medicine physician, has reviewed this event and concluded the apparent delay in removing the tube, given the chronology of events and information available at the time, was not an unreasonable course of action from a clinical perspective. Finally, reporting of the medical event was consistent with previous repeated statements by your regulatory staff that possible medical events should not be reported to the NRC Operations Center.

Our National Health Physics Program (NHPP) inspection cited the facility for escalated enforcement for violations similar to those identified in your letter except for reporting of the medical event. My staff had evaluated reporting and opined that the circumstances did not warrant citing a violation.

As follow-up actions, NHPP distributed to all VHA permittees on December 22, 2009, a special edition newsletter describing the medical event circumstances, root causes of the event, possible regulatory violations, and guidelines for use of a gastrostomy tube. NHPP issued a frequently asked question document about written procedures to emphasize preparation of more detailed and related training for unusual circumstances.

I request you perform a careful review of the facility's position, especially with consideration of the chronology of events that led up to the discovery and subsequent time line of reporting of the medical event. Please contact me if you have any questions or comments.

Sincerely,



Gary E. Williams
Interim Director, National Health Physics Program

Enclosure

DEPARTMENT of VETERANS AFFAIRS

VA San Diego Healthcare System (VASDHS)
3350 La Jolla Village Drive
San Diego, CA 92161

March 23, 2010

In reply refer to: 664/151

Mr. Gary E. Williams, Interim Director
National Health Physics Program (115HP/NLR)
Department of Veterans Affairs
2200 Fort Roots Drive
North Little Rock, AR 72114

Dear Mr. Williams:

Enclosed, please find our response to NRC Inspection Report No. 030-34325/2009-02(DNMS); EA-10-023.

We regret the occurrence of the medical event discussed in the report. Please be assured that VASDHS takes our commitment to patient safety and regulatory compliance very seriously.

Our Nuclear Medicine and Radiation Safety staff have implemented strong measures to ensure that a similar event does not reoccur and that all medical administrations of radioactive drugs are performed correctly in full compliance with NRC regulations. Executive management and the Radiation Safety committee will monitor compliance with these measures.

Should you have any questions regarding our response, please contact me at (858) 642-3201 or Mr. René Michel, VASDHS Radiation Safety Officer, at (858) 642-1059.

Sincerely,

for Stan Johnson, FACHE
Director

Enclosure

Response to Apparent Violations in Inspection Report No. 030-34325/2009-02; EA-10-023

The numbering in the following response corresponds to the apparent violations listed in NRC Inspection Report No. 030-34325/2009-02; EA-10-023:

1. **Failure to develop, implement and maintain written procedures to provide high confidence that each administration is in accordance with the written directives as required by 10 CFR 35.41 (a)(2).**

   a) **Reason(s) for the apparent violation.** The primary reasons identified during the root cause analysis for the apparent violation were the lack of detailed policies and procedures describing the preparation and work direction for the administration of byproduct material through an unfamiliar medical apparatus (i.e., gastrostomy feeding tube). While a brief procedure was in place, the permittee did not have step-by step, written procedures in place to provide high confidence that the administration through this apparatus was performed in accordance with the written directive (WD).

   b) **Corrective steps that have been taken and the results achieved.** The permittee promptly halted all gastrostomy tube administrations and limited the involvement of the technologist who administered the byproduct material to procedures that do not require a WD. These suspensions remained in place until the root causes of the event were identified and corrective measures were implemented to prevent reoccurrence. The permittee developed a detailed written procedure in order to provide high confidence that future radiation therapies via gastrostomy feeding tubes are performed in accordance with WDs. Besides including step-by-step actions on how to safely administer the byproduct material, this procedure also requires improved communication between the Radiation Safety Office and Nuclear Medicine Service, and a "time-out" process when encountering unfamiliar medical apparatuses. This procedure was reviewed and endorsed by the facility's Radiation Safety Committee (RSC) during its quarterly meeting held on January 26, 2010.

   c) **Corrective steps that will be taken to avoid further violations.** A member of the Radiation Safety Office staff and the authorized user (AU) will closely monitor future therapies via gastrostomy feeding tubes to ensure that the developed procedure is followed and administrations are performed in accordance with WDs.

   d) **Date when full compliance will be achieved.** The procedure discussed in 1.b was completed on November 25, 2009. Full compliance with NRC regulations was achieved when the temporary suspension of administrations through a gastrostomy tube was implemented on September 30, 2009. Modifications to written procedures, to ensure regulatory compliance and prevent a recurrence involving administrations through a gastrostomy tube or another unfamiliar apparatus, were fully implemented on January 26, 2010.

2. **Failure to instruct supervised individuals on procedures for administering byproduct material through a gastrostomy feeding tube in order to ensure that byproduct material was administered in accordance with the written directive as required by 10 CFR 35.27 (a)(1).**

   a) **Reason(s) for the apparent violation.** The primary reasons identified during the root cause analysis for the apparent violation were the lack of detailed policies and procedures describing the preparation and work direction for the administration of byproduct material through an unfamiliar medical apparatus (i.e., gastrostomy feeding tube). Nuclear Medicine personnel involved in the administration of byproduct material did not have a step-by step, written

procedure and appropriate training to ensure that administration through gastrostomy tubes are performed in accordance with WDs.

b) **Corrective steps that have been taken and the results achieved**. Following the medical event, the RSO had regular, informal meetings with each member of the Nuclear Medicine staff. The purpose of these meetings was to discuss the specifics of the medical event, to identify deficiencies, and to develop new procedures to correct them. Besides the corrective steps discussed in 1.b, the licensee revised the facility's radiation safety manual and developed new training programs to provide high confidence that future administrations through gastrostomy tubes will be performed safely and in accordance with WDs. These documents were reviewed and endorsed by the facility's RSC during its quarterly meeting held on January 26, 2010. All Nuclear Medicine personnel, including physicians and technologists, were provided with formal instruction on the proper use of the procedure discussed above. This training was completed on February 10, 2010.

c) **Corrective steps that will be taken to avoid future violations.** A member of the Radiation Safety Office staff and the AU will closely monitor future therapies via gastrostomy feeding tubes to ensure that trained personnel follow the developed procedure and that administrations are performed in accordance with WDs.

d) **Date when full compliance will be achieved.** Full compliance with NRC regulations was achieved when the temporary suspension of administrations through a gastrostomy tube was implemented on September 30, 2009. Modifications to written procedures, to ensure regulatory compliance and prevent a recurrence involving administrations through a gastrostomy tube or another unfamiliar apparatus, were fully implemented on January 26, 2010.

3. Failure to report a medical event to the NRC by the next calendar day after discovery as required by10 CFR 35.3045 (c).

a) **Reason(s) for the apparent violation and basis for disputing it.** The administration of byproduct material took place on September 21, 2009. After noticing that radiation levels from the patient were not dropping as expected, the patient was imaged in Nuclear Medicine on September 23, 2009. The obtained images revealed that the majority of the byproduct material administered was still located in the stomach area, but uptake was also observed in other areas of the body, indicating that some of the administered material had been absorbed and the patient was therefore receiving some benefit from the administration. At this point, the AU determined that the most likely explanation for the delayed absorption was adherence of a significant portion of the administered dose within the main lumen of the feeding tube vs. sequestration of the dose at/near the distal tip. Due to the observed physiologic uptake outside of the stomach, sequestration of the radionuclide within the gastrostomy tube balloon port was not considered a likely explanation for the gastric retention at that time. The decision was made to allow further observation time, anticipating that additional radioiodine would detach, or be released, from the feeding tube, allowing more of the intended dose to be absorbed. The AU recognized the complexities and potential complications associated with immediately replacing the gastrostomy tube, including removal of the patient from the radiation safe room, subjecting the patient to a potentially unnecessary invasive procedure, and possible contamination of the interventional radiation suite. In conjunction with the partial physiologic absorption observed on scintigraphy, it was deemed medically prudent to allow additional observation time prior to ordering extraction of the feeding tube. On September 24, 2009, the patient was informed that the feeding tube would need to be removed unless a significant drop in the measured radiation exposure reading could be documented within the next 12-18 hours. Since this did not occur,

the feeding tube was removed early the next morning, on September 25, 2009. The suspicion that a portion of the dose was permanently sequestered within the feeding tube was not confirmed until September 25, 2009, when the feeding tube was removed. At that time an exposure rate survey indicated that the majority of the dose was no longer in the patient, but in a bag containing the removed feeding tube and other surgical waste. Therefore, the medical event became evident around noon on September 25, 2009, after the Radiation Safety Officer (RSO) surveyed the patient and confirmed that the byproduct material, which was causing the unusually high radiation levels, was no longer in the patient, but in the bag containing the gastrostomy tube. With this information, the RSO contacted the AU immediately and both agreed that reporting the event was necessary. The RSO reported the medical event to the National Health Physics Program (NHPP) about 2 pm on this day (about two hours after the medical event was identified). After a detailed review of the documented radiation level measurements, the NRC inspector determined that information was available on September 23 and 24, 2009, to make the determination that a medical event had occurred. The basis for disputing this apparent violation is that the permittee considers that medical events must be reported, as required, only after there is definite information that such event had occurred, not when there is a suspicion that the event may have occurred. The permittee considers that definite information was not available to support taking such action until September 25, 2009, after the gastrostomy tube was removed, the RSO surveyed the patient, and it was evident that the majority of the byproduct material was no longer within the patient's body.

b) **Corrective steps already taken.** The permittee developed a detailed written procedure that formally outlines communication between Nuclear Medicine and the Radiation Safety Office during radioiodine therapies. This procedure documents required monitoring of the patient's external radiation levels and actions to be taken (e.g. evaluating the need to report a medical event) if certain trigger levels are reached (e.g., radiation levels after specific times do not decrease to an expected, predetermined rate). All Nuclear Medicine personnel, including physicians and technologists were provided with formal instruction on the proper use of this procedure, as well as the reporting requirements established in 10 CFR 35.3045 (c).

c) **Corrective steps that have been taken and the results achieved.** The Radiation Safety Office and AUs will closely monitor radioiodine therapies to ensure that the developed procedure is followed and that any discovered medical events are promptly reported as required by 10 CFR 35.3045 (c).

d) **Date when full compliance will be achieved.** Full compliance with NRC regulations was achieved when the temporary suspension of administrations through a gastrostomy tube was implemented on September 30, 2009.

The following discussion addresses the two areas of concern identified in Inspection Report No. 030-34325/2009-02; EA-10-023:

1. **The manner in which the permittee staff handled and transferred the I-131 dosage within the patient's room, prior to the administration, could have resulted in a spill and contamination of personnel.**

   a) **Reason(s) for the concern.** The primary reason identified for this area of concern was the lack of proper planning. The permittee did not analyze the task in detail and did not have a written procedure and use the proper equipment (i.e., fume hood) to sufficiently reduce the risks of radioactive material spillage and contamination of personnel.

b) **Corrective steps that have been taken and the results achieved.** The permittee developed a written procedure titled, "The Safe Handling and Transferring of I-131 Doses in Nuclear Medicine." This procedure includes actions that personnel must take to reduce the risks of radioactive material spillage and contamination of personnel when transfers of I-131 liquid doses are required. The permittee also revised its radiation safety manual to require all work with volatile compounds (including liquid radioiodine) to be performed in a fume hood in accordance with written procedures. This policy revision was reviewed and approved for implementation by the facility's RSC. All Nuclear Medicine personnel, including physicians and technologists, were provided with formal instruction about the use of this new procedure and the policy revision.

c) **Corrective steps that will be taken to avoid reoccurrence.** The Radiation Safety Office staff will closely monitor future therapies involving liquid radioiodine to ensure that the revised policy and developed procedure are followed.

d) **Date when corrective measures were implemented.** The facility's RSC approved the policy revision during its quarterly meeting held on January 26, 2010. Training of Nuclear Medicine personnel was completed on February 10, 2010.

2. **The permittee's "As Low As Reasonably Allowable" (ALARA) assessment, regarding the I-131 dosage transfer, did not exhibit conservative decision-making.**

a) **Reason(s) for the concern.** The primary reasons identified for this area of concern were that the permittee did not perform a thorough ALARA assessment before transferring the I-131 in the therapy suite and did not have a written procedure to ensure that occupational doses to personnel were kept ALARA during such process.

b) **Corrective steps that have been taken and the results achieved.** The permittee developed a written procedure titled, "The Safe Handling and Transferring of I-131 Doses in Nuclear Medicine." This procedure includes actions that personnel must take to maintain occupational doses ALARA. The permittee also revised its radiation safety manual to require all work with volatile compounds (including liquid radioiodine) to be performed in a fume hood in accordance with written procedures when transfers of I-131 liquid doses are required. This policy revision was reviewed and approved for implementation by the facility's RSC. All Nuclear Medicine personnel, including physicians and technologists, were provided with formal instruction about the use of this new procedure and the policy revision.

c) **Corrective steps that will be taken to avoid reoccurrence.** The Radiation Safety Office staff will closely monitor future therapies involving liquid radioiodine to ensure that the revised policy and developed procedure are followed.

d) **Date when corrective measures were implemented.** The facility's RSC approved the policy revision during its quarterly meeting held on January 26, 2010. Training of Nuclear Medicine personnel was completed on February 10, 2010.