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

In Reply Refer To: 598/115HP/NLR

JUN 17 2010

Roy P. Zimmerman
Director, Office of Enforcement,
Nuclear Regulatory Commission (NRC)
One White Flint North, 11555 Rockville Pike
Rockville, MD 20852-2738

Re: NRC License 03-23853-01VA; Reply to a Notice of Violation (EA-10-023)

Dear Mr. Zimmerman:

I am responding to the NRC, Region III, letter dated June 2, 2010, that issued a Notice of Violation and assessed a civil penalty for NRC inspection findings at VA San Diego Healthcare System, San Diego, California. I affirm acceptance of the violations in the NRC report.

Our previous letter, dated March 29, 2010, reviewed root causes, corrective actions, and compliance dates for the inspection findings at the facility. The NRC reports dated March 5 and June 2, 2010, provided additional statements of the key issues. As further information, I am enclosing a facility response dated June 11, 2010.

While I accept the violations, I note the violation related to discovery of a medical event is based on a regulatory determination. That determination about feasibility of discovery of a medical event at a particular point in the patient treatment is contrary to the opinion of both NRC and VHA medical experts.

I will provide separate correspondence to confirm payment of the civil penalty. Please contact me if you have any questions or comments.

Sincerely,

Gary E. Williams
Director, National Health Physics Program

Enclosure

cc: Regional Administrator, NRC Region III

DEPARTMENT of VETERANS AFFAIRS

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

June 11, 2010

In reply refer to: 664/151

Mr. Gary E. Williams, Acting 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 Notice of Violation EA-10-023.

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

Our Nuclear Medicine and Radiation Safety staffs continue taking proactive measures to ensure that a similar event does not reoccur and that all medical administrations of radioactive drugs are in full compliance with NRC regulations.

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,

Stan Johnson, FACHE
Director

Enclosure

Reply to Notice of Violation: (No. EA-10-023)

The numbering in the following response corresponds to the alleged violations listed in NRC Notice of Violation No. EA-10-023:

A. Violations Assessed a Civil Penalty

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) **Admission or denial of the alleged violation.** The permittee accepts the alleged violation.

   b) **Reason(s) for the alleged violation.** The primary reasons identified during the root cause analysis for the alleged 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). Additionally, Nuclear Medicine personnel involved in the administration of byproduct material did not have appropriate training to ensure that administration through gastrostomy tubes are performed in accordance with WDs.

   c) **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.

   Additionally, the permittee 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, the revision of the radiation safety manual and the developed training programs.

   d) **Corrective steps that will be taken to avoid further violations.** Radiation Safety Office staff and authorized users (AUs) 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.

e) **Date when full compliance will be achieved.** The procedure discussed in 1.c 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. As of June 11, 2009 no procedures requiring the use of unfamiliar medical apparatus, including gastrostomy feeding tubes, have been performed at the facility.

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

a) **Admission or denial of the alleged violation.** The permittee accepts the alleged violation.

b) **Reason(s) for the alleged violation.** 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 to the permittee 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 all documentation and interviews with key personnel, the NRC concluded that information was available on September 23, 2009, to make the determination that a medical event had occurred. The permittee accepts this determination and the alleged violation.

c) **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).

d) **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).

e) **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.

B. <u>Violation Not Assessed a Civil Penalty</u>

Failure to instruct supervised individuals (i.e., members of the interventional radiology staff) in the use of written radiation protection procedures (including the proper handling of patient's contaminated gastrostomy tube), written directive procedures, applicable regulations and license conditions with respect to the use of byproduct material as required by 10 CFR 35.27(a)(1).

a) **Admission or denial of the alleged violation.** The permittee accepts the alleged violation.

b) **Reason(s) for the alleged violation.** On Friday morning, September 25, 2009, Nuclear Medicine personnel coordinated the removal of the gastrostomy tube and the transportation of the patient to the interventional radiology suite. Upon arrival to the suite, the member of the Nuclear Medicine staff transporting the patient informed those members of the surgical team present that the gastrostomy tube was "hot" and that they needed to place all waste generated from the procedure in a biohazard waste bag. However, no formal instruction on radiation safety precautions (i.e., waste and contamination control) was provided. The permittee did not provide the interventional radiology staff with proper instruction before initiating the steps to replace the patient's contaminated gastrostomy tube.

c) **Corrective steps that have been taken and the results achieved.** The permittee developed a detailed written procedure and new training program to ensure that anyone participating in medical procedures involving Nuclear Medicine patients is properly informed of the expected

hazards, as well as the protective measures that must be followed to properly control waste and contamination. 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 and the developed training program.

d) **Corrective steps that will be taken to avoid further violations.** Members of the Radiation Safety Office staff and Nuclear Medicine personnel will closely monitor future therapies, including those involving gastrostomy feeding tubes to ensure that the developed procedure is followed and involved personnel are properly trained before initiating any work.

e) **Date when full compliance will be achieved.** Full compliance was achieved on January 26, 2010, when these documents were reviewed and endorsed by the facility's RSC. Medical personnel (physicians, nurse, technologists, etc.) will be trained, as needed.