



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

OCT 07 2009

In Reply Refer To: 598/115HP/NLR

Cassandra Frazier
Division of Nuclear Material Safety
U.S. Nuclear Regulatory Commission (NRC), Region III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

Re: NRC License 03-23853-01VA; Event Number 45383

Dear Ms. Frazier:

I am enclosing the 15-day written report for the medical event that occurred at the VA San Diego Healthcare System, San Diego, California. The report is in the format of a memorandum signed by the healthcare system director and submitted per 10 CFR 35.3045(d). The healthcare system holds VHA Permit Number 04-15030-01 under our master material license.

The medical event involved a radiopharmaceutical therapy for thyroid cancer that was performed on September 21, 2009. The healthcare system discovered and reported the medical event to us on September 25, 2009. We notified the NRC Operations Center on September 26, 2009.

My staff initiated an on-site reactive inspection at the healthcare system on September 30, 2009, to evaluate circumstances of the medical event, review initial actions to prevent a recurrence, and assess regulatory compliance. This inspection remains open.

If you have any questions, please contact me at 501-257-1571.

Sincerely,

A handwritten signature in black ink, appearing to read "G. Williams".

Gary E. Williams
Interim Director, National Health Physics Program

Enclosure

RECEIVED OCT 09 2009



DEPARTMENT OF VETERANS AFFAIRS
San Diego Healthcare System
3350 La Jolla Village Drive
San Diego, CA 92161

October 5, 2009

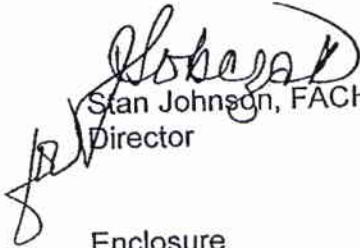
In reply refer to: 664/151

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

Dear Mr. Williams,

Enclosed is our report pursuant to 10 CFR 35.3045, regarding the medical event discovered on September 25, 2009 at VA San Diego Healthcare System (VASDHS). If you have questions with regard to this report, please contact me at (858) 552-8585 extension 3201 or Mr. René Michel, VASDHS Radiation Safety Officer, at extension 1059.

Sincerely,


Stan Johnson, FACHE
Director

Enclosure

The following information is submitted, pursuant to 10 CFR 35.3045, regarding a medical event that was discovered on September 25, 2009:

The licensee's name:

The licensee is the US Department of Veterans Affairs.

The permittee is the Veterans Affairs San Diego Healthcare System (VASDHS).

b) The name of the prescribing physician:

The prescribing physician is Ernest V. Belezzuoli, M.D.

c) A brief description of the event:

Another VA healthcare facility referred a patient with a history of metastatic thyroid carcinoma to VASDHS for treatment. The patient had recently undergone surgical de-bulking of metastases in his neck and axillae resulting in a requirement for a tracheostomy tube and difficulty swallowing. At the time of his admittance to VASDHS the patient was receiving nourishment and medications via a percutaneous endoscopic gastrostomy (PEG) tube. On September 21, 2009, the prescribing physician informed the patient that treatment using radioactive iodine (I-131) in the form of sodium iodide was indicated. The prescribing physician reviewed with the patient the intended route of administration (via the PEG tube) as well as the risks and benefits of treatment. After the patient's consent was obtained, the therapeutic agent was administered to the patient via his PEG tube on September 21, 2009.

Soon after the administration, Radiation Safety measured and recorded radiation levels from the patient. On the mornings of September 22nd and 23rd, radiation levels from the patient were measured, recorded, and reported to the Nuclear Medicine Service; these levels were higher than expected. On September 23rd, Nuclear Medicine personnel performed their own measurements of the patient and confirmed that radiation levels were higher than those expected following normal biological uptake and elimination of the therapeutic agent. The Nuclear Medicine Service, at the direction of the prescribing physician, obtained gamma camera images of the patient to evaluate distribution of the therapeutic agent. These images indicated that much of the therapeutic agent remained within the stomach/abdominal region of the patient. The decision was made to continue monitoring the patient into the following day to allow for additional uptake and improved clearance of the therapeutic agent. However, radiation levels from the patient remained elevated on the morning of September 24th.

In the afternoon on September 24th, the prescribing Nuclear Medicine Physician explained to the patient that he suspected that a portion of the therapeutic agent was being retained in the PEG tube. He advised the patient that he would wait another 24 hours to see if the uptake of the therapeutic agent improved and if radiation exposure levels would further decrease. If the level did not decrease, the prescribing physician advised the patient that the PEG tube would need to be removed. The patient acknowledged understanding, and agreed with, this plan.

In the morning of September 25th, radiation levels from the patient were found to still be higher than expected. Nuclear Medicine Service consulted with Interventional Radiology staff on replacing the existing PEG tube with a new PEG tube. In the late morning of September 25th, the patient's PEG tube was replaced in Interventional Radiology with a Senior Nuclear Medicine Technologist present to oversee the radiation safety aspects of the procedure. The patient tolerated the procedure well and was transferred back to his room.

Immediately after removal of the PEG tube, the permittee's Radiation Safety Officer (RSO) performed a follow-up measurement of the patient and observed a significant radiation level decrease (to below the accepted release limit). The RSO then contacted the Nuclear Medicine Physician to inform him of the potential medical event. At this point, the decision was made to promptly report the potential medical event to the VA National Health Physics Program (NHPP). Later that same day, the patient was informed of the event and discharged in good condition.

d) Why the event occurred:

It appears that the PEG tube unexpectedly retained a large amount of the radioiodine, estimated at this time with considerable uncertainty to be approximately 50% of the prescribed dosage. The cause of the event is not certain at this time. Investigation is ongoing to attempt to determine the cause of the retention. Per analysis of the Interventional Radiologist who replaced the PEG tube and is experienced at PEG tube placement, it is possible that intermittent kinking of the tube resulted in reflux of a portion of the administered dose into the distal portion of the alternate/medication port. Without flushing of the other ports, a portion of the prescribed dose could remain sequestered within the PEG tube. Other potential explanations include unexpected adherence of the radionuclide to the internal lumen of the PEG tube and/or radioiodine adherence to an external portion of the PEG tube following successful delivery of the radioiodine into the stomach.

e) The effect, if any, on the individual who received the administration:

The radioactive iodine retained in the PEG tube may have imparted a larger than expected radiation dose to tissues in the vicinity of the tube and may have caused acute radiation injury to those tissues in the event that the entire sequestered dose was directly adjacent to a portion of the stomach wall. A dosimetric assessment, using worst-case assumptions, was promptly performed to predict potential complications and to ensure that the patient received, if needed, immediate medical care. It is predicted that this radiation dose could result in some mild sloughing of the stomach wall and transient gastritis. In consultation with an established expert in the field of medical effects of ionizing radiation, the most serious complication that would be expected from the estimated level of exposure is a fistula. The patient did not require any immediate medical attention and has not displayed any symptoms or signs potentially attributable to the prolonged exposure to the radioiodine. The medical condition of the patient is being closely followed, and VASDHS Nuclear Medicine Service personnel have been communicating with the patient on a regular basis. As of October 5, 2009, the patient has continued to report no adverse reactions.

f) What actions, if any, have been taken or are planned to prevent recurrence:

As a precaution, the permittee has temporarily ceased performing administrations of iodine-131 sodium iodide through gastrostomy tubes until:

- 1) An investigation is completed to attempt to determine the cause of the retention of the radiopharmaceutical in the PEG tube.
- 2) The written procedures involving these administrations are thoroughly reviewed and revised as necessary to ensure that they can be performed safely and in compliance with NRC regulations.
- 3) All personnel involved in this procedure are properly trained in the implementation of these procedures.

g) Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not:

We certify that we notified the individual of the medical event.

From: Origin ID: LITA (501) 257-1571
Kelly Mayo
VHA National Health Physics Pr
2200 FORT ROOTS DR
B101 R208D
NORTH LITTLE ROCK, AR 72114



Ship Date: 07OCT09
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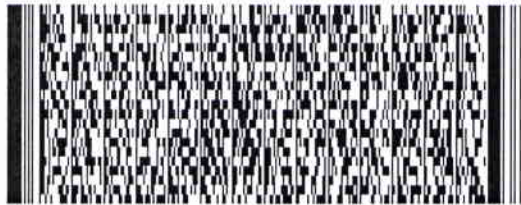
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SHIP TO: (501) 257-1571 BILL SENDER
Cassandra Frazier
Nuclear Regulatory Commission
2443 Warrenville Road
Suite 210
Lisle, IL 60532

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Invoice #
PO #
Dept #

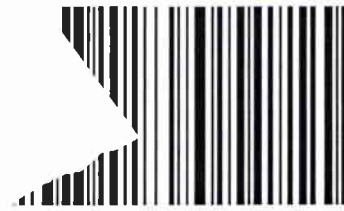
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