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HERITAGE VALLEY
Health System

720 Blackburn Road
Sewickley, Pennsylvania
15143-1498

November 3, 2006

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D.C. 20555

RE: Reply to a Notice of Violation
Heritage Valley Health System

Docket No. 03003143 License No. 37-11562-01

Gentlemen:
In response to your request for explanation concerning the two violations, we believe that we have already fully responded to each violation in our previously submitted formal investigation reports for the two medical events that are the root cause of the violations. We have attached a copy of the report for your reference. This report was submitted to the NRC by fax and electronically on 10/8/06. It was also mailed on 10/9/06.

If you have any further questions, please do not hesitate to contact the undersigned.

Terry Biss
Vice President
Heritage Valley Health System

Cc: Regional Administrator
Region I
U.S. Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, PA 19406-1415

IE07

Report for Medical Event at Heritage Valley Health System; Sewickley Valley Hospital Campus; date of occurance: 9/21/06; date of discovery 9/25/06

License name: Heritage Valley Health System
RAM license number 37-11562-01

Referring physician: Gerald Goltz, M.D.

On 9/21/06, at the Sewickley Valley Hospital campus of the Heritage Valley Health System, a medical event occurred. Per written directive, a patient who was to receive 25 mCi of I-131 for hyperthyroid treatment, only received 1 of the 2 capsules sent by the radiopharmacy for a total dose of only 5.3 mCi. The dose arrived from the radiopharmacy as 2 capsules in a vial inside of a lead pig. The vial was labeled with the dose and patient information. The vial was assayed to ensure the dosage was approximately that of the written directive. The tech administered the dose by shaking the dose out of the vial into the patient's hand. One capsule apparently stuck in the vial and went unnoticed by the technologist. The patient ingested the capsule and left the department. The vial was returned to a lead pig which went into a lead-lined delivery case. The case was surveyed as per procedure with only a background reading noted. The case was picked up and transferred to the radiopharmacy. The error went unnoticed until the radiopharmacy notified the chief nuclear medicine technologist on 9/25/06 at 4:40 PM that an I-131 capsule had been returned to the pharmacy. The radiation safety officer was notified at 7:15 AM on 9/26/06. The referring physician was notified by the chief nuclear medicine technologist before 9:00 AM. The chief nuclear medicine technologist notified the patient later that day. During the investigation of this event, a second medical event was discovered that had occurred on 9/1. A separate report will be issued on the second event.

The primary cause of the medical event was technologist error although this must be strongly mitigated by factors such as inaccurate documentation from the radiopharmacy and the physical appearance of the capsules inside of the vial.

The packing slip delivered with the dose contains the drug and dosage information of the contents along with the bar code. The bar code was scanned into the NMIS software in the hot lab and the technologist noted the drug, the dose and volume of one (1) capsule. The technologist relied on the packing slip information as scanned into the computer to be accurate so she only expected a single capsule and proceeded under that assumption.

The label on the lead pig had a capsule volume of (1) which was crossed out by the pharmacist when prepared and replaced with a (2) (see enclosed documentation). This went unnoticed by the technologist. She assayed the vial and found the dose to be in compliance with the written directive. The vial itself is small and clear, the capsules are large and white and a large white desiccant packet is packed along with the capsules. The resulting lack of contrast makes it difficult to easily discern if a capsule is in the vial.

There was no harm to the patient. After notification, the referring physician ordered that the remainder of the dose be given to the patient. The patient received the remainder of the dose as a new administration on 9/28/06.

Steps taken to prevent recurrence: The hospital has instituted policy changes that require the technologist to visually inspect the empty vial and reassay the empty vial in the dose calibrator prior to discharging the patient to ensure that the entire dose has been administered. In addition, we have requested the radiopharmacy cancel and reprint the prescription label when the dose and/or volume of capsules vary from the original printed prescription label. The change will also be reflected in the barcode scanned by the NMIS.

We certify that the patient has been notified of the medical event. She has already been administered the remainder of her prescribed dose.

Report for Medical Event at Heritage Valley Health System; Sewickley Valley Hospital Campus; date of occurance: 9/1/06; date of discovery: 9/26/06

License name: Heritage Valley Health System
RAM license number 37-11562-01

Referring physician: Gerald Goltz, M.D.

During the hospital's RSO's investigation of a medical event that had occurred on 9/21/06 (see previous report), the radiation safety officer was informed by the radiopharmacy that another capsule had been found by the radiopharmacy on 9/11/06. The capsule was traced to an administration from 9/1/06. A miscommunication within the radiopharmacy resulted in the hospital not being notified of the event until the hospital's RSO contacted the radiopharmacy as part of his investigation on 9/26/06. The events, causes, steps taken to prevent recurrence as outlined below are nearly identical to the 9/21 medical event.

On 9/1/06, at the Sewickley Valley Hospital campus of the Heritage Valley Health System, a medical event occurred. Per written directive, a patient who was to receive 100 mCi of I-131 for cancer therapy treatment, only received 1 of the 2 capsules sent by the radiopharmacy for a total dose of approximately 36 mCi. The dose arrived from the radiopharmacy as 2 capsules in a vial inside of a lead pig. The vial was labeled with the dose and patient information. The vial was assayed to ensure the dosage was approximately that of the written directive. The tech administered the dose by shaking the dose out of the vial into the patient's hand. One capsule apparently stuck in the vial and went unnoticed by the technologist. The patient ingested the capsule and left the department. The vial was returned to a lead pig which went into a lead-lined delivery case. The case was surveyed as per procedure with only a background reading noted. The case was picked up and transferred to the radiopharmacy. The referring physician was notified immediately. The chief nuclear medicine technologist notified the patient later that day.

The primary cause of the medical event was technologist error although this must be strongly mitigated by factors such as inaccurate documentation from the radiopharmacy and the physical appearance of the capsules inside of the vial.

The packing slip delivered with the dose contains the drug and dosage information of the contents along with the bar code. The bar code was scanned into the NMIS software in the hot lab and the technologist noted the drug, the dose and volume of one (1) capsule. The technologist relied on the packing slip information as scanned into the computer to be accurate so she only expected a single capsule and proceeded under that assumption.

The label on the lead pig had a capsule volume of (1) which was crossed out by the pharmacist when prepared and replaced with a (2). This went unnoticed by the technologist. She assayed the vial and found the dose to be in compliance with the written directive The vial itself is small and clear, the capsules are large and white and a

large white desiccant packet is packed along with the capsules. The resulting lack of contrast makes it difficult to easily discern if a capsule is in the vial.

There was no harm to the patient. After notification, the referring physician ordered that the remainder of the dose be given to the patient. The patient is currently on Synthroid and must stop taking the drug and wait until the drug is cleared from her system prior to receiving the remainder of her dose.

Steps taken to prevent recurrence: The hospital has instituted policy changes that require the technologist to visually inspect the empty vial and reassay the empty vial in the dose calibrator prior to discharging the patient to ensure that the entire dose has been administered. In addition, we have requested the radiopharmacy cancel and reprint the prescription label when the dose and/or volume of capsules vary from the original printed prescription label. The change will also be reflected in the barcode scanned by the NMIS.

We certify that the patient has been notified of the medical event. She will receive the remainder of her dose in approximately 5-6 weeks.

SWVH Rx 659366 412-749-7239

Kim - Reported 1440 25Sep. (Upon Discovery)

20.7 mCi

Lakeshore Isotopes
2727 West 21st Street Erie Pennsylvania 16505
800-539-8505 37-28520-02MD

Rx#659366 Run: [#1 09-21-06 03:00]

Customer: SEWICKLEY VALLEY
Doctor : R. GREENSPAN Rph : PP
Patient : LORDI
Proc : THYROID THERAPY
Rad.Phar: I-131 Caps [redacted]
Inv/Lot#: 60633/91906PP3
Cal Act :25.00mCi 09-21-06@13:00
Manuf : In-house prep.
Disp Act: 25.09mCi 09-21-06@12:00
Vol./Qty: 2
Expires : 10-21-06 13:00

This radiopharmaceutical is licensed by the U.S. Nuclear Regulatory Commission for distribution to persons licensed persuant to 10CFR35.14 35.100, 35.200, 435.300 and to persons who hold an equivalent license in an agreement state.

26.1 mCi / 2 cc/r

Lakeshore Isotopes
2727 West 21st Street Erie Pennsylvania 16505
800-539-8808 39-24520-02MD

Rx#655272 Run: [#1 09-01-06 03:00]

Customer: SEWICKLEY VALLEY
Doctor : R. GREENSPAN Rph : PP
Patient : MYERS
Proc : THYROID THERAPY
Rad.Phar: I-131 Caps [redacted]
Inv/Lot#: 60082/060831-5PP
Cal Act :100.00mCi 09-01-06@12:00
Manuf : In-house prep.
Disp Act: 100.00mCi 09-01-06@12:00
Vol./Qty: 1Cap
Expires : 10-01-06 12:00

This radiopharmaceutical is licensed by the U.S. Nuclear Regulatory Commission for distribution to persons licensed pursuant to 10CFR35.14 35.100, 35.200, 35.300 and to persons who hold an equivalent license in an agreement state.

107.7
/2