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

FEB 0 4 2004

In Reply Refer To: 598/115HP/NLR

Kevin G. Null
Division of Nuclear Material Safety
Nuclear Regulatory Commission (NRC), Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

Re: NRC License 03-23853-01VA

Dear Mr. Null:

I am forwarding the enclosed medical event report for Event Number 40465.

This report is submitted under 10 CFR 35.3045 for a medical event occurring on December 29, 2003, at the VA Ann Arbor Healthcare System, Ann Arbor, Michigan, VHA Permit Number 21-00159-04. The event was discovered on January 21, 2004, and reported to the NRC Operations Center on January 22, 2004.

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

Sincerely,

E. Lynn McGuire
Director, National Health Physics Program

Enclosure

FEB 6 2004

Report of Medical Event Under 10 CFR 35.3045(d)

1. The licensee's name:

a. Licensee

Department of Veterans Affairs
Under Secretary for Health
Washington, D.C. 20420
Nuclear Regulatory Commission (NRC) License Number 03-23853-01VA

b. Permittee:

VA Ann Arbor Healthcare System
2215 Fuller Road
Ann Arbor, Michigan 48105
VA Permit Number 21-00159-04

2. The name of the prescribing physician: David H. Woodbury, M. D.

3. A brief description of the event:

a. This event occurred on December 29, 2003. The written directive for a patient therapy procedure prescribed four millicuries ^{90}Sr. The patient was administered 3.98 millicuries ^{89}Sr chloride. The clinical intent was for the patient to be administered ^{89}Sr chloride.

b. This event was discovered on January 21, 2004. An NRC inspector noted the discrepancy between what was prescribed in a written directive (i.e., ^{90}Sr) and what was administered to the patient (i.e., ^{89}Sr chloride).

4. Why the event occurred:

a. From a root cause analysis perspective, the events, conditions, and causal factors for this event are noted below:

(1) The Nuclear Medicine Technologist did not verify the radioisotope associated with the radioactive drug.

(2) The written directive form required the authorized user physician to hand write the specific radioactive drug versus using a selection system of predefined and approved radioactive drugs that require written directives.

(3) ^{89}Sr chloride is the only isotope of strontium available as a radiopharmaceutical for palliative treatment.

(4) The original written directive of December 11, 2003, was misplaced thus requiring a new written directive to be prepared on December 29, 2003.

(5) The Nuclear Medicine Technologist ordered ^{89}Sr chloride on December 26, 2003, based on the original written directive of December 11, 2003.

(6) The package containing the ^{89}Sr chloride was not labeled per Department of Transportation regulations. An investigation of the mislabeled package by the Radiation Safety Officer and the Nuclear Medicine Technologist clarified the package contained a vial with four millicuries ^{89}Sr chloride confirming to the staff the radioactive material was as ordered.

(7) A second Nuclear Medicine Technologist recalls a discussion with prescribing physician on December 29, 2003, just prior to preparation of the new written directive that reflected on the physician's historical involvement with the Food and Drug Administration regarding approval of radionuclides for human use. The discussion with the technologist included exposure risks from ^{89}Sr versus ^{90}Sr.

b. From a root cause analysis perspective, the underlying root cause is written procedures followed incorrectly.

5. The effect, if any, on the individual(s) who received the administration:

a. The patient received the intended administration of ^{89}Sr chloride.

b. The prescribing physician concluded the patient will not suffer any adverse effects.

6. What actions, if any, have been taken or are planned to prevent recurrence:

The permittee completed the following corrective actions.

a. The written directive form was changed to a select list of choices for the radioactive drug to be prescribed rather than for the prescribing physician to hand write the radioactive drug.

b. The checklist used for verification of written directives was changed to a select list of choices for the radioactive drug from which to choose, rather than for the prescribing physician to hand write the information specified in the written directive.

c. All authorized users and technical staff was trained on the use of revised written directive and checklist forms.

d. The written procedures for administrations requiring a written directive were evaluated. No changes were deemed necessary to the written procedures.

e. The auditing procedures for ensuring administrations are preformed per written directives were evaluated. No changes were deemed necessary to the written procedures.

f. The other locations of use for radioactive materials were reviewed for possible applicability of the circumstances that resulted in the event. No changes were deemed necessary for the other locations of use.

7. Certification that the licensee notified the individual (or the individuals responsible relative or guardian) and if not, why not:

a. The Radiation Safety Officer informed the patient's referring clinician of the medical event.

b. The clinician responded in writing that she would not inform the patient of the error and stated informing the patient would be harmful.

c. The referring oncology physician concurred with the clinician not to inform the patient, since informing the patient might be harmful.