

JAN 30 2008

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

DEPARTMENT OF VETERANS AFFAIRS

In Reply Refer To: 598/115HP/NLR

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

Re: NRC License 03-23853-01VA

Dear Ms. Frazier:

I am forwarding the enclosed event report for Event Number 43917. The report is in the format of a letter dated January 28, 2008, and signed by the Radiation Safety Officer. The report has the information required under 10 CFR 35.3045.

This report is submitted per 10 CFR 35.3045(a)(2) for a possible medical event that occurred on January 17, 2008, at VA Boston Healthcare System, Boston, Massachusetts, and was discovered the same day. The circumstances involved administration of a radiopharmaceutical that might have resulted in more than 50 rem to tissue and involved a wrong route of administration.

For a dose estimate to tissue, we assumed 3.6 mCi F-18 FDG infiltrated into tissue within a 60 cm³ sphere @ 1.06 g/cm³ with a range of mean residence time from 0.006 to 2.6 hours. Based on these parameters, the dose to tissue might range from 0.2 to 96 rem.

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

Sincerely,

É. Lynn McGuire Director, National Health Physics Program

Enclosure

RECEIVED JAN 3 1 2008



DEPARTMENT OF VETERANS AFFAIRS

VA Boston Healthcare System 1400 VFW Parkway West Roxbury, MA 02132

IN RESPONSE REPLY TO: 523/11

January 28, 2008

Gary E. Williams National Health Physics Program Veterans' Health Administration North Little Rock, Arkansas Re: VHA Permit Number 20-00671-02 VA Boston HealthCare System Telephone report of January 18, 2008

Dear Mr. Williams,

In this communication I follow up my notification of a potential Medical Event here on January 17, 2008.

During IV administration of 3.6 milliCi of F-18-FDG for a PET scan, a substantial portion of the intended administered dose leaked from the injected vein and infiltrated much of the antecubital soft tissue adjacent to the left elbow. The leak was discovered upon image acquisition one hour after the radiopharmaceutical administration. Prescribing physician: Rachel A. Powsner, MD.

We surmise the cause was inaccurate placing of an intravenous needle in a very small vein. The needle was carefully checked for infiltration using a 10 mL flush and a 100 mL infusion prior to injection of the F-18-FDG.

The nature of the radioisotope involved is such that a large particulate dose can be delivered when the injectate is confined to a circumscribed area. As we discussed with you last Friday, various assumptions about the unmeasured biological parameters in this instance lead to large and varied absorbed dose estimates. Because of the possibility that the actual dose exceeded the threshold for a Medical Event as defined in 35.3045(a), we seek your advice. The patient and his primary care physician were notified of the event.

We identified no adverse effects except for the subcutaneous swelling due to the saline infusion. On January 25, one week after the infiltration, examination of the left forearm, elbow, and antecubital fossa revealed no discernible abnormality. Fortunately, the patient has several upcoming office visits, so we will be able to scrutinize the irradiated area of the elbow over a period of time.

We plan to include in the next Nuclear Medicine staff meeting a review and discussion of choice of peripheral vein and of placing the needle accurately therein.

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David E. Drum, MD Acting Radiation Safety Officer

