



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

JUL 31 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

Dear Ms. Frazier:

I am forwarding the enclosed medical event report for Event Number 44548. The report is in the format of a memorandum signed by the permittee director and is submitted pursuant to 10 CFR 35.3045(d). The report addresses a medical event that occurred at the VA Medical Center, Cincinnati, Ohio. The medical center holds VHA Permit Number 34-00799-03 under our master material license.

The medical event addressed by the enclosed report was reported to the NRC Operations Center on July 23, 2009. The event involved permanent implant prostate seed brachytherapy. This event was discovered as part of an expanded review performed in response to the six events reported October 7, 2008, for this permittee.

My staff initiated an on-site reactive inspection of the VA Medical Center, Cincinnati, Ohio, on October 16-17, 2008, to evaluate the circumstances of the six medical events reported earlier, evaluate initial actions to prevent a recurrence, and assess regulatory compliance. Circumstances associated with this additional medical event are being included in this inspection.

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

Sincerely,

A handwritten signature in black ink, appearing to read "E. Lynn McGuire".

E. Lynn McGuire
Director, National Health Physics Program

Enclosure

RECEIVED AUG 04 2009

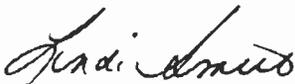
**DEPARTMENT OF
VETERANS AFFAIRS**

Memorandum

Date: July 28, 2009
From: Director, VA Medical Center, Cincinnati, Ohio (539/00)
Subj: Report of Medical Event
To: Director, VHA National Health Physics Program (115HP/NLR)

1. The enclosed report is submitted to you, per 10 CFR 35.3045, for medical events discovered on July 22, 2009. . Following the notification of the NRC on October 7, 2008, of the six medical events described in Event Report No. 44548, the VA National Health Physics Program (NHPP) initiated a reactive inspection of Cincinnati VA Medical Center on October 16, 2008. As a result of this inspection and related clinical reviews, the NHPP notified the NRC Operations Center on July 23, 2009 of one additional medical event at the Cincinnati VA Medical Center, for a total of seven medical events at this facility. This event, involving a prostate brachytherapy procedure performed with I-125 seeds on May 22, 2008 was discovered on July 22, 2009.

2. If you have any questions, please contact Chris Rauf, Radiation Safety Officer, at (513) 475-6319.



Linda Smith

Enclosure

Report of Medical Event

1. The VHA Master Material License Permittee's name:

VA Medical Center
3200 Vine Street
Cincinnati, OH 45220
VHA MML Permit Number 34-00799-03

2. Name of the Prescribing Physician: Kevin Redmond, M.D.

3. Description of the event:

In response to medical events discovered at the VA Medical Center Philadelphia which have been reported under NRC Event Number 44219, reviews have been performed of samples of patient charts from other VA facilities with permanent prostate iodine-125 seed implant brachytherapy programs. Following the notification of the NRC on October 7, 2008, of the six medical events described in Event Report No. 44548, the VA National Health Physics Program (NHPP) initiated a reactive inspection of Cincinnati VA Medical Center on October 16, 2008. As a result of this inspection and related clinical reviews, the NHPP notified the NRC Operations Center on July 23, 2009, of one additional medical event at the Cincinnati VA Medical Center, for a total of 7 medical events at this facility. This event, involving a prostate brachytherapy procedure performed with I-125 seeds on May 22, 2008, was discovered on July 22, 2009. Like the previous six medical events, this additional medical event involves a D_{90} dose (the dose received by 90% of the prostate volume) less than 80% of the prescribed dose.

4. Why the event occurred:

The D_{90} dose that was calculated from the post plan was less than eighty percent of the prescribed dose based upon review of CT scan taken one-day post treatment.

The D_{90} doses for all seven events were based upon CT scans performed one day after the implants, when the prostate is subject to edema from the procedure. In addition, the true volume of the prostate is impossible to define at this time because of disrupted tissue planes from the procedure. The edema and disrupted planes commonly result in prostate volumes that are 30% to 90% greater than planned volume, which will cause underestimation of the true D_{90} . Furthermore, the prescribed doses were 160 gray, instead of the more common 145 gray. Thus, most if not all of these patients likely received clinically adequate dose distributions, despite the percent-wise slightly low D_{90} s.

5. The effect on the individual who received the administration:

The prescribed number of seeds was implanted and all seeds were placed in or very close to (i.e., within 1cm) of the prostate.

No adverse effects to the patient are anticipated. All treatments are being monitored by regular testing of prostate specific androgen (PSA) levels and all have values < 1ng/mL, consistent with successful treatment.

6. Actions taken to prevent recurrence:

The prostate brachytherapy program remains suspended since October 2008. During the intervening period, new standard VA procedures for prostate brachytherapy have been generated and implemented locally. When the prostate brachytherapy program is resumed, we will acquire post-implant CTs immediately after the procedure to minimize prostate volume overestimation. Prescriptions will be reduced from the historical 160 gray to the more common 145 gray, reducing the likelihood of D_{90} being less than 80% of prescribed dose.

7. Certification that the permittee notified the individual and if not, why not:

The prescribing physician has informed the patient and the referring physician as required by 10 CFR 35.3045.

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



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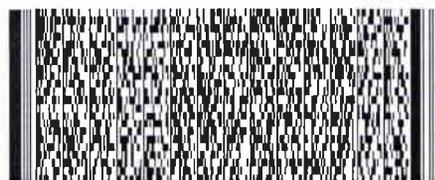


Ref #
Invoice #
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SHIP TO: (501) 257-1571 BILL SENDER
Cassandra Frazier
Nuclear Regulatory Commission
2443 Warrenville Road
Suite 210
Lisle, IL 60532

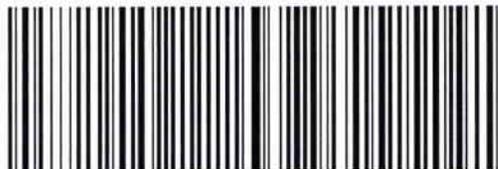
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