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

OCT 22 2008

In Reply Refer To: 598/115HP/NLR

Cassandra F. Frazier
Division of Nuclear Material Safety
U.S. Nuclear Regulatory Commission, 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 report regarding Event Number 44522. The report addresses a single medical event that occurred at the G.V. (Sonny) Montgomery VA Medical Center, Jackson, Mississippi, and is submitted pursuant to 10 CFR 35.3045(d). The medical center holds VHA Permit Number 23-08786-01 under our master material license.

The single medical event addressed by the enclosed report was reported to the NRC Operations Center on October 8, 2008. The event involved permanent implant prostate seed brachytherapy.

This event was discovered as part of an ongoing reactive inspection by my staff implemented in response to medical events reported earlier for this medical center. My staff performed the initial part of the reactive inspection at the permittee's facility on October 8-10, 2008, to evaluate the circumstances of these events, assess initial actions to prevent a recurrence, and assess regulatory compliance. This inspection remains open.

Seven medical events at this medical center were reported to the NRC Operations Center on September 25, 2008. These events also involved permanent implant prostate seed brachytherapy. This additional event was recorded by the NRC Operations Center as an update to Event Number 44522. This report addresses the additional medical event reported to NRC on October 8, 2008, and brings the total number of medical events reported for this facility to eight.

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

Sincerely,

E. Lynn McGuire
Director, National Health Physics Program

Enclosure

RECEIVED OCT 23 2008

Veterans Administration

VHA FAX TRANSMITTAL

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If you have received this communication in error, please notify us immediately at the telephone number shown below. Thank you.

DEPARTMENT OF VETERANS AFFAIRS
G.V. (Sonny) Montgomery VA Medical Center
1500 E. Woodrow Wilson Drive
Jackson, MS 39216

TO	FAX NUMBER ☐ FTS ☒ COMMERCIAL	DATE	NO. PAGES ATTACHED
Lynn McGuire	(501) 257-1570	10/22/2008	03

SUBJECT

Potential Medical Events

FROM	TELEPHONE NUMBER ☐ FTS ☒ COMMERCIAL
KENT A. KIRCHNER, CHIEF OF STAFF (586/11)	601-364-1206

Rep Org: VA NATIONAL HEALTH PHYSICS PROGRAM
Permit tee: G.V. (SONNY) MONTGOMERY VA MEDICAL CENTER
Region: III
City: JACKSON **STATE:** MS
County: HINDS
Permit #: 23-08786-01
Agreement State: Y
NRC Notified By: EDWIN LEIDHOLDT
NRC Notification Date: 10/09/2008
Notification Time: 5:30 pm [CDT]
Event Date: Discovered 10/08/2008
Event Time: Discovered 07:30 pm [CDT]
Prescribing Physicians: DR. WAYNE CHAN AND DR. JAISIRI JAIWANTANA
Emergency Class: NON EMERGENCY
10 CFR Section: 35.3045(a)(1) - DOSE <> PRESCRIBED DOSAGE

EVENT TEXT

POTENTIAL MEDICAL EVENTS DUE TO POSSIBLE MISCALCULATION OF PROSTATE VOLUME USE IN PRE AND POST TREATMENT PLANS

Notification of a possible medical event per 10 CFR 35.3045 - a brachytherapy procedure in which the administered dose may differ from the prescribed dose by more than 0.5 gray to an organ and the total dose delivered may differ from the prescribed dose by twenty percent or more.

Description of Events:
The patient in question received a brachytherapy treatment on April 6, 2005; however, the radiation oncologist failed to perform the post treatment plan review immediately following the treatment. While preparing for anticipated inspections by the VHA National Health Physics Program (NHPP) and the NRC, it was discovered that the post treatment plan review was missing for this case. The medical physicist and radiation oncologist prepared the post treatment plan review on the evening of October 7, 2008, and the review indicated that the prostate dose was 70% of the dose specified in the written directive and the pretreatment plan. Based on his memory of the treatment events and a review of the case file, the radiation oncologist stated that it was the intention once in the OR to actually weight the treatment more to a specific portion of the prostate as opposed to the entire prostate. The radiation oncologist provided recently dated case notes to the file detailing his recollections of the issues involved. He also included peer literature in the file indicating that such partial prostate treatment was possible. A review of the prostate treatment plan seemed to indicate that treatment was weighted more to one portion of the prostate; however both the medical physicist and the radiation safety officer (RSO) questioned the fact that the written directive made no mention of any weighted treatment. Additionally, the treatment appeared to be more in keeping with the pretreatment plan to treat the entire prostate. This case was presented to the NHPP and NRC inspectors who were onsite reviewing the facility

brachytherapy program. They also agreed that for such an option to be considered it should be documented in the written directive initially or by a change note. In the absence of this corroborating documentation, the NHPP inspector, the NRC inspector, the medical physicist, and the RSO agreed that this treatment fell outside the +/- 20% acceptable margin for brachytherapy treatments based on treatment of the entire prostate and therefore should be considered a recently discovered medical event. The NRC was formally notified of this medical event on the evening of October 9, 2008, within the 24 hour notification time limit.

Following a discussion with the radiation oncologist regarding the patient's possible poor health [not related to the prostate treatment], it was decided by the RSO that the patient would not be contacted until the referring physician could be reached and the patient's current health status confirmed. The patient's original referring physician was no longer employed by VHA. So an attempt was made to locate the physician currently responsible for the patent's health. On the morning of October 10, 2008, a telephone conference was held with the nurse practitioner who had most recently met with the patient. Despite the patient's ongoing health issues, it was the opinion of the nurse practitioner that the patient could understand the information regarding his case and that this information would not negatively affect his current medical condition. At that point the RSO advised the radiation oncologist, the medical physicist, and the acting Chief of Staff that the notification of the patient should proceed. That notification process was started immediately after the telephone conference.

Why the Event Occurred:

According to the notes provided by the radiation oncologist after the generation of the post treatment plan review, the patient's medical issues prompted the radiation oncologist to consider in the OR weighting the treatment to the more diseased portion of the prostate. By weighting or focusing the dose on a portion of the prostate, the dose delivered over that portion would have been greater than the minimum 80% below which would have constituted a medical event. However when the dose delivered was considered over the entire volume of the prostate rather than focusing on a portion of the prostate, as indicated in the pretreatment plan, the dose was 70% rather than the minimum 80% of prescribed dose resulting in a medical event. The radiation oncologist not performing the post treatment plan review in a timely fashion delayed the discovery of the medical event by the medical physicist and the RSO. Once discovered, the medical event was discussed with NHPP and NRC representatives on site and promptly reported to the NHPP.

Actions Taken:

Following discussions with the nurse practitioner providing care for the patient, the patient notification process was initiated. The RSO provided a written notice to the nurse practitioner caring for the patient, and a report was filed with the NHPP for transmission to the NRC within 15 days of the discovered medical event. As a result of the program review conducted jointly by the NHPP and the NRC, the medical physicist

and the RSO will ensure that all post treatment plan reviews are completed in a timely fashion.

Effect on Patients: We do not anticipate any significant deterministic effects.

Linda F. Watson
Center Director
G. V. (Sonny) Montgomery VAMC (586/00)
1500 E. Woodrow Wilson Drive
Jackson, MS. 39216

From: Origin ID: LITA (501) 257-1571
Kelly Mayo
VHA National Health Physics Pr
2200 FORT ROOTS DR
B101 R208E
NORTH LITTLE ROCK, AR 72114

FedEx Express

JCLS091608/20/23

Ship Date: 22OCT08
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CAD: 5250401/INET8091
Account#: S *********

Delivery Address Bar Code

Ref # Medical Event Report
Invoice #
PO #
Dept #

SHIP TO: (501) 257-1571 **BILL SENDER**

Cassandra Frazier
Nuclear Regulatory Commission
2443 Warrenville Road
Suite 210
Lisle, IL 60532

TRK# 0201 7970 8920 1903

THU - 23OCT **A2**
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