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

DEC 30 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 December 17, 2008. The event was recorded as an update to Event Number 44522. The event was discovered by medical center staff on December 16, 2008. My staff performed the initial part of a reactive inspection at the permittee's facility on October 8-10, 2008, to evaluate the circumstances of related events, assess initial actions to prevent a recurrence, and assess regulatory compliance. The inspection remains open, and this most recent event is being included in this inspection.

In recent weeks, ten medical events have been reported to the NRC Operations Center for this medical center under Event Number 44522. Seven events were reported September 25, 2008; one was reported October 8, 2008; one was reported October 30, 2008; and one was reported December 17, 2008. All events involved permanent implant prostate brachytherapy using iodine-125 seeds. The seed brachytherapy program at this medical center is suspended with no date for restart planned at this time.

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

Sincerely,

for E. Lynn McGuire
Director, National Health Physics Program

Enclosure

Veterans Administration

VHA FAX TRANSMITTAL

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
Dr. Thomas Huston	(501) 257-1570	12/30/08

SUBJECT

NRC Notice to NHPP

FROM	TELEPHONE NUMBER ☐ FTS ☒
KENT A. KIRCHNER, MD, CHIEF OF STAFF	(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
Permit #: 23-08786-01
NRC Notified By: THOMAS E. HUSTON, PH.D.
NRC Notification Date: 12/17/2008
Notification Time: 12:35 am [EST]
Event Date: DISCOVERED 12/16/08
Event Time: DISCOVERED 5:00 pm [CST]
Prescribing Physicians: DR. JAISIRI JAIWATANA
10 CFR Section: 35.3045(a) (1) - DOSE <> PRESCRIBED DOSAGE

EVENT TEXT

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 Event:
During a recent internal review of the facility brachytherapy program, it was discovered that CT scans could not be located for three cases. The patient in this case was initially treated on October 31, 2007, during a period of connectivity problems between the facility CT scanners and the Variseed treatment planning system. A follow up CT scan was scheduled December 16, 2008, in order to complete the post treatment plan review that was lacking. Utilizing the data from the follow up CT scan, it was determined by the radiation oncologist and medical physicist that the D90 for the post treatment plan review was 49.7% of the prescribed dose of 145 Gy. This was reported to the RSO by the medical physicist at the end of the day on December 16, 2008. The RSO agreed that this case represented a medical event due to the radiation dose delivered to the prostate differing by 20% or more from the dose specified in the written directive completed prior to treatment. The RSO contacted the NHPP the next morning on December 17, 2008, to report that a medical event had been discovered, following a final consultation with the radiation oncologist.

Why the Event Occurred:

The medical event was most likely due to suboptimal seed placement. Another contributing factor may have been the inability to locate an original CT scan immediately following the treatment of this patient. There was a delay of 13 ½ months from the day of treatment to the completion of a follow up CT scan.

Effect on Patient: We do not anticipate any significant deterministic effects at this time.

Actions Taken:

The patient's progress will continue to be monitored. As a result of the post treatment plan review indicating a lower than anticipated dose to the prostate, options are being considered that include supplementing the radiation dose delivered to the patient's prostate using beam therapy or additional brachytherapy treatment at another facility. At the present time the brachytherapy program at the Jackson VA Medical Center is suspended. Resumption of the program would be subject to the approval of the VA National Radiation Safety Committee and the VHA National Health Physics Program. Resumption would also be in accordance with the NRC Confirmatory Action Letter CAL 3-08-004 dated October 14, 2008.

Notification of the Patient:

The patient notification process required in 10 CFR Part 35.3045 was initiated, and the patient contacted by telephone within 24 hours. A follow up registered letter was also sent to the patient, and the referring physician was notified as required. A report was filed with the NHPP for transmission to the NRC within 15 days of the discovered medical event.