



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

OCT 09 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 seven medical events 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 seven medical events addressed by the enclosed report were reported to the NRC Operations Center on September 25, 2008. The events involved permanent implant prostate seed brachytherapy. These events were discovered as part of an ongoing review implemented in response to events reported earlier for the VA Medical Center, Philadelphia, Pennsylvania.

My staff plans to begin a reactive inspection at the permittee's facility on October 8, 2008, to evaluate the circumstances of these events, assess initial actions to prevent a recurrence, and assess regulatory compliance.

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



Veterans Administration

VHA FAX TRANSMITTAL

This transmission is intended only for the use of the person or office to whom it is addressed and may contain information that is privileged, confidential, or protected by law.

All others are hereby notified that receipt of this message does not waive any applicable privilege or exemption from disclosure and that any dissemination, distribution, or copying of this communication is prohibited.

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 LYNN MCGUIRE	FAX NUMBER <input type="checkbox"/> FTS <input checked="" type="checkbox"/> COMMERCIAL (501) 257-1570	DATE 10/9/2008	NO. PAGES ATTACHED 03
SUBJECT Notification of Possible Medical Event per 10 CFR 35.3045—Brachytherapy			
FROM MIKE SMITH, RADIATION SAFETY OFFICER (586/114B)	TELEPHONE NUMBER <input type="checkbox"/> FTS <input checked="" type="checkbox"/> COMMERCIAL 601-362-4471 ext. 1419		

Rep Org: VA NATIONAL HEALTH PHYSICS PROGRAM
Permit to: 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: 09/25/2008
Notification Time: 5:12 pm [PT]
Event Date: Discovered 09/25/2008
Event Time: Discovered 10:30 [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:

While preparing for anticipated inspections by the VHA National Health Physics Program (NHPP) and the NRC, it was discovered that equipment incompatibility had contributed to a loss of post treatment CT scans of some brachytherapy patients. All but three of these CT scans were eventually recovered. Radiation Therapy was instructed by the Chief of Staff (COS) to review all brachytherapy files for completeness and to correct all CT data issues. During this internal review, the Radiation Safety Officer (RSO) discovered that other post treatment plan reviews had not been printed, reviewed, signed, and posted to other patient files in a timely fashion. Radiation Therapy immediately began the process of retrieving as much CT scan data as possible and properly documenting post treatment plan reviews to correct this self identified deficiency. This has been completed for all but four unrecovered CT scans. Following conversations with the NHPP, the G.V. (Sonny) Montgomery VA Medical Center (JVAMC) voluntarily suspended the brachytherapy program until all identified issues were corrected to the satisfaction of the NHPP.

In response to action item: 16-08-06-121 mandated by the Deputy Under Secretary for Health for Operating and Management (DUSHOM), all VHA brachytherapy facilities submitted ten cases to the Seattle VAMC for external review. In light of the issue identified above, our facility requested that the review of our submitted ten cases be

expedited. The Seattle VAMC staff utilized the CT scan data provided by the JVAMC for each case and redrew the shape of each patient's prostate, recalculated the CT distances for seed placements, and prepared a revised post treatment plan. The JVAMC was notified by NHPP on September 25, 2008 that based on the Seattle VAMC calculations, seven out of ten reviewed cases were less than 80% of the prescribed dose. The JVAMC oncology staff is awaiting the re-constructed data from the Seattle VAMC.

Why the Event Occurred:

On September 25, 2008 at approximately 10:30 am CDT, the NHPP notified the JVAMC that in the medical opinion of the Seattle VAMC staff, the prostate volumes used in the JVAMC post treatment plan reviews were underestimated in seven of ten cases. If confirmed, this would have resulted in under treatment of these patients with a radiation dose delivered that was less than 80% of the prescribed dose. Upon receiving the information from the Seattle VAMC review, the NHPP instructed the JVAMC to continue the suspension of the brachytherapy program until further notice. The NHPP notified the NRC on September 25th that seven possible medical events may have occurred at the JVAMC. The NHPP then instructed the JVAMC to make arrangements to notify patients and referring physicians.

Prior to receiving this notice, JVAMC had completed the criteria specified by the NHPP to resume the brachytherapy program and was prepared to request permission to restart the program.

Actions Taken:

Following discussions with the NHPP and the Seattle VAMC staff, the JVAMC decided to seek an independent third party analysis of the ten cases in an attempt to resolve the differences in professional medical judgment relating to prostate size. The NHPP advised the NRC by email on the afternoon of Thursday, September 25, 2008 that seven possible medical events may have occurred at the JVAMC. As instructed by the NHPP and in accordance with NRC regulations, the JVAMC notified the seven patients involved the afternoon of Friday, September 26, 2008 and notified the referring providers via electronic e-mail Monday, September 29, 2008. Follow-up phone calls were made to the effected patients on Wednesday, October 1, 2008. Patients are being advised that additional information will be made available to them as their case reviews continue.

Radiation Therapy has recovered the CT scan data for post treatment plan reviews on all but three patients. This CT scanned data is being applied to post treatment plan reviews. Arrangements are being made to reschedule CT scans in an attempt to complete post treatment plan reviews for the remaining four patients. All but four brachytherapy patient cases reviewed to date are complete with documented post treatment plan reviews prepared, printed, reviewed by the radiation oncologist and medical physicists, and signed. All post treatment plan reviews to date, but one, were

deemed by JVAMC Radiation Therapy staff to be within the regulatory guidelines for treatment at the time the reviews were conducted – including the 10 cases reviewed by the Seattle VAMC. JVAMC Radiation Therapy is developing a comparison of patient PSA levels to determine the medical affect of treatments conducted for the past 3 ½ years. Additional actions will depend on the outcome of a third party review of the ten cases reviewed by the Seattle VAMC.

The permanent implant brachytherapy program has been suspended by the JVAMC, and an inspection by the NHPP and NRC has been scheduled for October 8-9, 2008.

It is our belief that, until a more thorough review can be completed, these seven cases cited by the NHPP represent a difference of medical opinion. It must also be noted that the NRC's soon to be adopted Proposed Rule for Medical Use of Byproduct Material – Amendments/Medical Event Definitions will use as the criteria to define a medical event the placement of a percentage of the prescribed isotope activity in the correct organ or tissue rather than dose. The Proposed Rule states that “this change focuses on what the AU (authorized user) can control; namely into which organ or treatment site the sources are implanted, instead of the absorbed dose distribution.”

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



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