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

SEP 22 2010

In Reply Refer To: 598/115HP/NLR

Cassandra F. 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; VHA Permit Number 23-08786-01; Event Number 46236

Dear Ms. Frazier:

I am enclosing a 15-day written report per 10 CFR 35.3045(d) for 11 medical events reported under NRC Event Number 46236. The written report is from the G.V. (Sonny) Montgomery VA Medical Center, Jackson, Mississippi. The 11 medical events occurred at this medical center during calendar years 2005 through 2008 for patient treatments with permanent implant prostate seed brachytherapy using iodine-125.

The events were discovered September 8, 2010, by the medical center, working with the VHA National Health Physics Program (NHPP). NHPP reported the events to the NRC Operations Center on September 9, 2010.

My staff initiated an on-site reactive inspection at the medical center on September 8, 2010, immediately following discovery of the events. The inspection remains open. The purpose of the inspection is to evaluate circumstances of the medical events, review causes and corrective actions, assess regulatory compliance, and collect dosimetry information about the events. I note that the brachytherapy program at the medical center was suspended in September 2008 and terminated in August 2009.

I also enclose additional information collected for these 11 medical events as well as the 10 medical events previously reported (under NRC Event Number 44522) during calendar years 2008 and 2009. I note that D90 dose values have been updated for the 10 cases reported earlier. The final D90 values, in column 6 of this enclosure, include corrections for edema.

A total of 21 medical events have been reported for Jackson. For 10 previously reported events, four (i.e., patient reference numbers 1, 2, 5, and 7 in the second enclosure) might be considered for retraction since the corrected D90 doses are not within the criteria of a medical event.

I might send a separate letter to request retraction of the four medical events but do not request retraction at this time. If retraction was completed, then the final number of medical events at the medical center would be 17.

RECEIVED SEP 23 2010

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

Sincerely,

Gary E. Williams
Director, NHPP

Enclosures

Rep Org: VA NATIONAL HEALTH PHYSICS PROGRAM
Permittee: 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: 09/09/10
Notification Time: approximately 1:00 pm [CST]
Event Date: DISCOVERED 09/08/10
Event Time: DISCOVERED 4:10 pm [CST]
Prescribing Physicians: DR. JAISIRI JAIWATANA AND DR. WAYNE CHAN
10 CFR Section: 35.3045(a) (1) - DOSE <> PRESCRIBED DOSAGE AND
10 CFR Section: 35.3045(a) (3) - DOSE <> OTHER THAN TREATMENT SITE

EVENT TEXT

Notification of ten medical events per 10 CFR 35.3045(a) (1) - 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.

Notification of one medical event per 10 CFR 35.3045(a) (3) – a dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent more of the dose expected from the administration defined in the written directive.

Description of Event:
Following a 2008 facility wide mandated review of VHA brachytherapy programs involving a sampling of ten cases from each facility, it was determined that all ninety-two brachytherapy cases treated by the Jackson VA Medical Center [JVAMC] should be evaluated by an independent group of experts. The Director of the VHA National Radiation Oncology Program established a panel to (1) devise an evaluation format that would be able to determine with a high degree of certainty that the dose delivered during the brachytherapy treatment did not deviate from the prescribed dose by twenty percent or more (2) ensure that the format used could also evaluate the dose to surrounding critical organs and tissue and (3) apply this format to the evaluation of the ninety-two brachytherapy cases from the JVAMC. With the assistance of experts at Duke University and the Image Therapy Center at Washington University in St. Louis, as well as medical physics experts, a format was developed and used to evaluate the JVAMC brachytherapy cases. The results of that evaluation were provided to the Director of the VHA National Radiation Oncology Program who provided the report data to the JVAMC on September 8, 2010. Following a check of the data for accuracy by the RSO, the data was presented to a facility review committee. That committee, based on the data contained in the report and on the recommendation of the RSO, declared 11 medical events as discovered at 4:10 pm CST on September 8, 2010 – ten based on edema-corrected D90 doses delivered to the treatment site lower than prescribed doses

and one based on a dose to surrounding tissue that was calculated to be greater than 150% of the dose expected from the administration defined in the written directive. The calculated percentages for doses based on the external review report were as follows for the 11 cases declared as medical events:

1) JVAMC Ref # 1: D90 = 73% of Prescribed Dose (PD, 145 Gy for all 11 cases)
2) JVAMC Ref #21: D90 = 69% of PD
3) JVAMC Ref #32: D90 = 66% of PD
4) JVAMC Ref #36: D90 = 62% of PD
5) JVAMC Ref #41: D90 = 77% of PD
6) JVAMC Ref #43: D90 = 63% of PD
7) JVAMC Ref #46: D90 = 45% of PD
8) JVAMC Ref #71: D90 = 66% of PD
9) JVAMC Ref #83: D90 = 64% of PD
10) JVAMC Ref #86: D90 = 67% of PD

11) JVAMC Ref #88: Dose to highest 1 cm^3 of rectum = 160.8% of expected dose, where expected dose was the prescribed dose of 145 Gy (D90 = 104% of PD).

The JVAMC had previously reported 10 medical events to the NRC in 2008 which led to the review of all JVAMC brachytherapy cases. The RSO also reported to the review committee that, based on the data contained in the recent report, four of the ten medical events reported to the NRC in 2008 were not medical events, and a request could be made by the facility for retraction. Eliminating these four medical events would leave a total of 17 medical events declared by the JVAMC for 92 brachytherapy patients treated. Sixteen of these medical events would be due to doses delivered lower than prescribed doses, and one medical event would be based on a dose to surrounding tissue that was greater than 150% of the dose expected from the administration defined in the written directive.

Why the Event Occurred:

The medical events resulted from suboptimal seed placement. The basic causes for the suboptimal seed placement and for not detecting this suboptimal seed placement can be attributed to the causes identified in the August 23, 2010, NRC inspection report for the VHA brachytherapy program inspection, as well as the July 15, 2010, NHPP letter to NRC and NHPP inspection report of the same date addressing the JVAMC inspection. The inspection reports concluded the JVAMC did not develop, implement, and maintain adequate and sufficient written procedures to ensure each administration was per the written directive and to verify that administrations were per the written directive.

Effect on Patients: We have not observed, nor do we anticipate, any significant deterministic effects for patients involved in these medical events.

Actions Taken:

The patients' progress has been and 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 licensed facility, if necessary. The brachytherapy program at the Jackson VA Medical Center was suspended in September 2008 and terminated in August 2009. 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 Patients:

Patient notifications were in accordance with 10 CFR Part 35.3045 with documentation of notifications maintained on file for review.

Summary Information for Prostate Seed Implant Medical Events Reported for VA Medical Center, Jackson, Mississippi

Patient Reference (NRC Notification Date)	JVAMC Patient Reference # (DRO Ref #)	Implant Date	Prescribing Physician[1]	Uncorrected D90, in Gy (Previously Reported)	Edema-Corrected Delivered D90 in Gy for Treatment Volume (% Prescribed Dose)[2]	Doses to Other Organs and Tissues (Expected Dose = Prescribed Dose)	Seed Order Lot Numbers[3]	Number of Seeds Intended to be Implanted	Total Activity Intended to be Implanted (mCi)	Number of Seeds Implanted	Total Activity Implanted (mCi)
I. Updated Information (Dose, D90) for Medical Events Reported Earlier (NRC Event No. 44522; NMED Item No. 080606)											
1 (9/25/2008)	72 (88)	02/05/2008	WC	113	120.4 (83%)[4]	< 150% Expected	80644	76	28.35	78	29.09
2 (9/25/2008)	74(89)	02/25/2008	WC	102	126.2 (87%)[4]	< 150% Expected	80887	73	27.59	80	30.24
3 (9/25/2008)	73 (86)	02/25/2008	JJ	90	110.2 (76%)	< 150% Expected	80885	80	30.24	79	29.86
4 (9/25/2008)	77 (90)	03/24/2008	JJ	73	81.2 (56%)	< 150% Expected	81333	87	32.89	94	35.53
5 (9/25/2008)	78 (87)	04/07/2008	JJ	91	145 (100%)[4]	< 150% Expected	81587	84	31.75	79	29.86
6 (9/25/2008)	79 (85)	04/07/2008	WC	67	103 (71%)	< 150% Expected	81591	63	23.81	57	21.55
7 (9/25/2008)	81(84)	04/14/2008	WC	97	139.2 (96%)[4]	< 150% Expected	81750	84	31.75	84	31.75
8 (10/8/2008)	5 (77)	04/06/2005	WC	102	108.8 (75%)	< 150% Expected	51227	96	32.74	96	32.74
9 (10/30/2008)	92 (78)	08/25/2008	JJ	64	88.5 (61%)	< 150% Expected	84120	77	29.11	77	29.11
10 (12/17/2008)	56 (22)	10/31/2007	JJ	72	88.5 (61%)	< 150% Expected	74597	82	30.26	82	30.26
II. Information for Medical Events Reported on September 9, 2010 (NRC Event No. 46236; NMED Item No. 100457)											
11 (9/9/2010)	1 (55)	02/16/2005	WC	NA	105.9 (73%)	< 150% Expected	50544	90	32.49	70	23.87
12 (9/9/2010)	21 (3)	11/21/2005	JJ	NA	100.1 (69%)	< 150% Expected	54416	95	28.025	84	24.78
13 (9/9/2010)	32 (69)	12/05/2006	JJ	NA	95.7 (66%)	< 150% Expected	64897	90	28.53	96	30.432
14 (9/9/2010)	36 (43)	04/30/2007	JJ	NA	89.9 (62%)	< 150% Expected	71757	67	21.507	66	21.186
15 (9/9/2010)	41 (58)	05/23/2007	WC	NA	111.7 (77%)	< 150% Expected	72145	87	32.103	91	33.584
16 (9/9/2010)	43 (68)	05/31/2007	JJ	NA	91.4 (63%)	< 150% Expected	72286	74	24.86	70	23.52
17 (9/9/2010)	46 (6)	06/11/2007	WC	NA	65.3 (45%)	< 150% Expected	72423	73	25.456	68	23.689
18 (9/9/2010)	71 (26)	01/28/2008	WC	NA	95.7 (66%)	< 150% Expected	80321	72	27.216	73	27.565
19 (9/9/2010)	83 (27)	06/23/2008	JJ	NA	92.8 (64%)	< 150% Expected	82944	93	35.12	85	32.113
20 (9/9/2010)	86 (25)	07/07/2008	JJ	NA	97.2 (67%)	< 150% Expected	83243	92	34.776	96	36.288
21 (9/9/2010)	88 (1)	08/04/2008	JJ	NA	150.8 (104%)	D1cc (rectum) = 233.2 Gy (160.8% Expected)[5] Other Tissues < 150% Expected	83684	94	35.494	104	39.27

Notes:

NA = not applicable

1. JJ = Dr. Jaisiri Jaiwatana; WC = Dr. Wayne Chan

2. The prescribed dose to the treatment site was 145 Gy for all cases in table. The edema-corrected D90 values for treatment site for all cases are updated values determined by an external review and reanalysis of pre- and post-treatment imaging. The external review was coordinated by Dr. Michael Hagan, National Director, Radiation Oncology Program, Veterans Health Administration. The external review results were provided to VA Medical Center, Jackson, Mississippi, on September 8, 2010.

3. For all cases, seeds were Iodine-125, Model 125SL, manufactured by Core Oncology, Inc. (formerly Mills Biopharmaceuticals, LLC). The seeds are aggregated in a seed order, and the order is assigned a unique order number by the manufacturer.

4. Patient references 1, 2, 5, and 7 do not meet medical event reporting criteria based on updated edema-corrected D90 values determined by the external review..

5. In all cases except patient reference 21, medical events were based on low D90 (less than or equal to 80% of the prescribed dose). For patient reference 21, the medical event was based on a dose to highest 1 cubic centimeter of uninvolved rectum tissue greater than or equal to 150% of the expected dose, where the expected dose is equal to the prescribed dose.

6. Data in the last five columns are from the completed written directives.

ENCLOSURE 2