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

In Reply Refer To: 598/115HP/NLR

July 13, 2023

Bryan Parker
Division of Nuclear Material Safety
Nuclear Regulatory Commission (NRC), Region III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352
(forwarded via Email)

Re: NRC License No. 03-23853-01VA

Dear Mr. Parker:

Pursuant to 10 CFR 35.3045, we are providing a written report regarding a medical event that occurred at the Michael E. DeBakey VA Medical Center, Houston, Texas. A brief description of the event, possible causes of the event, actions taken to prevent recurrence, and other required information are contained in the enclosure. The medical center holds VHA Permit Number 42-00084-06 under our master material license.

The medical event occurred and was discovered on June 28, 2023. The event involved treatment of a patient with yttrium-90 microspheres. Two vials of microspheres were administered, with a separate written directive for each vial. Measurements indicated that, for one of the vials, only about 28 percent of the prescribed activity was delivered. (For the other vial, measurements indicated that about 97 percent of the prescribed activity was delivered.) We notified the NRC Operations Center by telephone on June 29, 2023, and the event was assigned Event Number 56596.

We are conducting an inspection to evaluate the circumstances of the medical event, actions to prevent recurrence, and regulatory compliance. Please contact me, at 501-257-1571, if you have any questions about this matter.

Sincerely,

EDWIN LEIDHOLDT

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Date: 2023.07.13 08:46:07 -07'00'

Edwin M. Leidholdt, Jr., Ph.D., FACR
Executive Director, VHA National Health Physics Program

Enclosure

Department of Veterans Affairs

Memorandum

Date: July 10, 2023

From: Director (580/00), Michael E. DeBakey VA Medical Center, Houston, Texas

Subj: 15 Day Medical Event Report

To: Director, VHA National Health Physics Program (NHPP) (11SPEC12)

Pursuant to NRC 10 CFR 35.3045 (d), the following information is provided:

1. The licensee is the US Department of Veterans Affairs, Master Materials License Number 03-23853-01VA. The medical event occurred at the Michael E. DeBakey VA Medical Center, 2002 Holcombe Blvd, Houston, Texas 77030, VHA Permit Number 42-00084-06

2. The name of the prescribing physician is David Sada, M.D.

3. On June 28, 2023, a patient was administered Yttrium-90 (^{90}Y) microspheres (TheraSphere®) to treat lobe segment 4, anterior and posterior (segmentectomy) of the liver for hepatocellular carcinoma (HCC). Two vials of microspheres were to be administered. The first dosage of 0.753 GBq was prescribed, with 0.790 GBq being measured in the vial. The second dosage was prescribed to be 0.264 GBq, with 0.264 GBq measured in the vial. IR Radiology Technologists (IR DRT) used the *Therasphere Administration Checklist* to set up the administration device. A patient safety "time out" was completed, in which the patient was verified by two methods (full name and full SSN) and the treatment to be received was confirmed. Nothing abnormal was reported leading up to the time of administration. After the physicians gained access to the administration site, Dr. Sada requested that the assisting IR DRTs start reading the checklist and perform the steps as instructed. During administration of the first dose, the patient was noticeably agitated and moving his leg on the table. It was also noted that more saline solution than normal was ejected from the tubing assembly. Dr. Sada asked the Radiation Safety Officer to do a quick scan of the fluid to ensure that there was no contamination. No contamination was confirmed and the procedure continued. After completion of the saline flushes, the remainder of the checklist was followed including the recording of the dosimeter reading, which was "zero" mR/hr. Besides this note, the administration of the microspheres appeared to be routine. After the procedure, the microcatheter, administration kit and stock vial were placed in a Nalgene® waste container. Multiple measurements were taken on the Nalgene® container to determine the highest dose rate from the container. The administered dosage for the first vial was calculated to be approximately 28.6 % of what was prescribed. The administered dosage for the second vial was calculated to be 97.4 of what was prescribed. Dr. Sada was notified and he subsequently informed the patient. Additional conversation with the patient and family were conducted afterward in addition

to notifying the referring physician. The Vendor was also contacted with conversations continuing.

4. The cause of this event is not entirely known and is being investigated. We hypothesize that there might be two (2) independent or codependent causes:

a. It is possible that the tube holding the micro-catheter had a kink, which slowed the flow rate. Also, the patient moved his leg frequently during the administration of the dose, which could have kinked the micro-catheter. The resultant kink may have caused a significant number of microspheres to settle out in the main tubing, as discovered during the scan of the administration set.

b. There may be flaws in the administration set of the current lot number. The vendor came on site July 5, 2023 to take the lot number of the administration set used. After the contents in the waste container, including the administration set, have decayed for about a month, the contents of the waste container will be shipped to the vendor for further analysis.

5. Adverse effects to the patient are not expected, except that which can be associated with an incomplete treatment of the tumor. According to the administering physician, the patient will most likely undergo a second treatment since only about 25 percent of the intended dosage from the first vial was delivered to the tumor. This second treatment has not yet been scheduled as of this notice.

6. As noted above, the cause of this event is not entirely known and, after discussion with the vendor, we hope to have more clarification on the root cause of the issue. We hope to receive further information regarding possible issues with the delivery sets from the Vendor. Our clinicians will continue to take measures to check for kinks and continue to follow Vendor guidelines for treatment.

7. The patient was notified of the event on June 28, 2023.

8. Should you have any questions, please feel free to contact the Radiation Safety Officer at telephone number 713.791.8340 or via email at davida.cunanan@va.gov

LINDSEY CRAIN

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Date: 2023.07.12 12:50:04 -05'00'

Francisco Vazquez
Medical Center Director

Martha Pavon

From: Edwards, Mark W. <Mark.Edwards5@va.gov>
Sent: Thursday, July 13, 2023 12:32 PM
To: Bryan Parker
Cc: Leidholdt, Ed; Abell, Clinton E.; Kidwell, Calvin B; Bravenec III, Joseph S (HOU); Kwasniewski, John Curtis; Edwards, Mark W.
Subject: [External_Sender] 2023 07 13 Houston Event Letter to NRC (Event No. 56596)
Attachments: 2023 07 13 Houston Event Ltr to NRC.pdf

Mr. Parker,

On behalf of Dr. Leidholdt.

Please find attached copy of a written report regarding an incident that occurred at the Michael E. DeBakey VA Medical Center, Houston, Texas; Permit No. 42-00084-06.

Would you please reply to this message to acknowledge receipt?

Please do not hesitate to call if you have any questions.

v/r Mark

Mark W. Edwards
Mark W. Edwards
National Health Physics Program (11SPEC12)
North Little Rock, Arkansas
Office: 501-257-1515 **I** **Iphone:** **501-257-0590**
mark.edwards5@va.gov

800-815-1016 (NHPP Safety Hotline)
U.S. AIR FORCE

Martha Pavon

From:	Bryan Parker
Sent:	Thursday, July 13, 2023 1:14 PM
To:	Martha Pavon
Cc:	Sandy Pavon; Tammy Tomczak; Bob Orlikowski
Subject:	15-day report for VA-Houston
Attachments:	665 for 15 day rpt. VA Houston.pdf; [External_Sender] 2023 07 13 Houston Event Letter to NRC (Event No. 56596)

Hey Martha,

Please place the attached 15-day report into ADAMS. A 665 is also attached.

Please let me know if you have any questions.

Thanks.

Bryan