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Washington University
Medical School
ATTN: Walter W. Davis, Jr.
Assistant Dean for Facilities
and Chief Facilities for School
of Medicine
P. O. Box 8010, 660 S. Euclid Avenue
St. Louis, MO 63110-1093

License No. 24-00167-11
Docket No. 030-02271

Dear Mr. Davis:

This refers to two incidents which occurred on January 7, 1993, and February 26, 1993 which were later identified as misadministrations. These misadministrations were subsequently reviewed during the routine safety inspection conducted by the NRC on November 15, through November 18, 1993, of activities authorized by NRC Byproduct Material License No. 24-00167-11. This also refers to letters related to the incidents dated April 14, 1993, September 23, 1993, October 6, 1993, November 23, 1993, December 8, 1993, and May 19, 1994.

The first misadministration occurred during the administration of a single pre-operative intracavitary implant to a patient using a "MicroSelectron" Low-Dose-Rate remote afterloading device (SN 3031). The device ejected a radioactive source (8.6 mgRaEq Heyman-Simon Cs-137 source), without the device being programmed to do so and without the applicator attached to the corresponding "umbilical tube orifice." The source lay near the patient's leg for approximately five minutes at an approximate distance of three centimeters from the nearest skin surface. The licensee estimated that less than 0.1 rad of additional dose was delivered to the skin surface.

The second misadministration, which occurred on February 26, 1993, was very similar to the first. It also involved the administration of a single pre-operative intracavitary implant, using the same remote afterloading device (but to a different patient). The device again ejected the same strength and type of radioactive source, without being programmed to do so. However, in this case, the source lay near the patient's leg for approximately sixty to seventy-five minutes, at an approximate distance of five centimeters from the nearest skin surface. The licensee estimated the additional dose to the unintended treatment site to be approximately 3.5 rad. In both cases, the treatment of each patient was completed on another low-dose-afterloading device in another room of the medical center.

Documentation of the two events was sent to Region III at the request of the NRC following discussions by telephone. This documentation was reported to NMSS Headquarters and reviewed by the NRC Region III and NRC Headquarters staff. Based on the information provided, the incidents were determined to be misadministrations. Section 35.2(5)(i) of 10 CFR includes as a misadministration,

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"a brachytherapy radiation dose involving the wrong patient, wrong radioisotope, or wrong treatment site." It was concluded that even though the doses received were below the threshold of significant consequence, the two events were misadministrations, because in both cases there was a brachytherapy radiation dose delivered to the wrong treatment site. The cause of the misadministrations was equipment failure.

As a followup to the two misadministrations, Region III sent a letter dated September 23, 1993, to the licensee which detailed its determination in the incidents and requested that the licensee review each case to determine whether required notifications had been made pursuant to 10 CFR 35.33. These included the verbal as well as written followup notifications to the patient and referring physician. The response received from the licensee, stated in part, that the referring physician and the treating physician had, based on their medical judgment, concluded that providing further information to the patients would be harmful to them. A letter dated November 23, 1993, was sent to the licensee requesting additional information as to the reason for not notifying the patients in writing. The licensee's response dated December 8, 1993, provided additional description regarding the medical basis for not notifying the patients. In summary, this letter states that both physicians believed, in their best medical judgement, that sending written notifications of these incidents, several months after they took place, would cause increased psychological stress and anxiety to the patients. The licensee also held the opinion that the events have no medical significance to these patients since the doses were very small and the patients are of an advanced age. This matter was reviewed by the NRC and provided to you in a letter dated May 12, 1994.

The NRC's evaluation of these matters was as follows:

1. If the referring physician personally informs a licensee that based on medical judgment, notifying the patient would be harmful, the licensee is required to inform the patient's responsible relative or guardian, even if the patient is a competent adult.

2. Regardless of whether the licensee or the referring physician notified the patient, the licensee is still responsible for providing the written report to the patient or the patient's responsible relative or guardian.

3. The licensee is not required to notify the patient or the responsible relative (or guardian) if the referring physician has personally informed the licensee that, based on medical judgement, telling the patient or the responsible relative (or guardian) would be harmful to one or the other or both.

The NRC concluded based on the information provided that the licensee is required to provide written notification of the misadministrations to the patients or the responsible relative (or guardian).

Your letter dated May 19, 1994 indicated compliance with 10 CFR 35.33(a)(4), and we acknowledge that you have taken corrective action per the requirements of 10 CFR 35.33(a)(4) by sending the patients a description of the misadministrations and the consequences as they may affect the patient. Nonetheless, certain of your activities, pertaining to the lateness of the written report to the patients, were found to be in violation of NRC requirements as described in the enclosed Notice. The inspection and your letters show that actions have been taken to correct the identified violation and to prevent recurrence. Consequently, no reply to the violation is required and we have no further questions regarding this matter at this time.

In accordance with 10 CFR 2.790 of the Commission's regulations, a copy of this letter will be placed in the NRC Public Document Room.

We will discuss any questions you have concerning this inspection.

Sincerely,

John A. Grobe, Chief
Nuclear Materials Inspection
Section 2

cc: John Eichling
Radiation Safety Officer

Enclosure: Notice of
Violation

RIII
Jones/bt
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