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RADIATION
SAFETY OFFICE

September 24, 2007

U.S. Nuclear Regulatory Commission, Region III
Material Licensing Section
2443 Warrenville Road
Suite 210
Lisle, IL 60532-4352

Re: Report of Medical Event – NRC License No. 13-02752-03

Dear Sir/Madam:

Attached please find a written report for two a medical event that occurred on September 10, 2007 and was subsequently identified as a medical event on September 11, 2007. This report is being submitted in compliance with the requirements of 10 CFR 35.3045(d). Should you have any questions regarding this report or the circumstances surrounding the medical event, please do not hesitate to contact this office.

Sincerely,

A handwritten signature in black ink that reads "Mack L. Richard".

Mack L. Richard, M.S., C.H.P.
Radiation Safety Officer

Attachments: 1

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*IU School of Medicine
IU Medical Center &
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REPORT OF MEDICAL EVENT

This report is hereby submitted in accordance with 10 CFR 35.3045(d) due to a “medical event” that occurred on Monday, September 10, 2007.

Name of Licensee: IUPUI/Indiana University Medical Center (NRC License No. 13-20752-03)

Name of Prescribing Physician: Donald Schauwecker, M.D., Ph.D.

Brief Description of Event: On September 10, 2007 a written directive was generated for 64.3 mCis (2.38 GBq) of ⁹⁰Y labeled microspheres (MDS Nordion Theraspheres) to be administered to a patient for treatment of liver cancer. The unit dosage received from the vendor was assayed and contained 66.1 mCis (2.45 GBq) which was within 2.8% of the prescribed dosage.

The microspheres were infused into the patient at approximately 11:00 am. A representative from MDS Nordion was present during the patient treatment and indicated that written procedures consistent with those recommended by MDS Nordion were followed with no apparent problems.

After the microspheres were infused, the catheters (an outer “guide” catheter in which a “microcatheter” that delivers the microspheres is inserted) were removed from the patient and deposited in a plastic disposal container along with the original dose vial and other contaminated items. Per standard procedures, measurements were made on the disposal container and compared to the measurements of the original dosage vial in the same container to determine what percentage of the dosage was administered. These measurements indicated that only 47.7 mCis (1.76 GBq) were administered to the patient. This corresponds to an “underdose” of 25.8%.

In an effort to determine what part of the administration apparatus contained the residual radioactivity (~17 mCis), the disposal container was transferred to the Radiation Safety Office and the various items were carefully removed and surveyed. The results of those surveys indicated that practically all of the residual activity resided in the catheters. Further analysis could not be performed safely at that time due to the high radiation levels. It was decided that a more detailed evaluation of the catheters would be performed the next week to allow the radiation levels to decay to a more manageable level (⁹⁰Y has a 2.7 day half-life).

After consultation with the MDS Nordion representative, the Authorized User, the Interventional Radiology (IR) physician who performed the administration, and the Radionuclide Radiation Safety Committee (RRSC), it was determined that a medical event had occurred. The Radiation Safety Officer notified the Nuclear Regulatory Commission Operations Center by telephone on Tuesday afternoon, September 11, 2007.

Why the Event Occurred: Due to the radiation levels measured as described above, it was originally thought that the microcatheter might have developed a leak, allowing some of the microspheres to enter the guide catheter.

A follow-up, detailed evaluation and survey of the catheters was performed by the MDS Nordion representative and the Radiation Safety Staff on Wednesday, September 19, 2007. This evaluation was performed in the presence of three NRC representatives who were on site, investigating the medical event. Following the evaluation, it was determined that the microcatheter had not leaked; however, a "kink" was noted in the microcatheter approximately 11 inches from the proximal end of the microcatheter and about 12 inches before the microcatheter entered the proximal end of the guide catheter. Radiation surveys performed with a high range ion chamber indicated that the highest radiation levels were at the kink and about 1" downstream from the kink, indicating that microspheres had collected in that area. Additional radiation levels measured further downstream from the kink indicated the presence of microspheres in gradually decreasing amounts. With the microcatheter still in place, the guide catheter was flushed with water and the fluid collected. There was no indication of the presence of microspheres in the collected fluid; therefore, it was concluded that the microcatheter had not leaked into the guide catheter farther downstream from the kink. While some contamination was detected on items associated with the procedures (e.g., blood-soaked sponges) at the conclusion of the treatment, the level of contamination on those items was not high enough to indicate an actual leak in the microcatheter. Thus, it appears that the microspheres were contained in the microcatheter. Attempts to physically remove the microcatheter from the guide catheter were unsuccessful due to the presence of dried blood that caused the catheters to stick together.

The results of this detailed evaluation were somewhat surprising to the MDS Nordion representative. From his experience in the past, whenever catheters were kinked, the flow would essentially cease and the microspheres simply could not be administered without replacing the kinked catheter. It was his opinion that in this case, the flow through the microcatheter was reduced, but not totally stopped by the kink. Due to the reduced flow, the microspheres could "settle" out along the catheter and also collect just downstream from the kink due to eddy currents in the liquid flow (similar to the way snow or sand sometimes collects just beyond solid obstructions due to turbulent wind currents).

Effect on the Patient: According to the treatment planning, the prescribed dosage was designed to deliver a tumor dose of approximately 120 Gy. Due to the lower administered dosage, the estimated dose delivered to the tumor was approximately 90 Gy. For these types of treatments, a dose of 80 Gy to 150 Gy is considered a therapeutic dose. Thus, the patient should benefit from this treatment and would not experience any deleterious affect from the underdose.

Actions Taken to Prevent Recurrence: Since the kink in the catheter was visually noticeable, the IR physician administering the microspheres will visually verify the integrity of the catheters prior to infusing the microspheres for all future patients. Any noted kinks or other imperfections in the catheters will result in the replacement of the catheter before proceeding with the microsphere infusion. The written procedures/checklist utilized for the infusion process has been modified to include this additional check of the catheter integrity. A copy of the revised procedures was provided to the NRC representatives who were present during the catheter evaluation.

Notification of Patient: The patient was notified both verbally and in writing that the medical event had occurred on September 11, 2007.

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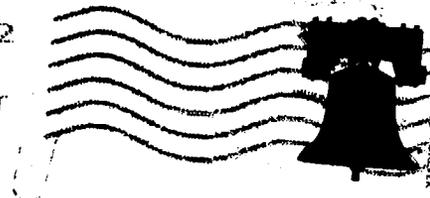


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