Hospital	Event Number: 45034
Rep Org: INDIANA UNIVERSITY MEDICAL CENTER Licensee: INDIANA UNIVERSITY MEDICAL CENTER Region: 3 City: INDIANAPOLIS State: IN County: License #: 13-02752-03 Agreement: N Docket: NRC Notified By: MACK RICHARD HQ OPS Officer: DONALD NORWOOD	Notification Date: 04/30/2009 Notification Time: 14:51 [ET] Event Date: 04/29/2009 Event Time: 13:30 [EDT] Last Update Date: 04/30/2009
Emergency Class: NON EMERGENCY 10 CFR Section: 35.3045(a)(1) - DOSE <> PRESCRIBED DOSAGE	Person (Organization): DAVID HILLS (R3DO) CHRISTEPHER MCKENNEY (FSME)

Event Text

MEDICAL EVENT INVOLVING AN UNDERDOSAGE DURING TREATMENT FOR LIVER CANCER

"At approximately 1:30 pm, on April 29, 2009 a medical event occurred at Indiana University Medical Center, NRC License No. 13-02752-03. This medical event involved the treatment of a patient with Y-90 microspheres (Nordion TheraSpheres). A dosage of 61.3 mCi was prescribed by the Authorized User. TheraSpheres are provided as a unit dosage and said dosage was assayed at 12:15 pm (4/29/09) to contain 60.1 mCi. Based upon a radiation monitoring device affixed to the TheraSphere delivery system, the pre-treatment reading was 7 milliroentgens per hour (mR/hr). Following the administration of the microspheres and four subsequent flushings of the delivery system, the radiation monitor exhibited a reading of 2 mR/hr, indicating that approximately 28.6% (17.2 mCi) of the dosage remained in the delivery system. When the subsequent flushing failed to reduce the remaining activity in the system, an independent measurement of the residual activity was performed to confirm that the entire dosage had not been delivered as prescribed.

"The vendor (Nordion) was notified of this event earlier today (4/29/09). Based upon discussions with their technical representatives, it is their opinion that the residual microspheres may be attached to the septum of the dose vial. For future treatments, the vendor representative suggested that the dose vial be given a good shake during the check-in and assay procedure to help dislodge any microspheres that may have adhered to the vial septum during shipment. They also suggested that during the administration process if the residual dosage appears to be present in the dose vial, tilting and tapping the dose vial and/or the acrylic box containing the dose vial may dislodge any microspheres that may adhere to the vial septum. These suggestions are being incorporated into the written procedures for TheraSphere treatments.

"The Radiation Safety Office attempted to perform some radiation measurements of the delivery system to determine the location of the residual activity. Due to the relatively high exposure rates from the residual radioactivity in the delivery system, it was not possible to definitively determine the distribution of the residual activity in the system at this time, mainly due to the potential for contamination and elevated radiation levels to RSO staff. More thorough evaluations may be possible once the radioactivity in the system diminishes due to radioactive decay.

"Notification of the referring physician of the occurrence of this medical event was made at 10:25 am today (4/30/09). The patient's wife was notified of the occurrence of the medical event at 10:30 am today."

A Medical Event may indicate potential problems in a medical facility's use of radioactive materials. It does not necessarily result in harm to the patient.