General Information or Other	Event Number: 42364
Rep Org: NEW YORK STATE DEPT. OF HEALTH Licensee: NOT DISCLOSED BY STATE LAW Region: 1 City: State: NY County: License #: Agreement: Y Docket: NRC Notified By: R. DANSEREAU (via fax) HQ OPS Officer: STEVE SANDIN	Notification Date: 02/22/2006 Notification Time: 15:25 [ET] Event Date: 11/05/2004 Event Time: [EST] Last Update Date: 02/22/2006
Emergency Class: NON EMERGENCY 10 CFR Section: AGREEMENT STATE	Person (Organization): PAMELA HENDERSON (R1) GREG MORELL (NMSS)

Event Text

AGREEMENT STATE REPORT INVOLVING AN I-131 RADIOPHARMACEUTICAL MISADMINISTRATION

The following information was received via facsimile:

"NY-06-007

"Radiopharmaceutical therapy misadministration involving Iodine-131 (NYS DOH Internal Tracking Nos. 265 & 342)

"Date 11/5/2004

"New York law prohibits the release of any identities in cases of medical events. Therefore the facility name, etc., is not contained in this report.

"A 150 mCi therapeutic dose (capsule) of Iodine-131 was prescribed for a patient, however the patient received only one of two 75-mCi capsules. The capsule was eventually retrieved after a waste container tripped a radiation monitor at a waste transfer station. Patient has been notified and the hospital is conducting clinical follow-up. The following is a summary of the incident:

"The Bureau of Environmental Radiation Protection (BERP) received a request to issue a DOT exemption to allow BFI of Buffalo, NY to return a contaminated municipal solid waste in a compactor container from American Ref-Fuel to the Hospital. DOH staff went to the site to conduct a radiological survey of the trash compactor. The maximum reading at contact was 15 mR/hr (bkg = 0.02 mR/hr). Driver side reading was background. The DOT exemption was issued and the trash container was returned to the hospital. Upon return of the waste compactor it was isolated behind the utility building and the workers, plant engineering staff, were informed of the precautions - stay away.

"On 11/17/04 DOH participated in a conference call with hospital staff (Radiation Safety Officer, the treating MD and the Chief Nuclear Medicine Tech). The patient was prescribed a dosage of iodine 131, which was contained in 2 capsules supplied by a radiopharmacy. The treating MD stated that he saw the patient put each of the two capsules in the mouth, one at a time followed by water. Each capsule was in a separate cup. They claim that the patient stated that she took both.

"A post administration rad survey reading was taken, as per their routine procedure, and the results were within the range of what was expected, given the activity of the material. This reading apparently was measuring the exposure from the material administered as well as the capsule in the trash next to the patient. In this geometry, the measurement appeared to indicate that the patient had taken the full dose - both capsules. One of the capsules was either not taken or was spit out into the cup. This was then discarded in the normal trash.

"The capsule was isolated intact on 11/12/04 by a person who works for an asbestos firm. He did

not have a personal rad monitoring device and the hospital was not aware of his level of radiation safety training. This unqualified person apparently sifted through the waste in the presence of the Chief CNMT - she had the survey meter. The capsule activity on the day of treatment was 75 mCi and about 40 mCi on the date of recovery. Hospital staff were aware that a capsule was lost and that a significant misadministration occurred but they did not immediately report either event to the Department as required by 10 NYCRR 16.15 and 16.25.

"On 11/22/04, DOH staff performed an onsite investigation. Hospital staff including the RSO; Performance Improvement Manager; Chief CNMT; radiation therapy physicist; Radiology Manager; and the authorized user that administered the I-131 were interviewed. The Director of Facilities was unavailable as he had an emergency surgery the day before this scheduled investigation. Hospital staff informed us that the Director of Facilities was primarily involved with this incident because he manages the hospital's waste. Hospital staff could not explain why the RSO or RSC were not more involved in this incident. They were informed of the immediate reporting requirements for lost sources and misadministrations. It was also strongly suggested that they evaluate why the RSO and RSC did not take a greater role in responding to this incident.

"A consultant provided conservative dose estimates as follows: Housekeeper who emptied the waste container - 35 mrem, in-house waste handler 63 [mrem] and the asbestos contractor 101 mrem. DOH staff interviewed housekeeping staff and reconstructed the handling times for this person, and determined the handling time assumptions used by the consultant were greatly overestimated so the dose estimates were likely lower. The contractor that entered the dumpster was not available to be interviewed.

"Due to the nature of the violations and manner in which the facility mishandled the event including allowing an unqualified person to retrieve the capsule and lack of RSO and RSC involvement/oversight, enforcement action was pursued and the facility was fined."