IEMA
Illinois Emergency Management Agency
Division of Nuclear Safety

Rod R. Blagojevich, Governor
William C. Burke, Director

October 28, 2003

James Lynch, Agreement State Liaison Officer
U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, IL 60532-4351

Mr. Lynch,

Please find enclosed a final copy of the abnormal occurrence report that the Agency has prepared. Previously, supporting information including correspondence from the two involved parties as well as investigation reports from Agency representatives have been provided.

If you or any member of the review group who is looking into this event requires any additional information or has suggestions for future updates, please do not hesitate to contact me. I can be reached at (217) 785-9929 or at Perrero@iema.state.il.us.

Sincerely,

Daren Perrero, Supervisor
Inspection and Enforcement

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IL-03-001 Medical Event involving a patient at Rush Copley Medical Center, Aurora, IL Illinois Radioactive Materials License No. IL-01207-01

In accordance with the criteria of a medical misadministration that results in a dose that is equal to or greater than 1000 rad to any organ (other than bone marrow, lens of the eye or gonads) and represents a prescribed dose that is the wrong radiopharmaceutical, this event is considered an abnormal occurrence.

This event occurred on July 28, 2003 at the licensee's facility in Aurora, IL

Nature and Probable Consequences: The Illinois Emergency Management Agency received a call July 29, 2003 from a nuclear medicine technologist, at Rush Copley Medical Center in Aurora, IL. She reported that a patient who was to receive a 4 millicurie unit dose of Tl-201 for a heart test instead received a 4 millicurie unit dose of I-131 on July 28, 2003.

Circumstances surrounding the event, as reported by the technician, indicate that both the exterior lead container and syringe were labeled as containing a diagnostic unit dose of Tl-201. Although the injection occurred the previous day it was not determined that I-131 was involved until the morning of July 29th. Service engineers had been called to the site both days to inspect the gamma cameras used after attempts to image the patient had failed. The reason became evident when a gamma camera flood source that had been made from what was thought to be the remaining Tl-201 material in the syringe from July 29th showed peaks consistent with I-131, rather than the expected Tl-201. The syringe had been assayed by the medical center before injection. The assayed amount from Monday's records showed the dose to be within the prescribed range for a typical 4 millicurie Tl-201 diagnostic dose and as such, was considered to be normal, although the assay variance exceeded 10 percent. The patient had been admitted the day before the event through the emergency room with an order to perform a treadmill heart stress test. The patient remained hospitalized at the facility until discharged after July 30, 2003.

The day of the event, the agency called the Medi Physics/Amersham Health, (IL-01052-01) Wood Dale, IL pharmacy facility where the doses had been prepared the previous Friday. Mr. Hughes, Corporate RSO, indicated at the time that they were in the process of determining what had occurred, but it appeared that when prescriptions and labels were taken from the computer system, a 4 milliCi Tl-201 prescription was mistakenly put in with other prescriptions for 4 milliCi unit doses of I-131. Subsequently, the Tl-201 request was mistakenly filled as an I-131 prescription. The pharmacist did not note the error when the pre-generated Tl-201 labels were applied to the syringe and lead container, which instead had been mistakenly compounded with I-131.

The Agency sent an investigator to the medical center on the morning of July 30 to observe the labeling on the container and syringe, receipt records, gamma camera QA tests and to verify by gamma spectrum analysis the presence of I-131 as well as to conduct preliminary interviews to obtain additional facts. The investigation then moved on to the pharmacy to continue their review of the event. Based on those visits, the information obtained by the investigators confirmed the preliminary notification.

The written report from the medical center was received by the Agency on August 14, 2003. The medical center estimates that some small amount of residual activity remained adhered to the walls of the syringe. Therefore, they estimate the amount of injected I-131 to be 3.9 millicurie. Based on the package insert information for this material and the assumptions made (an injected NaI solution of oral I-131 results in a radiation absorbed dose similar to oral administration; the patient had normal thyroid function of 25% uptake; and the estimated quantity) the dose to the patient's thyroid is approximately 5,195 rads and the effective dose equivalent is 1,587 rads.

The Agency received a preliminary report from the pharmacy on August 13. That report indicated that prescriptions for the Veterinary Service Center (VSC) and Rush Copley Medical Center were received on Friday July 25, 2003. Five unit dose syringes of I-131 of 4 millicurie each and two unit dose syringes of Tl-201 of 4 millicurie each were in those orders.

When the computer generated orders were segregated, one of the prescriptions for a unit dose of Tl-201 was mistakenly substituted for a unit dose of I-131. The syringe and lead carrier were subsequently labeled with the pregenerated Tl-201 labels from the stack. Early on Monday, July 28 the pharmacy facility manager noted that an unfilled I-131 prescription was in the Tl-201 prescription pile. Assuming the dose had not been filled with the others the previous Friday, he filled an additional unit dose syringe with I-131 to complete the order for the Veterinary Services Center. As such, it was believed that there were no 'extra doses' of I-131 that had been compounded.

Patient Notification: The medical center technician indicated that the patient involved had been contacted by the referring physician, the onsite oncologists, the medical center's Administrator and lawyer and was informed as to what had happened at the initial time of discovery of the event. Later a copy of the medical center's report to the Agency was also provided to the patient. The medical center offered to perform routine blood analysis throughout the year to monitor any changes in thyroid activity. The patient had been advised as to the potential health effects of the misadministration during that time and the need for routine follow-up testing. .

Medical Effects: The RSO (and an oncologist) at the facility, Dr. Pavitar Singh, was contacted by the Agency. He indicated that it is very unlikely that any medical changes will be noted in the patient. He reports that the dose administered, is only slightly larger than that typically ordered for whole body scans using I-131. Blood tests were taken immediately following the discovery of the event. Those tests suggest that the patient was hypothyroid as a preexisting condition to admittance. As of, September 23, 2003, the patient has not returned to the medical center for any additional testing, diagnosis or consultation.

Causes: Upon review of the submitted reports and the investigations by the Agency, it was determined that the primary cause of the event was the mislabeling of the unit dose syringe. Other factors that also lead to the misadministration include improper segregation of the prescriptions at the pharmacy and lack of a second means of verifying proper completion of filling the order.

Actions Taken to Prevent Recurrence: The pharmacy's final report was received on September 8, 2003 and indicated that one of its corrective items was to cease the dispensing of I-131 in unit dose syringes. This would preclude the possibility of a unit dose of diagnostic material being mistakenly filled with a quantity of therapeutic material. Additional corrective actions included retraining of pharmacists, institution of a dual verification system for all prescriptions received, a triple check system for dispensing of compounds and the testing of a new bar code system for tracking all prescriptions. The pharmacy was cited for failure to properly fill the prescription as ordered by the physician. The Agency is holding this item open pending enforcement action and will include a review of the corrective actions taken during its next annual inspection of the facility.

Status: The Agency does not expect any additional significant information to be received or other notable action to be taken outside of the enforcement process.