

June 4, 2025

U.S. Nuclear Regulatory Commission, Region I
ATTN: Kelli Trotter, Health Physicist
(email: Kelli.Trotter@nrc.gov)

Subject: Loss of Licensed Material (NRC License No. 52-24937-01)

Dear Kelli Trotter,

As requested, following this cover letter, we identify the causes and the respective corrective steps taken after the incident event that occurred on May 29, 2025. The procedure of receiving and disposal of packages was reviewed with technologist involved to prevent future incidents relating to failure to adhere to the established protocol.

Chain of events in the Lu-177 incident

1. Two 200 mCi Pluvicto (Lu-177) doses came in the same box. This was not the usual case and may have been a source of confusion when working under pressure. One of the doses was administered to a patient without incident on 05/28/2025. The second dose was left on the box (to be decayed) to be used the next day(05/29/2025) for another patient, per authorized user instructions. The technologist forgot that the second dose was left inside the box.
2. The technologist removed all radiation labels from the transport box and placed it outside the hot lab to be discarded as regular trash. The trash was picked up after 3:00 p.m. and the box was put into the compactor container.
3. The dose was not determined to be missing until the next day (05/29/2025) in the morning at 7:00 a.m. The technologist notified the facility manager and then RSO. The RSO instructed the technologist to take surveys of the compactor container and call the NRC to report the incident.

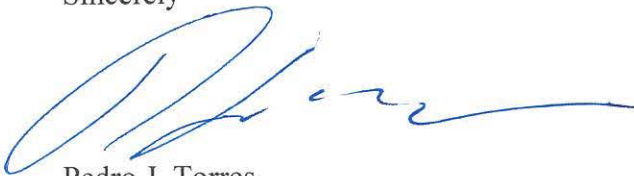
Action taken

1. A meeting with the facility manager, the quality control manager (newly appointed position), the RSO (remotely through the phone), and the technologist was done to review the chain of events. Following this meeting, we called the NRC at 10:10 a.m. on 05/29/2025 to report the incident.
2. We informed Hospital San Francisco security staff ,on which grounds the compactor is located, about the incident on May 29, 2025. Upon consulting with them, we were unable to access the compactor interior due to its security configuration. Immediately, the technologist surveyed the compactor, taking measurements around and inside it. The hospital staff mentioned that Conwaste (the owners of the compactor) usually picks it up every 3 to 5 days or when it is full.
3. Around 4:00 p.m., we submitted the 361A Form to the NRC, we got a confirmation it was received by a Headquarters Operations Officer, and we awaited further instructions.
4. Next day, Friday May 30, 2025, a phone call from Ms. Kelli Trotter from the NRC was received. Ms. Trotter spoke with Sylvia Rodriguez (Quality Control Supervisor) and with Pedro Torres (Facility Administrator). During that call a summary of the incident was presented to Ms. Trotter and after that, at 2:00 p.m., an email with further instructions was received.

5. We contacted ConWaste, the company that owns the compactor container and it's in charge of disposing the trash inside them, to inform them about the contents of the box, the description of the isotope documented with photos and its medical use.
6. A review of the procedures for waste disposal and decay-in-storage (10CFR 35.2092 and 35.92) and surveys was done on 05/30/2025 in collaboration with the RSO.
 - a. Our protocols already stated how to proceed to monitor and discard empty packages. After reviewing the protocol, it was decided to add additional indication to clarify that packages, prior to be disposed of, should be double checked and additional survey measurement will be done to the shipping boxes that contain Lu-177 doses.

Further, more specific information will be provided on the final incident report, as required in the CFR 20.2201.

Sincerely



Pedro J. Torres
Administrator
Rio Piedras Sono-Nuclear Center