USNRC, Region I,
475 Allendale Road, Suite 102,
King of Prussia, PA 19406–1415
(email: *RidsRgn1MailCenter@nrc.gov*)

Subject: Rio Piedras Sono-Nuclear Center NRC License No. 52-24937-01,
30 Day Written Report Regarding Loss of Licensed materials

To whom it may concern:

The incident of the loss of licensed material that occurred on Thursday, May 29, 2025 is detailed in the following letter.

Please contact Mr. Pedro Torres or Ms. Brenda Manich if you have any questions regarding the report.

Sincerely,

Jorge R. Toro M.D.
Nuclear Medicine Department Director
Rio Piedras Sono-Nuclear

30 Day Written Report to NRC Region I Regarding Loss of Licensed Material

Licensee: Rio Piedras Sono-Nuclear Center

NRC License Number: 52-24937-01

Date Licensed Material Discovered Missing: Thursday, May 29, 2025

Date Reported by telephone to NRC Headquarter Operations Center: Thursday, May 29, 2025

In accordance with 10 CFR 20.2201 (b), Report of theft or loss of licensed material, the following incident happened.

1. **Description of the Licensed material Involved:**

   A. Material Description: PLUVICTO, Lutetium-177 vipivotide tetraxetan injection, intravenous use single-dose vial (inside its protective lead container), inside it's white shipping box measuring approximately 12 inches long, 12 inches wide, 9 inches tall.
   B. Activity: 201.16 mCi calibrated for Wednesday, May 28, 2025 at 11:00 a.m. (UTC-03:00) Atlantic Time Canada.

2. **Description of the circumstances under which the loss occurred:**

   A. Summary:

      On Tuesday, May 27, 2025, at approximately 2:00 PM, the white shipping box containing two Lu-177 Pluvicto injections (two separate single- dose vials) was delivered to the Nuclear Medicine Department at Rio Piedras Sono-Nuclear Center.

      On Wednesday, May 28, 2025, one of the doses was administered to a patient as planned and without any incidents. The second dose was to be decayed due to patient myelosuppression; the authorized user decided to reduce the dose to 160 mCi and it was left inside the box at the hot lab until it could be used for the second patient for administration (next day) on Thursday, May 29, 2025.

      A photo of a similar box and a Lu-117 dose lead container is included as **Exhibit A.**

Based on extensive and detailed review of the nuclear medicine technologist's account, on Wednesday, May 28, 2025 she assisted the authorized user for the administration of the first Pluvicto therapy. After the administration, she left the box in the hot lab with the second vial of 200 mCi of Lu-177. At the end of the day, around 2:30 p.m., while she performed the surveys to return radioactive waste unrelated to this incident (pharmacy-supplied syringes) to the other two local radiopharmacies, she cut the radioactivity labels from the surface of the white box from Novartis, obliterated the labels by marking through with a black marker, and left the box outside of the hot lab to be discarded as regular trash without reopening the box that still contained the second dose of Lu-177.

Afterwards, the janitor picked up the trash between 3:00 p.m. and 5:00 p.m., and the box was put into a compactor container localized at the end of the parking lot of the San Francisco Hospital. This compactor serves for our facility and the nearby hospital to dispose of regular trash.

A photo of the compactor is included as **Exhibit B.**

B. Description in detail of the Event: **Thursday, May 29, 2025**

7:00 a.m.- The technologist arrived at Sononuclear lab and performed routinary procedures of daily dose calibrations and when surveyed, wipe tested and logged the receiving dose packages into the logbook. While doing so, she remembered that the PLUVICTO dose shipping box that was left to be decayed since the day before, under the nuclear medicine hot lab bench for doses, was no longer there. The technologist could not locate the white box that contained the second vial.

A photo of hot lab bench is included as **Exhibit C.**

At approximately **7:10 a.m.**- The technologists informed the administrator and called the quality control manager to explain that she remembered that the day before, the box with the Pluvicto dose was put with the regular trash. The administrator and the quality control manager informed the RSO of the situation. The RSO (remotely through phone) gave instructions to the technologist to take surveys of the compactor where the shipping box was deposited and to call the NRC to report the incident. Meanwhile, the technologist and the quality control manager searched the area and surroundings where normally regular trash is left. Other areas of the Nuclear Medicine Department were inspected as well; finally, we concluded that the box was discarded in the container with the regular trash.

7:20 a.m. The administrator called the janitor to confirm if the trash of the day before was discarded at the compactor; it was confirmed.

7:45 a.m. As the compactor container is leased by the hospital, and our facility subleases its use to them, the administrator visited the hospital's administrative office to report the incident and to attempt to contact the hospital's Radiation Safety Officer, but the staff had not yet begun their work shift. Therefore, he contacted hospital security to obtain information about who was responsible for requesting the trash pickup service with the intention of seeing if it was possible to access the container. The person in charge notified that the waste container company is ConWaste, and it picked up the trash every 3 to 5 days. They did not provide a phone number where we could contact ConWaste as this was a matter that staff at the corporate level of the hospital handled.

At approximately 8:30 a.m.: The quality control manager explained the incident to the authorized user.

At 9:00 a.m.: A second visit was made by the administrator in order to reach both the RSO and the hospital administrator, but it was also unsuccessful. By the other hand, the technologist, along with the quality control manager, went to survey around and inside the compactor; the readings were background (5 urem/h inside, 6 urem/h outside)

Photos of survey readings is included as **Exhibit D.**

10:10 a.m.: The facility administrator called the NRC's Headquarters Operations Officer (HOO) and reported the loss of the licensed material.

10:28 a.m.: An email was received from HOO providing instructions to complete Form 361A. Compliance with this directive is requested within the indicated timeframe.

11:25 a.m.: A second survey readings were conducted to the compactor, where readings were indistinguishable from background (6 urem/h).

At 4:35 p.m.: The administrator submitted the 361A Form to the NRC, and a confirmation email was received by Headquarters Operations Officer at 4:39 p.m.

C. Description in detail of the Events on **Friday, May 30, 2025.**

12:00 p.m.: The administrator and the quality control manager received (by separate phone calls) a call from the NRC (Ms. Kelli Trotter) to discuss the timeline of the event and the compactor's status and whereabouts.

1:42 p.m. – The quality control supervisor and the technologist surveyed the container again. readings were indistinguishable from background (7 urem/h).

2:06 p.m.: An email with instructions was received from Ms. Trotter. We were informed that we should contact ConWaste directly and to attempt to stop the container before being picked up for final disposal.

3:00 p.m.: Due to being unable to reach ConWaste through the Hospital administration (the administration nor the Hospital RSO reached back to us), the regional supervisor of ConWaste in San Juan was contacted, and the incident was explained to him. We requested to make arrangements for the container not to be moved until further notice. He said he would gather information with his team and superiors and would reach back with more information.

3:36 p.m.: Our Radiation Safety Officer discussed the state of the investigation with the quality control manager and requested a review of the protocol with the technologist. The review of the Waste Disposal and Decay-in-Storage procedure was discussed solely with the technologist involved in the incident. The technologist was retrained to reinforce proper disposal procedures and prevent future occurrences.

4:30 p.m.: The regional supervisor of Conwaste requested additional information on the contents of the box, the description of the isotope documented with photos, and its medical use.

5:50 p.m.: The RSO contacted the administrator and quality control manager by phone to review surveillance or waste collection records, if available, to trace the exact time and route of disposal.

D. **Events after Friday May 30, 2025**

Saturday, May 31,2025: We tried reaching ConWaste supervisors again to see if more information about the container was available, but where not able to reach them. Ms. Trotter from the NRC requested the contact information on these supervisors and it was provided to them.

Monday, June 2 2025: Supervisor from ConWaste confirmed that the compactor that contained the lost Lu-177 dose was picked up from the Hospital grounds last Friday, May 30, 2025 around 7:00 AM. The contents of the compactor were taken to a ConWaste landfill destination and were put underground with the rest of the regular garbage. After emptied, the same compactor was returned to the Hospital were, as previously informed, it was surveyed by our staff believing it was still containing the lost dose. As reported, these measuring read background activity.

3. **Statement of disposition, or probable disposition, of the licensed material involved:**

The Lutetium-177 vipivotide tetraxetan injection while still in the protective lead shipping container, and inside the de-labeled white shipping box, was accidentally disposed of in the normal trash on the afternoon of Wednesday, May 28, 2025, and ultimately disposed of at a landfill Friday, May 30, 2025.

The white shipping box containing the Lu-177 injection was accidentally presumed to be empty of the actual Lu-177 injection vial, while still containing the Styrofoam packing materials (top and bottom) and the box discarded in the normal trash after obliteration of the labels and radioactive markings. The janitorial crew typically picks up trash between 3pm to 5 pm, and the box was placed in the compactor of normal trash on May 28, 2025, which would have been picked up by the waste disposal company at approximately 7:00 am on Friday, May 30, 2025 and transported to a landfill.

4. **Exposure of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas:**

Based on the emission spectrum from Lu-177, primarily beta particles, combined with injection packaging, there was no exposure of individuals to radiation in unrestricted areas. After 24 hrs decay (181.48mCi), approximately the TEDE is 0.1616 rems. Upon package arrival in the nuclear medicine hot lab on May 27, 2025 when Lu-177 shipment was surveyed and checked in, measurements at 1 meter from the box surface were .04 mrem/hr and measurement in contact with the box was .06 mrem/hr. The box was not handled directly by the janitorial staff once disposed of as the white box was inside a plastic lined trash bag. Only the plastic liner would have been handled when emptying the trash.

After the bag containing the box was disposed of inside the compactor, no human contact was possible as ConWaste informed that all access to this container is locked up until the moment it is put underground in the waste landfill upon final transportation for its disposal.

As mentioned, we measured the container after it was emptied (believing at first the waste containing the lost dose box was still there), and all measures were background, meaning the Lu-177 dose was not breached/spilled inside the container.

5. Actions that have been taken, or will be taken, to recover the material:

An extensive search was initiated on Thursday morning, May 29, 2025 upon discovery that the Lu-177 injection vial in its white shipping box was missing. This included searching throughout the nuclear medicine department, hallways, waste room and the waste disposal processes for regular trash in the compactor. Due to the compactor security characteristics, access inside it was not possible. Based upon the technologist account, it was determined that the loss Lu-177 dose had been disposed of in normal trash on Wednesday afternoon, May 28, 2025, and ultimately disposed of in the compactor that evening, and picked up by the waste disposal company at approximately 7:00 a.m. on Friday, May 30, 2025.

Because of the very low risk of any exposure of persons to radiation from Lu-177 emission profile, the very improbable proximity to any person, the containment within the vial and shipping box with packing materials, it was determined that recovery of the missing lu-177 injection shielded vial from the landfill was not necessary. Furthermore, it was concluded that attempting retrieval of the Lu-177 dose from landfill would pose significant and completely unnecessary safety risks due to the physical hazards associated with searching a landfill.

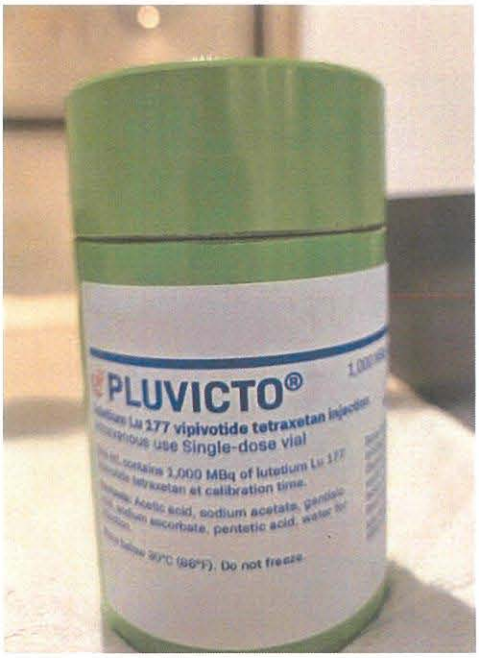
6. Procedures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed material:

Procedure for Disposition of Empty Shipping Box for Therapy Treatment

1. The shipping box is opened, and the internal Styrofoam lid or other protective lid is removed.
2. Box is visually verified to be empty of any vial or lead vial shield. Always should be double checked.
3. Box and Styrofoam should be surveyed and found to be background.
4. All radioactive labels are defaced or removed.
5. Imprinted words on box stating "radioactive" are removed.
6. Box labeled "empty' is writing to the sides of the open box.
7. A box labeled "empty" can be placed in the regular trash.

On May 30, 2025 the RSO and the Quality Control supervisor reviewed the procedures for waste disposal and decay-in-storage solely with the technologist involve in the incident. In addition, on June 4th, the same review was done with the other two technologists, who were on vacation during the incident. During both reviews we emphasized to always double check boxes before discarding.

Exhibit A



A-1. Lead Container of Lu-177 dose

A-2. Empty/De-labeled Shipping Box

Exhibit B

B-1. Waste Compactor

B-2. Measurements taken inside the compactor, May 29 2025 around 9:00A.M.

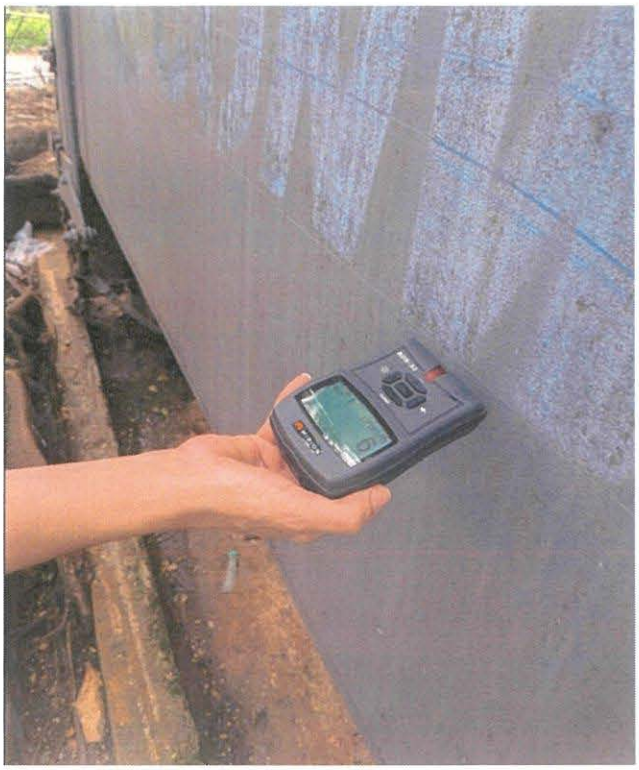
Exhibit C

C-1. Hot Lab Bench

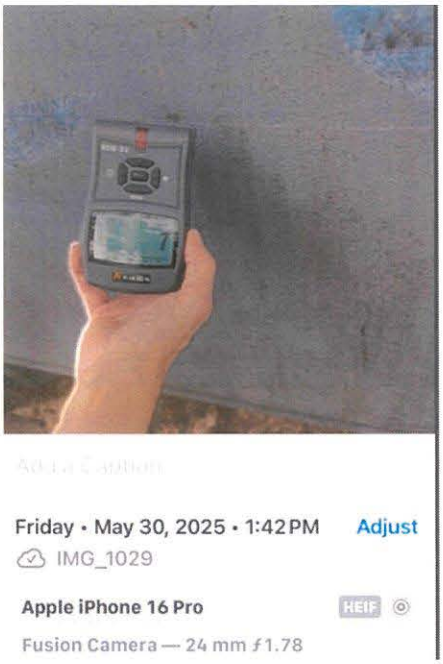
Exhibit D

D-1. Measurement at container side May 29, 2025 around 9:00A.M

D-2. Measurement inside the container May 29, 2025 around 9:00A.M



D-3. Measurement at container side May 29, 2025 around 11:25A.M.



D-4. Measurement at container side May 30, 2025 around 1:42P.M.