

June 3, 2025

U.S. Nuclear Regulatory Commission, Region I  
ATTN: Document Control Desk  
Washington, DC 20555

Reply to a Notice of Violation  
NRC Inspection No. 030-30140/2025-001  
License No. 52-24937-01

The purpose of this letter is to respond the five severity Level IV violations identified by the NRC inspector conducted on February 5, 2025 and the final teleconference conducted with our Radiation Safety Officer, the administrator and the NRC Health Physicist, on April 15, 2025.

A first reply to a Notice of Violation was submitted on May 6, 2025 and after receive on May 28, 2025 due to lacking of specific information, additional explanation is provided.

Violations as identified by NRC:

### **Violation A**

10 CFR 35.13(f) requires, in part, that a licensee shall apply for and must receive a license amendment before it adds to or changes the areas of use identified in the application or on the license.

Contrary above, from June 2024, the licensee failed to apply for and receive a license amendment before it added or changed areas of use identified in the application or on the license, notwithstanding any exceptions. Specially, the licensee added an area of use for Lu-177 administrations, a 10 CFR 35.300 activity, and began use of this area in June 2024, and did not apply for and receive a license amendment for this addition. Subsequent to the inspection the licensee submitted a request to add the area of use on March 7, 2025.

### Response for Violation A

1. Reason for Violation:

The event occurred as a result of not consulting the RSO or NRC 10 CFR regulations prior to activity; Also, not coordinating meetings with the appropriate personnel that have complete knowledge of this kind of procedures before starting the treatments. All these led to the licensee failure to apply for a license amendment.

2. Corrective Action Taken:

After the inspection of the NRC, the licensee applied for the license amendment on March 7, 2025 to establish a specific room for the therapies. Additional information for the amendment was requested on April 11, 2025 (mail control # 645541) This information was completed and submitted on May 7, 2025. The amended NRC license was received on May 21, 2025.

3. Corrective Steps that will be taken to avoid further violations:

For further changes on operational procedures, staff meeting will be held including the radiation safety officer, authorizer user, administrator; in conjunction with NRC consultation.

4. Date when Full Compliance will be achieved.

The full compliance was achieved on May 21, 2025.  
For further amendments or changes, doubts or final decisions in licensee operational procedures, we will consult with the NRC Regulations.

### Violation B

10 CFR 35.40 (a) requires, in part, that, a written directive must be dated and signed by an authorized user before the administration of any therapeutic dosage of unsealed byproduct material.

Contrary to the above, from June 2024, through February 2025, the licensee failed to have written directives dated and signed by an authorized user before administration of any therapeutic dosage of unsealed byproduct material. Specially, the licensee administered dosages of Lu-177 without obtaining a signature by an authorized user prior administration, and the authorized user signature was provided after administration but on the same day of treatment.

## Response for Violation B

### 1. Reason for Violation:

The reason for this violation was failure to adhere and follow the therapy protocol. The Lu-177 Therapies protocol describe in detail that a written directive is required prior to the administration of the radiopharmaceutical which must include patient's name, radiopharmaceutical identity, dosage for specific patient, route of administration, signature of the authorizer user, and dated.

### 2. Corrective Action Taken:

The Lu-177 therapy protocol was reviewed with the authorized user and the technologists on May 2, 2025. Also, it was established that on the day the patient comes in to the nuclear medicine lab for a consultation, orientation and an interview with the nuclear medicine physician, the treating physician (authorizer user) will issue the written directive for the Lu-177 therapy signed and dated with the day of the planning treatment.

### 3. Corrective Steps that will be taken to avoid further violations:

To ensure to be in full compliance with the regulations and follow protocols and procedures, the licensee will have annual meetings with technical staff, the authorizer user, RSO and quality control manager (newly appointed position as of May 8, 2025). The protocols will be updated annually or as needed. Changes or revisions must be dated and initiated by the Medical Director (authorizer user). Minutes for this protocol reviews will be documented.

The radiation safety officer, the authorizer user and the newly appointed quality control manager will conduct monthly reviews for therapies performed (Quality Management Program).

### 4. Date when Full Compliance will be achieved.

The Lu-177 (Pluvicto and Lutathera) therapy protocol was reviewed with the authorized user and the technologists on May 2, 2025. Immediately after the meeting the next therapies will be done following the new implementation in the therapy protocol.

## Violation C

10 CFR 35.60 (b) requires that licensee shall calibrate instrumentation to measure the activity of unsealed byproduct material before it is administered to each patient or human research subject in accordance with nationally recognized standards or the manufacturer's instructions.

Contrary to the above, in June 2024, the licensee failed to calibrate instrumentation to measure the activity of unsealed byproduct material before it is administered to each patient or human research subject in accordance with nationally recognized standards or the manufacturer's instructions. Specifically, the licensee failed to implement a nationally recognized standard for instrumentation used to measure the activity of unsealed byproduct material in order to assure the geometry independence using syringes and vials that are representative on the entire range of sizes used for administrations. The facility began use 30 mL vials of Lu-177 in June 2024 and failed to performed the geometry independence testing for 30 mL vials.

## Response for Violation C

### 1. Reason for Violation:

The reason for this third violation was failure to perform the geometry independence testing for 30 mL vial before starting the administration of the Lu-177 Lutathera Therapy; even though it was performed to the 20 mL vial that are administered to patients for Lu-177 Pluvicto Therapy. It was a misinterpretation of the regulations concerning this test.

### 2. Corrective Action Taken:

Dose calibrator was calibrated for 20 mL Lu-177 Pluvicto Therapies before starting the administration to patient, but not for the 30 mL vial for Lutathera Therapies. On March 18, 2025 geometry independence test using vial for 30 mL was performed and data was submitted on March 19, 2025.

### 3. Corrective Steps that will be taken to avoid further violations:

In the future, this test will be performed on our dose calibrator if it is moved, repaired, or changes in volume configuration are to be used, whether in syringes or vials.

4. Date when Full Compliance will be achieved.

The above corrective step is currently in compliance to NRC regulations and will be met in the future, as well.

### Violation D

10 CFR 35.63 (d) requires, in part, that unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range.

Contrary to the above, from January 10, 2023, through July 8, 2024, without otherwise being directed by an authorized user, the licensee used a dosage, and the dosage did not fall within the prescribed dosage range. Specifically, numerous cases of dosages being administered outside of approved range were identified during inspection, including but not limited to F-18 FDG PET dosages of 18.0 mCi on January 10, 2023, 18.8 mCi on May 31, 2024, 18.8 mCi on July 2, 2024, 17.54 mCi on July 8, 2024, when the approved dosage range 10-16 mCi for F-18 FDG.

### Response for Violation D

1. Reason for Violation:

The event occurred as a result of distractions in a high workload environment. This situation led to the technologist failure to follow and adhere to the approved dosage range.

2. Corrective Action Taken:

As a result of this violation, a meeting with technologists was conducted on May 2, 2025 to review approved dosage range for each nuclear study. A table with a list of radiopharmaceuticals used in each nuclear medicine procedure was given to the technologists and a copy of the table was posted on the bulletin board at the hot lab.

3. Corrective Steps that will be taken to avoid further violations:

Recently, the Nuclear Medicine Department was re-organized to achieve more quality control for the clinical area.

The following additional correction actions will be taken:

- a) Hold refresher meetings (bi-annual) with all nuclear medicine technologists to review protocols, safety rules and discuss the importance of compliance with NRC regulations.
- b) Reduce the number of scheduled patients when one of the technologists is on vacation.
- c) Administer the injection to the patient at the scheduled appointment time.

#### 4. Date when Full Compliance will be achieved

This correction process is in progress. We will perform a first audit between July 1-11, to evaluate these changes.

### **Violation E**

10 CFR 35.75(c) requires that a licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with 10 CFR 35.2075(a).

10 CFR 35.2075(a) requires, in part, that a licensee shall retain a record of the basis for authorizing the release of an individual in accordance with 10 CFR 35.75.

Contrary to the above, from June 2024, through February 5, 2025, the licensee failed to create or retain a record of the basis for authorizing the release of an individual in accordance with 10 CFR 35.75. Specifically, the licensee failed to perform an evaluation, create a record, or maintain a record to demonstrate the basis for authorizing the release of individuals using one of the methods described in 10 CFR 35.2075(a). Following identification, the NRC determined that all individuals who were released from the licensee's control were not likely to cause exposure to any other individual in excess of 5 mSv total effective dose equivalent and therefore met the release criteria in 10 CFR 35.75(a).

## Response for Violation E

1. Reason for Violation:

Personnel were not fully trained on these issues.

2. Corrective Action Taken:

All individuals who were released from the licensee's control were not likely to cause exposure to any other individual in excess of 5mSv total effective dose equivalent, as we are not using more than 200 mCi of Lu-177. Nevertheless, we will be working on a document for this purpose as soon as possible.

There is an article by K. Berry, B. Edwards & J. Kendrick about their Four Years of Experience Treating Patients with Lu-177 dotatate. There is a patient release equation to calculate the exposure from patient to determine if the patient can be released or would require a hospital stay. Equation is on page 2, Rad safety Considerations section 2.1. Ms. Valerie Stowell offered to help with this, but she is no longer at the agency.

Our patients are given written instructions prior to each administration of Lu-177 therapy to reduce their exposure to other individuals as low as reasonably achievable.

3. Corrective Steps that will be taken to avoid further violations:

A calculation will be performed after each treatment and included in patient's chart.

4. Date when Full Compliance will be achieved.

This has been implemented since May 17, 2025.