DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	2/19/2025-2/28/2025* FEI NUMBER 3016492204

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Melissa J. Etheridge, President

FIRM NAME	STREET ADDRESS
PALMETTO ISOTOPES, LLC	95 Bees Creek Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Ridgeland, SC 29936-7540	Nuclear Pharmacy

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Inadequate routine environmental monitoring in the ISO 5 area.

Specifically,

Environmental monitoring (EM) of the nuclear lab (Compounding Room (b)(4), used for processing radiopharmaceuticals intended to be sterile is inadequate. Air sampling for EM in the ISO 7 buffer room is conducted (b) (4) by a third-party company; however, viable air monitoring has never been conducted in the ISO 5 Primary Engineering Controls (PECs). There are (b) (4) ISO 5 PECs in Compounding Room (b)(4) (Equipment IDs: (b) (4)). Your firm produces approximately (b) (4) syringes of radiopharmaceuticals per day on average.

OBSERVATION 2

Failure to conduct media fills that closely simulate aseptic production operations under the worst-case, most-challenging, and stressful conditions.

Specifically,

The media fill conducted for the Compounding Room (b)(4) is inadequate, described as follows:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Taichun Qin, Investigator X Taichun Qin Investigator Signed By: 2001324646 Date Signed: 02-28-2025 09:27:21	2/28/2025

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A. The media fill process does not simulate the production of sterile radiopharmaceuticals. Your firm conducted a media fill every (b) (4) using a (b) (4) to withdraw non-sterile media into (b) (4) vials as control and into (b) (4) vials with a (b) (4) ; however, the operators produce approximately (b) (4) syringes of radiopharmaceutical products per day on average during the (b) (4) . This media fill process simulates the production of vial products; However, it does not consider the production of radiopharmaceutical products in syringes with significantly higher production volumes. For example on 2/24/2025, your firm produced (b) (4) batches of radiopharmaceutical products with a total of (b) (4) syringes by (b) (4) operators in the (b) (4) ISO 5 PECs (Equipment IDs: (b) (4)) during the (b) (4) .

B. The operator failed to conduct media fill in the ISO 5 Biological Safety Cabinet (BSC) used for producing sterile chemotherapy drugs or for the radiolabeling of white blood cells in Compounding Room (b) (4) Each operator involved in sterile compounding conducts media fill every (b) (4) . Pharmacist (b) (6), (b) conducted media fill in the ISO 5 PEC (b) (4) (Equipment ID: (b) (4) (b) (4)) in Compounding Room (b) (4) on 10/1/2024 and 3/22/2024; however, he failed to conduct media fill in either of the BSCs in Compounding Room (b) (4) For example, Pharmacist (b) (6), (b) produced Indium 111 WBC, 596.021 µCi on 1/17/2025 and reconstituted (b) (4) vials of DOCEtaxel, 40 mg/vial and (b) (4) vials of Gemcitabine, 1 g/vial.

OBSERVATION 3

Smoke studies were not performed under dynamic conditions.

Specifically,

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Your firm has no documented evidence demonstrating that the smoke study in the (b) (4) ISO 5 PECs in Compounding Room (b)(4) was conducted under dynamic conditions. The smoke study is performed (b) (4) by a third-party company. For example, the most recent smoke study, performed on 12/24/2024, demonstrated that the system complies with unidirectional airflow requirements as specified in the Unidirectional Airflow Test Protocol; however, no information, records, or videos demonstrating the smoke study was conducted under dynamic conditions were available for review. The only videos available for review were for the smoke study performed in 2020, showing that the smoke study was conducted under static conditions and no unidirectional airflow was demonstrated.

OBSERVATION 4

Production areas have difficult to clean or contain porous, particle generating, or visibly dirty equipment or surfaces.

Specifically,

On 2/19/2025, during the walkthrough of Compounding Room (b)(4) it was observed:

- The grid of the HEPA filter appeared dirty and discolored inside the ISO 5 PEC, Equipment ID: (b) (4) .
- There were hard-to-clean items inside the ISO 5 PEC, Equipment ID: (b) (4) including twisted charging cables connected to string lights and scanners.

Your firm uses this ISO 5 PEC to fill syringes with radiopharmaceuticals intended to be sterile, as well as for the radioactivity testing of radiolabeled white blood cells.

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OBSERVATION 5
Personnel engaged in aseptic processing were observed wearing non-sterile gloves.

Specifically,

During the production of MAA Tc99m (LEU), Lot# K-20250220-009 on 2/20/2025 and Sestamibi Tc99m, Lot# K-20250225-010 on 2/25/2025, both intended to be sterile, it was observed the operator wore non-sterile gloves for aseptic processing, including adding (b) (4) to the cold kits, drawing solutions from vials containing sterile saline or tagged cold kits, and capping the syringes. These two lots have been distributed to the firm's customers.

OBSERVATION 6
Use of a sporicidal agent in the facility's classified areas was improper.

Specifically,

A sporicidal agent is not used in the disinfection of any return dose container (pigs). According to the procedure for Cleaning and Disinfecting Lead Unit Dose Shields (PIGS), the exterior of the pigs is initially wiped thoroughly with the appropriate solution. The initial surface of the pigs is then sprayed with sterile(b) (4) ; however, a sporicidal agent has never been used to disinfect the pigs. Additionally, the interior surfaces of the pigs have never been wiped with any disinfectant. The pigs are used in ISO 5 PECs to hold finished syringes during the aseptic processing of radiopharmaceuticals.

***DATES OF INSPECTION**
2/19/2025(Wed), 2/20/2025(Thu), 2/21/2025(Fri), 2/24/2025(Mon), 2/25/2025(Tue), 2/26/2025(Wed), 2/27/2025(Thu), 2/28/2025(Fri)

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X Taichun Qin
Investigator
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09:27:21

DATE ISSUED
2/28/2025

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."