SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED	2. NRC/REGIONAL OFFICE
Dr. Isaac Gonzalez Martinez Oncology Hospital Puerto Rico Medical Center Carr 21, Bo. Monacillos San Juan, PR 00935 **REPORT NUMBER(s) 2024001**	Region 1 475 Allendale Rd Suite 102 King of Prussia, PA 19406

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-39358	52-35723-01	11/20/2024 - 05/23/2025

LICENSEE:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

☐ 1. Based on the inspection findings, no violations were identified.

☐ 2. Previous violation(s) closed.

☐ 3.The violations(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, to exercise discretion, were satisfied.

_____ Non-cited violation(s) were discussed involving the following requirement(s):

☑ 4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited in accordance with the NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11. (Violations and Corrective Actions)

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.

Condition 13 of NRC License No. 52-35723-01 requires, in part, that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below.

The application dated August 29, 2023, under Condition 13.A and the letter dated December 13, 2023, under Condition 13.C of NRC License No. 52-35723-01 identified a single operating room being used for the licensed material implant procedures.

The letter dated November 13, 2023, under Condition 13.B of NRC License No. 52-35723-01 stated that patients will be released under the provision (sic) 10 CFR 35.75.

Contrary to the above, prior to February 12, 2025, the licensee failed to apply for and receive a license amendment before it added to or changed the areas of use identified in the application or on the license; the licensee failed to conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed on the license; and patients were not released under the provisions of 10 CFR 35.75. Specifically, the licensee was utilizing surgical suites not identified as areas of use in the application and letter referenced above, though they were located in the same licensee-controlled area; additionally, the licensee was performing the therapies utilizing I-125 ophthalmic applicators on an in-patient basis without approval for the in-patient rooms. The licensee met all other requirements for the use of licensed materials in the surgical suites, such as performing appropriate surveys of the room, personnel, and patient and adhering to public dose limits. The licensee also met the requirements for the in-patient rooms, such as adhering to public dose limits, proper postings on the door and training for nurses, though patient visitors were not allowed during the patient's stay.

This is a Severity Level IV violation [Enforcement Policy 6.3.d].

As corrective action, the licensee submitted an amendment request on February 12, 2025, requesting an expansion in the approved areas of licensed material use, as well as requesting authorization to treat on an in-patient basis. These requests were approved under Amendment 1 to NRC License No. 52-35723-01 dated May 16, 2025.

B. 10 CFR 35.2406(b) requires, in part, that licensees maintain a record of brachytherapy source accountability which, for temporary implants, must include the number and activity of sources returned to storage, the time and date they were returned to storage, and the name of the individual who returned them to storage.

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Contrary to the above, prior to November 20, 2024, the licensee did not maintain a record of brachytherapy source accountability which, for temporary implants, included the number and activity of sources returned to storage, the time and date they were returned to storage, and the name of the individual who returned them to storage. Specifically, the licensee maintained a record of accountability for packages or lots of seeds but did not include all of the necessary information; examples were identified that lacked any information on being returned to storage after being removed from the patient, with other entries missing information on the time and date of seeds returning to storage. However, no seeds were lost during the period of noncompliance and all seeds were returned to the manufacturer for disposal.

This is a Severity Level IV violation [Enforcement Policy 6.3.d].

As corrective action, the licensee developed, implemented, and maintains a new system of tracking brachytherapy source accountability that tracks the necessary information for sources placed into or removed from storage.

Statement of Corrective Actions

I hereby state that, within 30 days, the actions described by me to the Inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE	DATE
LICENSEE'S REPRESENTATIVE	Julio J. Diaz-Padilla, M.D.		05-29-25
NRC INSPECTOR	Jonathan Pfingsten	JONATHAN PFINGSTEN Digitally signed by JONATHAN PFINGSTEN Date: 2025.05.29 10:53:59 -05'00'	
BRANCH CHIEF	Farrah Gaskins	FARRAH GASKINS Digitally signed by FARRAH GASKINS Date: 2025.06.04 17:14:32 -04'00'	