

**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

1. LICENSEE/LOCATION INSPECTED:  Centro de Radioterapia at Hospital Auxilio Mutuo Avenida Ponce de Leon #725, Parada 37 1/2 Hato Rey, PR 00918  REPORT NUMBER(S) 2021-001		2. NRC/REGIONAL OFFICE  Region I U. S. Nuclear Regulatory Commission 2100 Renaissance Boulevard, Suite 100 King of Prussia, PA 19406-2713	
3. DOCKET NUMBER(S)  030-36635	4. LICENSE NUMBER(S)  52-30937-01	5. DATE(S) OF INSPECTION  9/21/2021	

**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 violation(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.

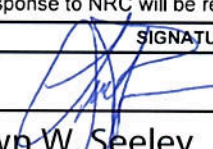
\_\_\_\_\_ Non-cited violation(s) were discussed involving the following requirement(s):

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 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)

See Next Page

**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	Luis Rivera		9/24/2021
NRC INSPECTOR	Shawn W. Seeley	Shawn W. Seeley	Digitally signed by Shawn W. Seeley Date: 2021.09.23 16:15:55 -04'00'
BRANCH CHIEF	Tara Weidner, Acting		

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(Continued)

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

Contrary to the above, on August 18, 2021 and August 31, 2021, written directives were not dated and signed by an authorized user before the administration of a therapeutic dosage from byproduct material. Specifically, the two written directives were not signed by an authorized user prior to the patient treatments.

The licensee took immediate corrective actions by requiring an authorized user listed on the license sign all written directives forwarded by referring physicians prior to scheduling patients for treatments. Additionally, they will ensure that only physicians authorized on the license sign the written directives prior to patient treatment as required by 10 CFR 35.40.