

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED CRMI Mennonite General Hospital Road PR 172, Turabo Gardens Nuclear Medicine, First Floor and Room 534-A Caguas, PR 00725 REPORT NUMBER(S) 2024001		2. NRC/REGIONAL OFFICE Region 1 475 Allendale Rd Suite 102 King of Prussia, PA 19406	
3. DOCKET NUMBER(S) 030-36911	4. LICENSE NUMBER(S) 52-25430-03	5. DATE(S) OF INSPECTION 02/14/2024 - 05/30/2024	

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.

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

A) 10 CFR 35.40(b)(6) requires, in part, that for permanent implant brachytherapy, the written directive before implantation must contain: the treatment site, the radionuclide, and the total source strength; and after implantation but before the patient leaves the post-treatment recovery area, the written directive must contain: the treatment site, the number of sources implanted, the total source strength implanted, and the date.

Contrary to the above, prior to October 24, 2023, the written directive before implantation did not contain: the treatment site, the radionuclide, and the total source strength; and after implantation but before the patient leaves the post-treatment recovery area, the written directive did not contain: the treatment site, the number of sources implanted, the total source strength implanted, and the date. Specifically, both the before implantation written directives and the after implantation written directives did not include the treatment site or total source strength. However, they did include the total dose to be administered and only prostate implants are performed.

As corrective action, the licensee updated the forms to include the required information and add an explicit line for dating the signature on post-implant written directives.

B) 10 CFR 35.404 requires, in part, that immediately after implanting sources in a patient or a human research subject, the licensee shall make a survey to locate and account for all sources that have not been implanted. 10 CFR 35.2404 requires, in part, that a licensee shall maintain a record of the surveys required by 10 CFR 35.404 for 3 years.

Contrary to the above, prior to October 24, 2023, the licensee did not maintain a record of the surveys required by 10 CFR 35.404 for 3 years. Specifically, immediately after implanting sources in a patient or a human research subject, the licensee made surveys to locate and account for all sources that had not been implanted but did not document and retain a record of the surveys.

As corrective action, the licensee generated a form for the post-implant surveys and committed to completing them after each procedure.

- 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)


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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	David Rhoe		6-5-24
NRC INSPECTOR	Jonathan Pfingsten		
BRANCH CHIEF	Anne DeFrancisco		