Mayagüez Medical Center

Manos que te cuidan.

Date: May 12, 2025

License No. 52-13598-04

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D.C. 20555
Cc. Regional Administrator, Region I
Jonathan Pfingsten
Mr. Health Physicist
U.S. Nuclear Regulatory Commission
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SUBJECT: MAYAGÜEZ MEDICAL CENTER - NRC INSPECTION NO. 030-37760/2024001 AND NOTICE OF VIOLATION DATED APRIL 17, 2025

Dear Mr. Jonathan:

This letter is in response to the notification sent on April 17, 2025. Based on the results of the inspection conducted on November 18 and 19, 2024 through March 28, 2025. We answered the violations received as follows:

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A. 10 CFR 35.24(f) requires, in part, that licenses that are authorized for two or more different types of uses of byproduct material under Subparts E, F, and H of this part shall establish a Radiation Safety Committee to oversee all uses of byproduct material permitted by the license.

The Committee must include an authorized user of each type of use permitted by the license. Contrary to the above, for calendar years 2023 and 2024 prior to the date of the inspection, the licensee was authorized

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for two or more different types of uses of byproduct material under Subparts E, F, and H of this part and established a Radiation Safety Committee to oversee all uses of byproduct material permitted by the license but failed to include an authorized user of each type of use permitted by the license. Specifically, the licensee is authorized for uses under Subparts E and H of 10 CFR 35, thus necessitating a radiation safety committee but the licensee failed to include an authorized user for 10 CFR 35.600 uses on the radiation safety committee.

The reason for the violation is due to the absence of the Part 35.600 authorized user from Radiation Safety Committee meetings was that a representative was attending committee meetings in his place. This situation was immediately corrected; Part 35.600 authorized users will actively participate in committee meetings. If any authorized user representing their area cannot attend, a new date will be rescheduled so that everyone can participate in committee meetings, thus ensuring compliance with CFR section 35.24(f) and subparts.

B. 10 CFR 35.63(d) requires 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 or if the dosage differs from the prescribed dosage by more than 20 percent. Contrary to the above, since the prior inspection, without otherwise being directed by the authorized user, the licensee used dosages that did not fall within the prescribed dosage range, or the dosage differed from the prescribed dosage by more than 20 percent. Specifically, numerous examples of cardiac and gastric emptying studies were found to be out of the approved ranges. For example, rest doses of 13.3 mCi, 14 mCi, and 14.5 mCi were administered outside of the approved range of 8 to 12 mCi on August 13, 2024. Gastric emptying study dosages of 699 µCi, 672 µCi, and 616 µCi were administered outside of the approved range of 800 to 1200 µCi on July 12, 2024, July 8, 2024, and July 7, 2024, respectively.

After the inspection, we investigated this violation with authorized technical personnel. In these cases, it was presumed that the correct dose had been included, when this was not the case. Authorized technical personnel will be double-checking to ensure that the doses being administered are within the approved ranges. This way, we will prevent these errors from recurring. In each study in which a dose is administered,

they must verify the dose ranges by study and make any necessary adjustments within acceptable ranges before administering the product.

C. 10 CFR 35.610(e) requires that a licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually. Contrary to the above, for calendar year 2023, the licensee failed to ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually. Specifically, the licensee did not conduct an emergency drill in 2023 for any of their staff; an emergency drill was successfully completed in 2024 for the necessary staff.

In reference to this violation: (emergency procedure drills) these had been coordinated for the end of 2023, due to multiple factors that were not under our control, including the availability of Varian, a new date was coordinated for the beginning of 2024. An emergency drill for personnel was successfully carried out in 2024. To comply annually with this emergency drill, more than one date will be scheduled during the year.

I am taking this opportunity to inform you that Mr. Jaime Maestre, MHSA, Executive Director, is no longer working as an administrator. I will be taking his place as Chief Executive Director of the Mayaguez Medical Center. And in addition, we want to add in our license Roberto A. Annexy Marquez, M.D. as authorized user for material and use for part 10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300; actually he is authorized user under License No. 52-24916-01.

Sincerely,

Andrea Vargas, MBA, MHSA
Chief Executive Director
Mayaguez Medical Center