CAGUAS Consolidated Medical Plaza Suite 101 201 Ave. Gautier Benitez

GUAYAMA

HUMACAO

AIBONITO La Fuente Town Center 706 Calle Marginal 18 Ave. Font Martelo 120 Calle José C. Vázquez frente al Hospital Menonita

April 16, 2025 Date

From Hiram Rivera Luna, M.D.

Director and RSO

Nuscan CSP

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Τо Kelli Trotter, Health Physicist

Medical and Licensing Assistance Branch

Division of Radiological Safety and Security United States Muclear Regulatory Comminsion

Region I

NUSCAN CSP, REQUEST FOR ADDITIONAL INFORMATION, SUBJECT

> MAIL CONTROL NO. 645783 License No. 52-17273-01 Docket No. 030-12483 Mail Control No. 645783

Dear Kelli Trotter:

To address your questions in a letter dated April 14, 2025 regarding our letter dated March 14, 2025, notifying the NRC about change of equipment for NRC License No. 52-17273-01.

- 1. Regarding the new Philips Ingenuity TF 128 PET/CT system, please provide the following information:
 - a. Is the new camera in a different room or position from the old camera that would require changes to the shielding evaluations currently on file with the NRC?

Answer: We certify that the new Philips Ingenuity TF 128 PET/CT system is exactly in the same room and in the same position as the previous Philips Gemini 16 PET/CT system.



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b. Is there a radioactive source inside of the PET/CT camera, and if so, does that source fall within the provisions of 10 CFR 35.65?

Answer: No, there is no radioactive source inside of the Philips Ingenuity TF 128 PET/CT camera.

2. Please confirm if the previous workload assumptions submitted January 4, 2024, are the same (i.e., 15 patients per week with a maximum F-18 dose of 15 mCi). If these have changed, please provide the updated shielding calculations with these new workloads to demonstrate if new shielding installation is required.

Answer: We confirm the same workload of 15 patients per week with a maximum F-18 dose of 15 mCi).

In fact, we were performing no more than 12 patients per week with the previous system and will perform no more than 15 patients per week with the new system because of limitations with personnel and problems with timing and logistic with the only radiopharmacy providing the F-18 in Puerto Rico. If, in the future, those limitations and logistic problems resolve such that the workload could be increased, we will perform new shielding calculations and install new shielding as needed and notify NRC immediately.