



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION I
475 ALLENDALE ROAD – SUITE 102
KING OF PRUSSIA, PA 19406-1415

December 18, 2024

Enrique E. Figueroa, M.D., Medical Director
Cardio Health
P.O. Box 79490
Carolina, PR 00984

SUBJECT: CARDIO HEALTH, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 644378

Dear Dr. Figueroa:

This is in reference to a letter dated December 5, 2024, requesting to amend NRC License No. 52-31320-01 to add an authorized user (AU). In order to continue our review, we need the following additional information. Please be aware that, unless stated otherwise, all “Item”, “Section”, and “Appendix” references below are referring to NUREG-1556, Volume 9, Revision 3, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses” found at <https://www.nrc.gov/docs/ML1925/ML19256C219.pdf>.

1. Form 313, Item 13, Certification - The NRC views a letter signed by a management representative as indication that management has reviewed the application and concurs with the statements and representations contained therein. As such, please provide the following:

- a. Please confirm that Desiree Trinidad Fornera, CNMT, is authorized to make legally binding commitments on behalf of the licensee’s organization.

OR

- b. If Desiree Trinidad Fornera is not authorized to make legally binding commitments on behalf of the licensee’s organization, please have an individual authorized to make legally binding commitments on behalf of the licensee’s organization provide either of the following:

- i. Confirm that you endorse the requests and statements submitted by Desiree Trinidad Fornera on behalf of your organization in the amendment request dated December 5, 2024.

OR

- ii. State that you do not endorse the requests and statements submitted by Desiree Trinidad Fornera on behalf of your organization in the amendment request dated December 5, 2024, and request to withdraw the requests and statements.

2. Item 7, Authorized Users (AU) – Your request included a confirmation from the

Certification Board of Nuclear Cardiology (CBNC) that the proposed AU has passed the board examination in nuclear cardiology and is currently certified. However, in accordance with 10 CFR 35.290, the board certification pathway for training AUs requires that board certifications be recognized by the NRC or an Agreement State as posted on the NRC's Medical Uses Licensee Toolkit web page found here: <https://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>. The CBNC is an approved certification board under 10 CFR 35.290, however a board certificate in the specialty area of "Nuclear Cardiology" must be provided that displays the wording "for Physicians trained in the United States".

If you wish to pursue adding the individual through the board certification pathway per 10 CFR 35.290, please provide a copy of the board certificate with the necessary wording; otherwise, submit the necessary information under a different pathway for approval as detailed in [NRC Form 313A \(AUD\)](#), "Authorized User Training, Experience, and Preceptor Attestation For Uses Defined Under 35.100, 35.200, and 35.500".

We will continue our review upon receipt of this information. Please reply to my attention at Jonathan.Pfingsten@nrc.gov.

In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter.

An electronic version of the NRC's regulations is available on the NRC Web Site at: www.nrc.gov. Additional information regarding medical uses of radioactive materials may be obtained on the NRC Web Site at: <http://www.nrc.gov/materials/miau/med-use-toolkit.html>. This site also provides the updated Training and Experience NRC Form 313A series of forms and guidance, as well as information on the revised regulations for naturally-occurring and accelerator-produced radioactive materials (NARM).

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web Site at: <http://www.nrc.gov/reading-rm/adams.html>. Please be aware that you may request that certain portions of your submittal to NRC be withheld from public disclosure as proprietary information. To do this, you must execute an affidavit as specified in 10 CFR 2.390. You must list all portions that you wish to be held proprietary, along with your reasoning as to why that is appropriate. While it is allowable, please refrain from submitting proprietary information in support of a license unless necessary. Keep in mind that all NRC licenses are considered to be in the public domain, and therefore may be viewed by any member of the public who requests to see them.

If you have any questions regarding this request for additional information, please contact me at 610-337-5170 or via electronic mail at Jonathan.Pfingsten@nrc.gov.

Thank you for your cooperation.

Sincerely,

Jonathan Pfingsten, Senior Health Physicist
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security
Region I

License No. 52-31320-01
Docket No. 030-37791
Mail Control No. 644378

cc: Juan Vila, M.D., Radiation Safety Officer

CARDIO HEALTH, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 644378 DATED DECEMBER 18, 2024

SUNSI Review Complete: Jonathan Pfingsten

After declaring this document "An Official Agency Record" it will be released to the Public.

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/end "E" = Copy w/ attach/end "N" = No copy

OFFICE	RI:DRSS	N					
NAME	JPfingsten/JBP						
DATE	12/18/24						

OFFICIAL RECORD COPY