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

August 22, 2022

Francis Palermo, M.D., President
Francis A. Palermo, M.D.
620 Christiana-Stanton Road
Newark, DE 19713

SUBJECT: FRANCIS A. PALERMO, M.D., REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 631509

Dear Dr. Palermo:

This is in reference to your application dated May 9, 2022, requesting to renew NRC License No. 07-28780-01. In order to continue our review, we need the following additional information:

1. Item 3, Address Where Licensed Materials Will Be Used or Possessed – Your renewal application provided an address for use or possession of licensed materials, however this address omitted the suite number currently listed on your license under License Condition 10. Please confirm that the full address for the location where licensed materials are to be used and stored is still "Metroform Medical Complex, **Suite 301**, 620 Christiana-Stanton Road, Newark, Delaware."

2. Items 5 and 6, Radioactive Material and Use – Your renewal application did not contain a request concerning which radionuclides, forms, quantity, or purpose for which you are seeking authorization. Please confirm you seek to retain your current authorizations as follows:
    a. Confirm you are requesting "Any byproduct material permitted by 10 CFR 35.200"
    b. Confirm you are requesting the materials in "Any form"
    c. Confirm you requesting a quantity of "As needed".
    d. Confirm the purpose of use is "Any imaging and localization study permitted by 10 CFR 35.200"
    e. Please confirm you are not seeking possession of any additional sources not authorized by 10 CFR 35.65, 35.100, or 35.200.

3. Items 5 and 6, Radioactive Material and Use – Please provide the following:
    a. Confirm that you will not utilize PET materials under this license. OR
    b. Confirm that you will utilize PET materials under this license and provide the following PET-related requests under Appendix C to NUREG-1556, Volume 9, Revision 3, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses":
        i. Please confirm which facility/facilities will utilize PET materials.
        ii. Please provide shielding calculations for your PET/CT facility. Please resubmit your PET/CT facility diagram, which should be drawn to scale with scale used indicated, and include information about the type, thickness, and density of any necessary shielding to enable

independent verification of shielding calculations. The calculations should include any workload assumptions used.

iii. Please provide principal use of adjacent rooms (e.g., office, file, toilet, closet, hallway), including areas above, besides, and below PET areas.

iv. For PET, provide a description of surrounding areas, including the occupancy factors, and indicate whether the areas are restricted or unrestricted, as defined in 10 CFR 20.1003. For calculations of the maximum exposure in any given hour, an occupancy factor will not be used.

4. Item 7, Radiation Safety Officer (RSO) – Your application does not contain either a confirmation that you will remain the RSO or requesting permission to name a new RSO. Please confirm that you, Francis Palermo, M.D., are seeking to remain the named RSO on the license.

5. Item 9, Dose Calibrator and Other Dosage Measuring Equipment – Your application contained a description of the procedures you have developed, implemented, and maintained for calibrating dose calibrators under "Item 9.3, 'DOSE CALIBRATOR CALIBRATION'". We do not require this procedure as part of your application process. This information was not reviewed as part of the licensing process and will not be tied down in your license; however, it may be reviewed in a future inspection. We will tie the following commitment to your license, as submitted in your renewal application: "Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions."

6. Item 10, Occupational Dose – Your renewal application contained a commitment to either perform a prospective evaluation demonstrating unmonitored individuals are not likely to receive a dose in excess of 10% of the limits in Part 20 or to provide dosimetry that meets the requirements in NUREG-1556, Volume 9, revision 2. The NUREG and its commitments have been updated in Revision 3. Additionally, your application contained the commitment: "We will maintain for inspection by the NRC, documentation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of the limits stipulated in 10 CFR 20.1502." Therefore, please provide the following:

   a. A statement that: "We will maintain, for inspection by the NRC, documentation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in 10 CFR 20.1502." OR
   b. A statement that: "We will monitor individuals in accordance with the criteria in the section titled, 'Radiation Safety Program-Occupational Dose' in NUREG-1556, Vol. 9, **Rev. 3**, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licensees." OR
   c. A description of an alternative method for demonstrating compliance with the referenced regulations.

7. Item 10, Material Receipt and Accountability – Your application contained the following commitment: "We will develop, implement, and maintain written procedures for licensed

material accountability and control to ensure that: license possession limits are not exceeded; licensed material in storage is maintained under constant surveillance and control and records of receipt (either from the licensee's own production operations or from another licensee), transfer, disposal of licensed material, are maintained." However, this differs from the guidance in NUREG-1556, Vol. 9, Rev. 3. Therefore, please provide a statement that:

"We will develop, implement, and maintain written procedures for licensed material accountability and control to ensure that:

a. license possession limits are not exceeded
b. licensed material in storage is secured from unauthorized access or removal
c. licensed material not in storage is maintained under constant surveillance and control
d. records of receipt (either from the licensee's own production operations or from another licensee), transfer, and disposal of licensed material, are maintained."

8. Item 10, Area Surveys – Your application contained a commitment to implement the model procedures outlined in NUREG-1556, Vol. 9, Rev. 3, Appendix R; the commitment to develop, implement, and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meets the requirements of 10 CFR 20.1501 and 10 CFR 35.70; and a table of action trigger limits for ambient exposure and removable contamination. However, the table of action trigger limits for ambient exposure and removable contamination does not match the model procedures found in Appendix R. Therefore, please update your commitment by providing the following:
    a. Provide the statement: "We have developed and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70." AND
    b. Rescind your commitment for action trigger limits for ambient exposure and removable contamination and the corresponding table found in your application

9. Awareness only, no response required – Your application contained commitments to establish and implement model procedures outlined in NUREG-1556, Vol. 9, Rev. 3, Appendix I, "Radiation Safety Officer Duties, Responsibilities, and Delegations"; Appendix O, "Model Procedures for Ordering and Receiving Packages"; and Appendix P, "Model Procedures for Safely Opening Packages Containing Radioactive Material". These commitments are not required to be submitted; therefore, they were not reviewed as part of the renewal process and will not be tied down in your license.

We will continue our review upon receipt of this information. Please reply to my attention at Patrick-John.Hann@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 form 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 610-337-5315 or via electronic mail at Patrick-John.Hann@nrc.gov.

Thank you for your cooperation.

Sincerely,

Patrick-John E. Hann

Digitally signed by Patrick-John E. Hann
Date: 2022.08.22 10:56:21 -04'00'

Patrick-John Hann, Health Physicist
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security
Region I

License No. 07-28780-01
Docket No. 030-32886
Mail Control No. 631509

cc: Michael Lairmore, M.S.

FRANCIS A. PALERMO, M.D., REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 631509 DATED August 22, 2022

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SUNSI Review Complete: Jonathan Pfingsten

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