



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

January 3, 2024

Rogelio Díaz Garcia, MHSA
Executive Director
Hospital Menonita Ponce, Inc.
P.O. BOX 1650
Cidra, PR 00739

SUBJECT: HOSPITAL MENONITA PONCE, INC. REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 637088

Dear Rogelio Díaz Garcia:

This is in reference to your application dated August 21, 2023, requesting to renew NRC License No. 52-252332-01. In order to continue our review, we need the following additional information:

1. Item 5, Radioactive Material - You have indicated a change in the maximum activity amount for Iodine-131 permitted by 10 CFR 35.300 in the Chemical/Physical form "Any" from the previously licensed amount of 350 millicuries to be increased to the amount of 500 millicuries. Please confirm your desire to increase the authorized possession limits as requested.
2. Item 6, Purpose(s) for Which Licensed Material Will Be Used - You have indicated that you are not performing PET-CT procedures "at this time".
 - a. If you plan to perform them in the future, please provide a timeline, necessary shielding calculations, survey results to indicate regulatory dose limits for public and workers would not be exceeded, and facility diagrams including locations of PET-CT material storage and use as well as describe access control to those areas.
 - b. If you do not plan to use them in the future, please confirm this and commit to submitting the required information if your plans change.
3. Items 5 and 6, Radioactive Material and Use – Your application requests authorization to possess and use any byproduct authorized by 10 CFR 35.300. However, you only specified that all uses under 10 CFR 35.300 will be performed on an outpatient basis, releasable per 10 CFR 35.75. Please confirm that all uses under 10 CFR 35.400 will be performed on an outpatient basis, as well.
4. Item 9, Facility Diagram
 - a. For awareness only, drawings and diagrams that provide the exact location of materials or depict specific locations of safety or security equipment should be marked as "Security-Related Information – Withhold Under 10 CFR 2.390." For future submittals, please include the security banner when appropriate.

- b. If applicable, please provide room numbers for areas in which byproduct materials are used, prepared for use or stored.
- c. Are there any other areas where material is used, prepared or stored (i.e. stress lab, imaging area, injection room)? If so, please identify them on the diagram(s).
- d. Doors should be indicated, and it should be specified on the diagram which doors are access controlled (i.e., locked). Specifically, please describe how security of any areas where material is stored is maintained.

We will continue our review upon receipt of this information. Please reply to my attention at Jonathan.Pfingsten@nrc.gov referencing Mail Control No. 637088

In order to continue prompt review of your application, we request that you submit your response to this letter by January 19, 2023.

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. 52-252332-01
Docket No. 030-33026
Mail Control No. 637088

cc: Carmelo Pérez, Radiation Safety Officer

HOSPITAL MENONITA PONCE, INC. REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 637088 DATED JANUARY 3, 2024

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SUNSI Review Complete: Hiba Ahmed

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