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

July 8, 2024

José M. Torres, MHSA
Chief Executive Officer
Metro Ponce, Inc.
d/b/a Hospital Metropolitano Dr. Pila
P.O. Box 331910
Ponce, PR 00733-1910

SUBJECT: METRO PONCE, INC., D/B/A HOSPITAL METROPOLITANO DR. PILA
REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 639915

Dear José Torres:

This is in reference to your application dated March 5, 2024, requesting to renew NRC License No. 52-25255-01. In order to continue our review, we need the following additional information. Please note that the specific requests and suggested format for responses to these items may be found in Appendix C 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. Item 3, Address Where Licensed Material will be Used or Possessed – Your application listed PO Box 331910, Ponce, PR 00733 as the location of use and storage. However, a post office box is not acceptable as a facility location. The address authorized on your current NRC license for location of use and storage of licensed radioactive material is Avenida Las Américas, Ponce, Puerto Rico. Therefore, please confirm that the address for the location of use and storage for this license is Avenida Las Américas, Ponce, Puerto Rico. In accordance with NUREG-1556, Vol. 9, Rev. 3, please specify the street address, city, and state.

2. Item 5, Radioactive Material, there is no information provided for the chemical and/or physical form of the requested material. Please confirm that you are requesting "any" form of radioactive material licensed under 10 CFR 35.100, 35.200, and 35.300.

3. Items 5 and 6, Radioactive Material and Use, and Item 9, Facility Diagram and Other Equipment and Facilities – Your application did not directly discuss the use of PET materials. Therefore, please confirm that you do not possess nor intend to use PET materials under this license.

4. Items 5 and 6, Radioactive Material and Use, and Item 9, Facility Diagram – Your application requests authorization for any byproduct material permitted by 10 CFR 35.300. However, this does not address the types of procedures and forms of materials that will be used under your license. Additionally, your current license only authorizes use for I-131 under 10 CFR 35.300. Therefore, please address the following:

    a. Regarding uses under 10 CFR 35.300:

i. Confirm that you are requesting authorization for Iodine-131 permitted by 10 CFR 35.300 performed only on an outpatient basis in accordance with the release criteria in 10 CFR 35.75.

OR

ii. Confirm that you are requesting authorization for any radiopharmaceutical therapy procedure permitted by 10 CFR 35.300 performed only on an outpatient basis in accordance with the release criteria in 10 CFR 35.75.

OR

iii. Confirm that you are requesting authorization for any radiopharmaceutical therapy procedure permitted by 10 CFR 35.300, including in-patient care for patients not releasable under 35.75. Please note, if requesting authorization for in-patient care rooms, additional information about the type, thickness, and density of any shielding for these areas are required to be submitted. Additional information can be found in NUREG-1556, Vol. 9, Rev. 3, Section 8.9.1, "*Facility Diagram*."

b. Regarding the form of material requested:

Indicate whether iodine-131 therapies administered under licensed 10 CFR 35.300 activities will be restricted to capsule form or if liquid form iodine-131 administrations are requested. Please note, if administering liquid form iodine-131, additional radiological controls for vial storage (e.g., fume hoods) are required. Additional information can be found in NUREG-1556, Vol. 9, Rev. 3, Section 8.9.1, "*Facility Diagram*."

c. Regarding the possession limit of material requested:

You requested an "as needed" possession limit for byproduct material permitted by 10 CFR 35.300. The NRC requires an actual possession limit for this category. Your current possession limit for I-131 permitted by 10 CFR 35.300 is 300 millicuries. Please indicate if your current possession limit is still acceptable.

5. Items 5 and 6, Radioactive Material and Use, and Item 9, Facility Diagram and Other Equipment and Facilities – Your renewal application indicated the request for a Mo99/Tc99m generator "as needed." Please note that generators used for the purpose of eluting radionuclides intended to be prepared and administered to patients require additional licensing commitments and/or authorizations, dependent on the type of generator. Therefore, please indicate if you possess a generator used for the purpose of preparing radiopharmaceuticals. If so, refer to NUREG-1556, Vol. 9, Rev. 3, and NUREG-1556, Vol. 13, Rev. 2 for additional information on licensing commitments, such as adding an authorized nuclear pharmacist or requesting authorization for depleted uranium as generator shielding.

6. Item 7, Radiation Safety Officer (RSO) – Your application seeks to retain Lyzbette Lopez as the RSO for this license. It was noted during this review that the name of the RSO in your 2013 renewal, along with in your current renewal, was listed as Lyzbette Lopez

Castellar. Therefore, please address the following:

a. Please confirm the correct name of your RSO, as it will appear on your license.

b. Please indicate if Lyzbette Lopez is a contractor/consultant. If the proposed RSO is an outside consultant or contractor, additional information is required to be submitted, which can be found in NUREG-1556, Vol. 9, Rev. 3, Section 8.7.1, "*Radiation Safety Officer (RSO) and Associate Radiation Safety Officers (ARSOs)*."

7. Item 8, Training for Individuals Working In or Frequenting Restricted Areas – Your renewal application did not contain the requested commitments concerning training for individuals working in or frequenting restricted areas. Therefore, please provide the following commitment:

> "We have developed and will implement and maintain written procedures for a program for training required under 10 CFR 19.12 for each group of workers, including (i) topics covered, (ii) qualifications of the instructors, (iii) method of training, (iv) method for assessing the success of the training, (v) initial training, and (vi) annual refresher training."

8. Item 9, Facility Diagram - Your application did not contain a facility diagram. However, applicants must describe the proposed facilities and equipment, as required by 10 CFR 30.33(a)(2) and 10 CFR 35.12. Therefore, please submit a facility diagram, including the following information:

a. Indicate a scale for the facility diagram, and ensure the drawing is to scale. The direction of north should also be indicated.

b. Location, room numbers (if they exist), and principal use of each room, including patient treatment rooms or areas where byproduct material is prepared, used, administered, and stored (e.g., decay room, injection rooms, stress lab, hot lab). If possible, please provide a diagram which shows where these areas are located relative to the hot lab/imaging suite.

c. Please indicate and specify the principal use of adjacent rooms (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below.

d. Indicate all doors, and specify which doors are access controlled (i.e., locked).

e. Please note: 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."

9. Item 9, Radiation Monitoring Instruments – Your application contained the following commitment:

> "Radiation monitoring instruments will be calibrated by a person qualified to perform meter calibrations."

However, this does not meet the intent of the requested information. Please confirm and update your commitment to the following:

> "Radiation monitoring instruments will be calibrated by a vendor who is licensed by the NRC or an Agreement State to perform instrument calibrations." AND
>
> "We reserve the right to upgrade survey instruments as necessary, as long as they are adequate to measure the type and level of radiation for which they are used."

10. Item 9, Radiation Monitoring Instruments – You indicated that you have a Biodex Ludlum Model 14C survey meter. Please provide the manufacturer and model number of the survey meter probe.

11. Item 9, Dose Calibrator and Other Equipment Used to Measure Dosages of Unsealed Byproduct Material – Your application did not contain the requested commitments concerning dose calibrator calibrations. Therefore, please provide the following commitments:

    > "Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions."
    >
    > AND, if applicable:
    >
    > "For measurement of alpha emitters where gamma or beta emissions are not measurable in a traditional dose calibrator, identify specialized measurement equipment and the nationally recognized standard used to calibrate the instrument or provide a copy of the manufacturer's instructions to calibrate the instrument."

12. Item 10, Occupational Dose – Your application did not contain the requested commitment concerning occupational dose. Therefore, please confirm one of the following commitments:

    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.'"

13. Item 10, Spill/Contamination Procedures – Your renewal application contained the following commitment:

    > "We have developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with 10 CFR 20.11001."

However, this does not meet the intent of the requested information. Please confirm and update your commitment to the following:

> "We have developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with **10 CFR 20.1101**."

14. Item 10, Material Receipt and Accountability – Your application did not contain the requested commitments concerning material receipt and accountability. Therefore, please commit to the following:

> "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 secured from unauthorized access or removal;
> - licensed material not 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, and disposal of licensed material, are maintained."

15. Item 10, Safe Use of Unsealed Licensed Material – Your application contained the following commitment:

> "We have developed and will implement and maintain procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101, 10 CFR 20.1201 and 10 CFR 20.1301."

However, the requested commitment has been updated in NUREG-1556, Vol. 9, Rev. 3. Therefore, please confirm and update your commitment to the following:

> "We have developed and will implement and maintain written procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1201."

16. Item 11, Waste Management – Your application contained the following commitment:

> "We have developed and will implement and maintain waste disposal procedures for licensed material in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of 10 CFR Part 20, Subpart K, and of 10 CFR 35.92."

However, this does not meet the intent of the requested information. Please confirm and update your commitment to the following:

> "We have developed and will implement and maintain **written** waste disposal procedures for licensed material in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of 10 CFR Part 20, Subpart K, and of 10 CFR 35.92."

17. Item 13, Certification – Your application was signed by José M. Torres, MHSA, Chief Executive Officer. However, the individual the NRC has listed on file as the CEO is Rafael Alvarado. To promote future communications, please provide contact information; including name, business title, business email, business phone number, and business facsmile number; for the current management point of contact.

18. Please confirm that you do not possess any sealed sources that do not meet the requirements of 10 CFR 35.65.

We will continue our review upon receipt of this information. Please reply to my attention at janice.nguyen@nrc.gov, referencing mail control number 639915.

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 610-337-5006 or via electronic mail at janice.nguyen@nrc.gov.

Thank you for your cooperation.

Sincerely,

JANICE NGUYEN

Digitally signed by JANICE NGUYEN
Date: 2024.07.08 15:49:51 -04'00'

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

License No. 52-25255-01
Docket No. 3033207
Mail Control No. 639915

cc: Lyzbette Lopez, CNMT, Radiation Safety Officer

METRO PONCE, INC., D/B/A HOSPITAL METROPOLITANO DR. PILA REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 639915 DATED JULY 8, 2024

DOCUMENT NAME: G:\WBL Documents\WBL License RAI\L52-25255-01.639915.RAI.docx

SUNSI Review Complete: JNguyen

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/encl "**E**" = Copy w/ attach/encl "**N**" = No copy

OFFICE	RI:DRSS	N						
NAME	JNguyen (JEN)							
DATE	7/8/2024							

OFFICIAL RECORD COPY