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

February 8, 2024

Marielis Guerra Rosado, MHSA
Executive Director
Bella Vista Hospital
PO Box 1750
Mayaguez, PR 00681-1750

SUBJECT: BELLA VISTA HOSPITAL, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 637707

Dear Marielis Guerra Rosado:

This is in reference to your application dated September 25, 2023, requesting to renew NRC License No. 52-25223-01. The specific requests and suggested format for responses to these items may be found in NUREG–1556, Vol. 9, Rev. 3, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses" found at https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/index.html. In order to continue our review, we need the following additional information.

1. Our records indicate a change in the licensee management representative. Please provide contact information, including a business phone number and business email address, for Marielis Guerra Rosado.

2. Item 1, *License Action Type* – Please note that the license number 52-25253-01 as seen on the application cover letter, Form 313, and checklist Item 7: Radiation Safety Officer and Authorized Users (AUs) does not match our records. Our records indicate your license number as 52-25223-01. Please confirm all references to that license were written mistakenly. Please state your correct license number for Item 7: RSO and Item 7: AUs. You may also resubmit your Form 313 stating the corrected license number with your response.

3. Items 5 and 6, *Radioactive Material and Use* – In your application, you have requested authorization to use any form of "only" Iodine-131 permitted by 10 CFR 35.300 limited to the quantity of 300 millicuries. Your current license authorizes use for "Any" byproduct material permitted by 10 CFR 35.300.

    a. Please confirm if the authorized material should be limited to I-131. If this is done be aware of the following:
        i. Use will be limited to I-131 only.
        ii. Miguel A. Vigo, M.D. will be limited to I-131 authorizations.
    b. Please indicate if the authorized material should remain as any material authorized under 10 CFR 35.300. If this is requested, please specify which other administrations you will be performing in addition to Iodine. Also note that if this is requested, Miguel A. Vigo will retain full authorization under 10 CFR 35.300.

    c. If either clarification above involves inpatient administrations, please provide

information concerning patient accommodations consistent with NUREG-1556, Volume 9, Rev. 3, Item 8.9.1. This must include: room diagrams and location of any patient isolation rooms as well as principal use and shielding of adjacent spaces (including above and below), in addition to any additional decay-in-storage, if necessary.

4. Item 9, *Facility Diagram* – Please provide the following:

    a. 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. No response is required for this item.

    b. It should be specified on the diagram which doors are access controlled (i.e., locked). Specifically, please describe how security is maintained of any areas where material is used, prepared, or stored (i.e. hot lab and waste room). Also indicate whether the areas are restricted or unrestricted, as defined in 10 CFR 20.1003.

    c. Attachment 9.2 of your application illustrates a facility diagram for your PET/CT Lab. Please clarify where "Wall B" is located on the diagram. Please indicate the principal use of the area adjacent to the uptake room outside of the right side, as shown.

    d. Attachment 9.1 and 9.2 of your application illustrate the Nuclear Medicine and PET/CT labs, respectively. Please describe the location of these labs relative to the facility/building including which floor they are located on and the associated room numbers, if applicable.

    e. We were not able to identify an area on your diagram for PET/CT radioactive waste. Please indicate the waste storage location for PET/CT radioactive waste and describe how access control is maintained.

5. For Item 9, *Radiation Monitoring Instruments* – You provided the make and model of your survey meters. Additionally, please provide the make and model of the respective probe attachments to ensure appropriate measurement in accordance with the type and level of radioactive materials being measured.

6. Item 9, *Dose Calibrator and Other Dosage Measuring Equipment* – Please provide the following:

    a. Commit to not using alpha emitters where gamma or beta emissions are not measurable in a traditional dose calibrator;

    OR

    b. If you are using 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.

7. Item 9, *Other Equipment and Facilities* – For PET radionuclide use, describe additional remote equipment for these uses, as applicable, such as lead-lined syringe carrier, tongs and specialized syringe shields that are specific to 511 keV.

8. Item 10, *Occupational Dose* – You provided a statement that addressed unmonitored individuals, please also indicate if you will be monitoring occupational dose of individuals likely to exceed exposure limits in 10 CFR 20.1502, and if so, please provide the following:

    a. 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

    b. A description of an alternative method for demonstrating compliance with the referenced regulations.

9. Item 10, *Leak Tests* – Leak test procedures were not found in your application as indicated. Please provide leak test procedures.

We will continue our review upon receipt of this information. Please reply to my attention at *hiba.ahmed@nrc.gov* referencing *Mail Control No*. 637707

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 and Procedure," 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 610-337-5283 or via electronic mail at hiba.ahmed@nrc.gov.

Thank you for your cooperation.

Sincerely,

Hiba Ahmed

Digitally signed by Hiba Ahmed
Date: 2024.02.08 09:23:47 -05'00'

Hiba Ahmed, Health Physicist
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security
Region I

License No. 52-25223-01
Docket No. 030-32986
Mail Control No. 637707

cc: Miguel A. Vigo, M.D., Radiation Safety Officer

BELLA VISTA HOSPITAL, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 637707 DATED FEBRUARY 8, 2024

DOCUMENT NAME: G:\WBL Documents\WBL License RAI\52-25223-01.637707.RAI.docx

SUNSI Review Complete: Hiba Ahmed

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