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

May 2, 2024

David A. Tam, M.D., MBA, FACHE
President and Chief Executive Officer
Beebe Medical Center
c/o Radiology Dept.
424 Savannah Road
Lewes, DE 19958

SUBJECT: BEEBE MEDICAL CENTER C/O RADIOLOGY DEPT., REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 639169

Dear Dr. David Tam:

This is in reference to your application dated December 12, 2023, requesting to renew NRC License No. 07-17792-01. In order to continue our review, we need the following additional information:

1. 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. Therefore, please address the following:

    a. Regarding uses under 10 CFR 35.300:

        i. 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

        ii. 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, Volume 9, Revision 3, Section 8.9.1, "*Facility Diagram."*

    b. Regarding the form of material requested:

        i. 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, Volume 9, Revision 3, Section 8.9.1, "*Facility Diagram*."

2. Item 7, Radiation Safety Officer (RSO) – Your application seeks to retain Lisa G. Whitlock as the RSO for this license. Because Ms. Whitelock is a contractor/consultant, you provided information regarding an in-house representative who will serve as the point of contact during the RSO's absence. To promote future communications, please provide contact information; including name, business title, business email, and business phone number; for this point of contact.

3. Item 7, Authorized Users (AUs) – Your current license authorizes Dennis Michael Flamini, D.O., and Kimberly Gardner, M. D., as AUs for 10 CFR 35.100, 35.200, and 35.300 uses. However, your application requested Dr. Flamini and Dr. Gardner as AUs for 10 CFR 35.100, 35.200, and 35.300 (limited to the oral administration of I-131 sodium iodide). Therefore, please provide either of the following:

    a. Confirm that you seek to retain Dennis Michael Flamini, D.O., and Kimberly Gardner, M. D., as AUs for 10 CFR 35.100, 35.200, and 35.300 uses.

    OR

    b. Request that you wish to limit Dennis Michael Flamini, D.O., and Kimberly Gardner, M. D., as AUs for 10 CFR 35.100, 35.200, and 35.300 (limited to the oral administration of I-131 sodium iodide).

4. 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."

5. Item 9, Facility Diagram and Other Equipment and Facilities – Your application did not include all the required information regarding facility diagrams. Therefore, please provide the following, including addresses on the facility diagrams necessary to identify each individual location:

    a. For 424 Savannah Rd, Lewes, DE – It was unclear which facility diagrams were specific to this location, and where individual rooms were located in relation to each other and surrounding areas. Therefore, please provide a consolidated facility diagram including the following information:

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

        ii. Location, room numbers (if they exist), and principal use of each room, including patient treatment rooms or areas where byproduct material is prepared, used, and stored.

        iii. Please indicate and specify the principal use of adjacent rooms (e.g.,

office, file, toilet, closet, hallway).

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

b. For 18941 John J. Williams Highway, Rehoboth, DE –

i. Please 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”:

1. Indicate the types of PET procedures performed (e.g., F-18 FDG, Rubidium Cardiac PET, etc.).

   AND

2. Please provide shielding calculations for your PET/CT facility. Shielding calculations were provided for the scanner room, but not for any injection/waiting areas. Additionally, the shielding calculations indicated lead was needed “in addition to standard building materials,” which were not specified. Therefore, 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.

   AND

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

   AND

4. 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.

   AND

5. For PET radionuclide use and radiopharmaceutical therapy programs, describe the additional equipment for these uses, as applicable (e.g., 2 inch lead glass L-block, tungsten syringe shields, flush counter mount for dose calibrator, shielded well counter, etc.).

ii. For all areas where byproduct material is prepared, used, administered, and stored:

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

2. Location, room numbers (if they exist), and principal use of each room, including patient treatment rooms or areas where byproduct material is prepared, used, and stored.

3. Please indicate and specify the principal use of adjacent rooms (e.g., office, file, toilet, closet, hallway).

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

c. For 19161 Healthy Way, Rehoboth, DE –

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

ii. Location, room numbers (if they exist), and principal use of each room, including patient treatment rooms or areas where byproduct material is prepared, used, and stored.

iii. Please indicate and specify the principal use of adjacent rooms (e.g., office, file, toilet, closet, hallway).

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

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

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

7. Item 10, Occupational Dose – Your application contained a commitment to either perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of regulatory limits in 10 CFR Part 20 or you will provide dosimetry that meets the requirements listed under "Criteria" in NUREG-1556, Vol. 9, Rev. 3. However, these commitments have been updated. Therefore, please confirm and update your commitment to 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.’”

8. 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
   - records of receipt (either from the licensee’s own production operations or from another licensee), transfer, and disposal of licensed material, are maintained.”

9. Item 8, Leak Tests – Your renewal application did not contain the requested commitment concerning leak testing of sealed sources. Therefore, please provide the following commitment:

   “We have developed and will implement and maintain written procedures for sealed-source leak testing that meet the requirements of 10 CFR 35.67.”

10. 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 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**.”

We will continue our review upon receipt of this information. Please reply to my attention at Valerie.Stowell@nrc.gov, referencing mail control number 639169.

In order to continue prompt review of your application, we request that you submit your response to this letter within 15 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 610-337-5193 or via electronic mail at Valerie.Stowell@nrc.gov.

Thank you for your cooperation.

Sincerely,

Valerie A. Stowell

Digitally signed by Valerie A. Stowell
Date: 2024.05.02 10:35:14 -04'00'

Valerie Stowell, Health Physicist
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security
Region I

License No. 07-17792-01
Docket No. 3013331
Mail Control No. 639169

cc: Lisa G. Whitelock, Radiation Safety Officer

BEEBE MEDICAL CENTER C/O RADIOLOGY DEPT., REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 639169 DATED MAY 2, 2024

DOCUMENT NAME: G:\WBL Documents\WBL License RAI\L07-17792-01.639169.RAI.docx
SUNSI Review Complete: V. Stowell
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	RIV:DRSS	N				
NAME	V. Stowell (VS)		M. Simmons					
DATE	5/1/2024		5/2/24					

OFFICIAL RECORD COPY