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

June 15, 2023

Frank DiGregorio, Chief Executive Officer
Molecular Imaging Services, Inc.
10 Whitaker Court
Bear, DE 19701

SUBJECT: MOLECULAR IMAGING SERVICES, INC., REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 634108

Dear Mr. DiGregorio:

This is in reference to your application dated December 23, 2022, requesting to renew NRC License No. 07-30790-01. In order to continue our review, we need the following additional information:

1. Item 3, Address Where Licensed Material will be Used or Possessed – Your application listed “One Centurian Dr,” Suite 208, Newark, DE as a location of use and storage. However, the address authorized on your current NRC amendment for location of use and storage of licensed radioactive material is “One Centurion Dr,” Suite 208, Newark, DE. Therefore, please confirm one of the following:

    a. Confirm that the address for the location of use and storage for this license is One Centurian Dr, Suite 208, Newark, DE.

    b. If you did move locations, provide the following information:

        i. The new address where licensed material will be used or possessed, along with the date that operations moved from One Centurion Dr, Suite 208, Newark, DE to the new location.

        ii. Confirm that all licensed activities at One Centurion Dr, Suite 208, Newark, DE have ceased and that all radioactive materials procured and/or possessed by this licensee under this license number cited above have been transferred to the new location of use.

        iii. Confirm that a radiation survey was conducted by the licensee, which certifies the absence of licensed radioactive material and that any remaining residual radioactivity is within the limits of 10 CFR 20, Subpart E, and is ALARA. Additionally, provide a copy of the survey radiation results.

2. 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. However, there was a PET room listed for one of your facility diagrams, and your previous 2012 renewal indicated the use of Rubidium Cardiac PET and F18-Amyvid

PET. Therefore, 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, and indicate the types of PET procedures performed.

AND

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.

AND

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

AND

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.

AND

v. 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.).

3. Item 7, Authorized Users (AUs) – Your current license authorizes Rajan Agarwal, M.D., as an AU for 10 CFR 35.100 and 35.200 uses. However, your application did not address whether Dr. Agarwal should be retained or removed from your license. Therefore, please provide either of the following:

a. Confirm that you seek to retain Rajan Agarwal, M.D., as an AU for 10 CFR 35.100 and 35.200 uses.

OR

b. Request the removal of Rajan Agarwal, M.D., as an AU.

4. Item 7, Authorized Users – Your application seeks to add Brent Duncan, M.D., to your license as an AU for 10 CFR 35.100, 35.200, and 35.500 uses. However, your previous license listed Brett Duncan, M.D., as an AU. Therefore, please confirm one of the following:

   a. Confirm that you seek to retain Brett Duncan, M.D., as an authorized user for 10 CFR 35.100, 10 CFR 35.200, and 10 CFR 35.500 uses on your renewal license.

   b. If you are confirming to add Brent Duncan, M.D., as an authorized user for your renewal license, please provide the information and/or documentation described in Section 8.7.2 of NUREG-1556, Vol. 9, Rev. 3 and as requested in NRC Form 313A (AUD) found at https://www.nrc.gov/docs/ML1216/ML12164A733.pdf.

5. 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."

6. Item 9, Facility Diagram – Your application contained a facility diagram that did not explicitly include all necessary information. Please provide the following information, in addition to the requested information listed above for PET facilities:

   a. For 200 Federal Street, Seaford, Delaware:

      i. Label all room numbers, if they exist (e.g., camera room, hot lab, etc.).

      ii. Please indicate any areas where radioactive materials are stored (e.g., waste storage area). If possible, please provide a diagram which shows where these areas are located relative to the hot lab.

   b. For 4512 Kirkwood Highway, Suite 202, Wilmington, Delaware:

      i. Label all room numbers, if they exist (e.g., camera room, hot lab, etc.).

   c. For One Centurion Drive, Suite 208, Newark, Delaware:

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

ii. Label all room numbers, if they exist (e.g., camera room, hot lab, etc.).

iii. Please indicate if there are any areas where radioactive materials are used or stored (e.g., waste storage area). Please provide an updated facility diagram including these additional areas. If possible, provide a diagram which shows where these areas are located relative to the hot lab/imaging suite.

iv. Specify which doors are access controlled (i.e., locked).

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

d. For Cardiology PC, Farmington Medical Arts, Twin Building B, 11 South Road, Suite 100, Farmington, Connecticut:

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

ii. Label all room numbers, if they exist (e.g., camera room, hot lab, etc.).

iii. Please indicate if there are any areas where radioactive materials are used or stored (e.g., waste storage area). Please provide an updated facility diagram including these additional areas. If possible, provide a diagram which shows where these areas are located relative to the hot lab.

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

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

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."

7. Item 9, Radiation Monitoring Instruments – In your renewal letter, you state that your facilities have a "Biodex 14-C" survey meter, two "Ludlum 14-C" survey meters, and a "Ludlum 3" survey meter. To confirm that these instruments are adequate to measure the type and level of radioactive material used, please provide both the make and model numbers of the probe attachments used, respective to each survey meter.

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

"Necessary radiation monitoring equipment will be calibrated by a qualified person authorized by the NRC or an Agreement State to perform radiation 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."

9. Item 10, Occupational Dose – Your application contained a commitment to either perform an evaluation demonstrating that unmonitored individuals are not likely to receive 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.'"

10. Item 10, Leak Tests – Your renewal request contained two separate leak test commitments. One statement indicated leak tests will be performed in-house for sealed sources authorized under 10 CFR Part 35, and the other statement indicated a contractor will perform leak tests for sealed sources other than those authorized pursuant to 10 CFR Part 35 (e.g., self-shielded irradiators, calibration sources). However, your application does not indicate the presence of any sealed sources other than those authorized pursuant to 10 CFR Part 35. Therefore, please update and confirm your commitment to the following:

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

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

    > "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 20.1301**."

    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.Gray@nrc.gov, referencing mail control number 634108.

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 610-337-5193 or via electronic mail at Valerie.Gray@nrc.gov.

Thank you for your cooperation.

Sincerely,

Valerie A. Stowell

Digitally signed by Valerie A. Stowell
Date: 2023.06.15 15:19:52 -04'00'

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

License No. 07-30790-01
Docket No. 030-36176
Mail Control No. 634108

cc: Sunil Selvin, Vice President of Operations and Clinical Education

MOLECULAR IMAGING SERVICES, INC., REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 634108 DATED JUNE 15, 2023

DOCUMENT NAME: G:\WBL Documents\WBL License RAI\L07-30790-01.634108.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						
NAME	V. Stowell (VS)							
DATE	6/15/2023							

OFFICIAL RECORD COPY