From: Hann, Patrick-John
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Cc: Elliott, Robin
Subject: NRC License 06-30624-01 Renewal Request for Additional Information
Date: Tuesday, December 14, 2021 11:27:00 AM

License No.: 06-30624-01
Docket No: 030-35657
Control No: 628270

Licensee Name: Molecular NeuroImaging, LLC

This refers to your request for renewal of your license dated August 17, 2021. In order to continue our review of your request, the following additional information is needed:

The following items are referenced in the quoted section of NUREG 1556 Vol 9 Rev 3 Consolidated Guidance About Materials Licenses, Program Specific Guidance About Medical Use Licenses, https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/index.html:

1. Section 8.8 discusses Training for Individual Working in or Frequenting Restricted Areas. 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."
2. Section 8.9.1 discusses your Facility Diagram and 8.9.5 Other Equipment and Facilities. Please provide the following:

    a. Since you have two floors, please indicate on your drawings which floor the areas are on. Also provide room numbers, and principal use of each room, including patient treatment rooms or area where byproduct material is prepared, used, and stored. 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."

    b. Principal use of adjacent rooms (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below therapy treatment rooms and Positron Emission Tomography (PET).

    c. Doors should be indicated, and specify which doors are access controlled (i.e., locked).

    d. Shielding calculations for PET facilities, in-patient rooms for 10 CFR 35.300 as applicable. Include information about the type, thickness, and density of any necessary shielding to enable independent verification of

shielding calculations, and a description of any portable shields used (e.g., shielding of proposed patient rooms used for implant therapy, including the dimensions of any portable shield, if one is used; source storage safe). The calculations should include the workload assumptions used.

e. For PET, and radiopharmaceutical areas, 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.
f. For PET radionuclide use and radiopharmaceutical therapy programs, describe the additional equipment for these uses, as applicable.

3. Section 8.9.2 discusses Radiation Monitoring Instruments. Please indicate whether you reserve the right to upgrade survey instrumentation as necessary, as long as they are adequate to measure they type and level of radiation for which they are used.
4. Section 8.10.2 discussed Occupational Dose. Please provide one of the following responses:
    a. "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. "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
    c. Provide a description of an alternative method for demonstrating compliance with the referenced regulations.
5. Section 8.10.2 discussed Occupational Dose. In your application dated August 17, 2021, you stated that students may be identified as individual users subject to your training program. Please confirm that these students are 18 years or older.
6. Section 8.10.5 discusses Spill/Contamination procedures. Provide the following:
    a. Either provide 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 20.11.01." OR
    b. Confirm that you want the procedure provided to be tied down to the license. If so, provide the following with respect to the procedures you provided:
        i. What protective equipment will be used to prevent contamination of shoes and clothing?
        ii. Provide guidance on cleaning from the perimeter to the center to avoid "smearing" contamination.
        iii. Specify what contaminations levels are acceptable for "clean."
        iv. Provide a copy of the incident report that will be used to document the spills and provide follow-up.
7. Section 8.10.11 discusses Leak Tests. Please provide the following:
    a. Either commit that you will follow the Model Leak Test procedures in Appendix N of NUREG 1556 Vol 9 Rev 3. for sources licensed under 10

CFR 35.67 and a similar commitment to follow the other referenced model procedures for sources licensed under 10 CFR Part 30. OR

b. Revise your procedures to include the following:
    i. Please refer to the definition of sealed sources as stated in 10 CFR 35.2,
    ii. Provide a description of the training provided for and the personal protective equipment used by the individuals who will conduct and analyze the leak tests,
    iii. Provide information regarding the facilities and equipment that will be used to analyze the samples.
    iv. Confirm that the leak tests will be taken in accordance with the guidance provided in the Sealed Source Registration Sheet and at the intervals specified.
    v. Specify what information will be included in the records maintained for the leak tests, include a sample report.

c. In Item 9 you state that "Alpha emitters are not used at this facility." In Item 10 – 4D you mention alpha emitting material. Will alpha emitters be used at your facility and if so, please address the dose calibrator requirements for these materials.

7. Section 8.11 discusses Waste Management. Relative to this item please provide the following commitment: "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 Subpart K to 10 CFR Part 20 and of 10 CFR 35.92."

The following items are referenced in the quoted section of NUREG 1556 Vol 7 Rev 1 Consolidated Guidance About Materials Licenses, Program Specific Guidance About Academic, Research and Development (R&D), and Other Licenses of Limited Scope, https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v7/index.html

1. Section 8.5.1 discusses Unsealed or Sealed Byproduct Material. Please provide the following:
    a. Specify if you will be using any volatile forms of I-125 or volatile materials authorized under 10 CFR 35.300, and if so, provide facility information (as described in section 8.9), engineering controls, and radiation safety procedures for handling these materials, including bioassay procedures.
    b. For sealed sources, indicate if all the sources are used under 10 CFR 35.67 or if 10 CFR 30.32(g) applies. If the later, provide the required information.
2. Section 8.6 discusses the Purpose(s) for which licensed material will be used. Please confirm that licensed materials will not be used in animal studies or tracer or field studies. If either type of use will occur, please refer to the referenced section and provide the information as described.
3. Section 8.10.3 discusses Material Receipt and Accountability. Please provide the following commitment, "Physical inventories will be conducted at intervals not to exceed 6 months, to account for all sealed sources and devices received and possessed under the license. Records of inventory will be maintained for a period of 5 years from the date of each inventory, and will include the radionuclides, quantities, manufacturer's name and model numbers, and the

date of the inventory."

4. Section 8.10.6 discusses Safe Use of Radionuclides, Security, and Emergency Procedures. Relative to your R&D use, provide the following:
    a. We will develop, implement, and maintain procedures for safe use, security
    and emergencies, **OR**
    b. We will adopt the procedures for the safe use of radionuclides, security and emergencies as published in Appendix L in NUREG–1556, Volume 7, Revision 1, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope, **OR**
    c. provide procedures for safe use of radionuclides, security of materials and emergencies.
4. Section 8.10.7 discusses Surveys and Leak Tests. Please submit one of the following for your R&D use:
    a. "We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix M in NUREG–1556, Volume 7, Revision 1, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope," **OR**
    b. Submit a description of an alternate radiation survey program, including survey frequencies and contamination levels, to evaluate a radiological hazard.
5. Section 8.11 discusses Waste Management. Please provide the following relative to waste generated from R&D activities:
    a. State that: "We will use the model waste procedures published in Appendix P in NUREG–1556, Volume 7, Revision 1, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope.'" **OR**
    b. If you wish to use only selected model procedures, state that: "We will use the [specify either (i) decay-in-storage or (ii) disposal of liquids into sanitary sewerage] model waste procedures that are published in Appendix P in NUREG–1556, Volume 7, Revision 1, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope.'"**AND**
    c. If you wish to compact or incinerate radioactive waste, provide the requested information concerning these activities in Appendix P to this NUREG.
7. Please confirm whether you will still distribute radiopharmaceuticals for immediate use by recipients conducting research and development projects and clinical research trials under investigational new drug applications (IND) in accordance with letter dated October 27, 2011.

Your reply must be an originally signed and dated letter by management. The letter may be scanned and submitted as a pdf document attached to an email (preferred); or it may be transmitted by facsimile to (610) 337-5269; or it may be sent by regular mail. In order to assume a prompt review of your renewal request, please reply within

30 calendar days from the date of this e-mail. If you require additional time for your response, please contact me.

Patrick-John E. Hann, MHP
Health Physicist
U.S. Nuclear Regulatory Commission