
January 26, 2022

U.S. NRC, Region I
2100 Renaissance Blvd.
King of Prussia, PA 19406
Robin Elliott, Health Physicist

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

Licensee Name: Molecular NeuroImaging, LLC

Dear Ms. Elliot,

Please see below our responses to the NRC's request for additional information dated January 20, 2022, in reference to the abovementioned license.

The following item is 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-ollections/nuregs/staff/sr1556/v9/index.html>:

1. Relative to your response to our inquiry regarding Section 8.10.2 discussing Occupational Dose, you replied, "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](#)." Please confirm that this commitment is in addition to the previous information provided in your August 17, 2021, submission labeled Item 10: Occupational Dose.

Response: We apologize for any misunderstanding or lack of clarity our earlier responses to section 8.10.2 included in the submitted letters dated August 17, 2021 and Jan 12, 2022 might have caused. Upon further review of the details under NUREG 1556 Vol 9 Rev 3, we would like to submit a new response as described below. At this time, we also request that the NRC disregard our earlier submitted responses from the letters dated August 17, 2021, and January 12, 2022.

Our clarified response; "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.'"

The following item is 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-ollections/nuregs/staff/sr1556/v7/index.html>

1. Section 8.5.1 discusses Unsealed or Sealed Byproduct Material. Please provide the following 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 as referenced in section 8.5.1 of NUREG 1556 Vol. & Rev 1.

Response: "All sealed sources are used under 10 CFR 35.67."

Relative to your response regarding the distribution of radiopharmaceuticals, please either attach a copy of the October 27, 2011, letter or we will continue to tie down that letter separately in Condition 18.

Response: Please find attached the October 27, 2011 letter to the NRC and an additional letter from the NRC dated October 6, 2014 regarding distribution of radiopharmaceuticals.

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 assure a prompt review of your renewal request, please reply no later than February 4, 2022. If you require additional time for your response or have questions regarding our request, please contact me.

Attachments:

- Attachment 1: October 27, 2011 letter from Molecular NeuroImaging regarding distribution of radiopharmaceuticals
- Attachment 2: October 6, 2014 letter from the NRC regarding Molecular NeuroImaging's license and distribution of radiopharmaceuticals

Please contact me should you have any questions or concerns and kindly include Jessica Frankel Trachten (email: jtrachten@invicro.com). Thank you for your assistance regarding our license renewal.

Sincerely,

DocuSigned by:
Denise Ferraiolo
00F8FF14093149B...

26-Jan-2022 | 15:43:09 CST

Denise Ferraiolo
Senior Vice President, Clinical Operations
Email: dferraiolo@invicro.com

 **MNI**
Molecular NeuroImaging, LLC

60 Temple Street • Suite 8A • New Haven, Connecticut 06510 • Phone: 203.401.4300 • Fax: 203.789.8037 • www.mnimaging.com

October 27, 2011

VIA Facsimile Mail: 610 337-5269; Mail Control No. 576256

United States Nuclear Regulatory Commission
Licensing Assistance Team
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region 1
475 Allendale Road
King of Prussia 19406-1415

RE: Amendment to License Number 06-30624-01

To Whom It May Concern:

Along with using radiopharmaceuticals for research purposes under 10 CFR 35.100, 35.200, & 35.300, Molecular NeuroImaging (MNI) intends to include distribution of radiopharmaceuticals from its facility as part of its license (Number 06-30624-01).

The distribution of radiopharmaceuticals would **not** be for the purposes of commercial distribution. Rather, the radiopharmaceuticals would be distributed for immediate use by recipients conducting research and development projects and clinical research trials under investigational new drug applications (IND).

Please contact me at 203-401-4333 if you have questions regarding this correspondence.

Sincerely,



John P. Seibyl, M.D.
MNI President

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