



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BLVD.
KING OF PRUSSIA, PA 19406-2713

November 21, 2018

Kimberly Fabrizio, Vice President
Regulatory Affairs and Compliance
Molecular NeuroImaging, LLC
60 Temple Street, 8th Floor
New Haven, CT 06510

SUBJECT: MOLECULAR NEUROIMAGING, LLC, LICENSE AMENDMENT, MAIL
CONTROL NO. 609594

Dear Ms. Fabrizio:

This refers to your license amendment request dated July 24, 2018. Please find enclosed Amendment No. 7 adding David W. Cheng, M.D., Ph.D. as an authorized user for medical use. Your amendment request letter also requested changing the Radiation Safety Officer from John, Seibyl, M.D. to Jennifer Madonia, M.S, PA-C. We were not able to approve Ms. Madonia to serve as Radiation Safety Officer because she does not meet the training requirements for Radiation Safety Officer pursuant to 10 CFR 35.50.

An environmental assessment for this action was not required, since this action is categorically excluded under 10 CFR 51.22(c)(14).

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please contact me at (610) 337-5182 or via electronic mail at Robert.gallagher@nrc.gov so that appropriate corrections or answers can be provided.

You will be periodically inspected by the NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action(s) against you. This could include issuance of a Notice of Violation, or Imposition of a Civil Penalty, or an Order Suspending, Modifying or Revoking Your License as specified in the NRC Enforcement Policy. The NRC Enforcement Policy is available at:
<http://www.nrc.gov/reading-rm/doc-collections/enforcement/>.

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).

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web Site at: <http://www.nrc.gov/about-nrc/safety-culture.html>. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure 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>.

Thank you for your cooperation.

Sincerely,



Tara Weidner, Senior Health Physicist
Medical and Licensing Assistance Branch
Division of Nuclear Materials Safety
Region I

License No. 06-30624-01
Docket No. 03035657
Mail Control No. 609594

Enclosure:
Amendment No. 7

cc: John Seibyl, M.D., RSO

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Thank you for your cooperation.

Sincerely,

Tara Weidner, Senior Health Physicist
Medical and Licensing Assistance Branch
Division of Nuclear Materials Safety
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cc: John Seibyl, M.D., RSO

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SUNSI Review Complete: Robert Gallagher

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DATE	<i>11/21/18</i>		<i>11/21/18</i>					

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