

Molecular NeuroImaging, LLC (MNI)

60 Temple Street
New Haven, CT 06511

Phone: 203-401-4333
Fax: 203-789-8037

Memorandum

P-7
MS16

Date: November 9, 2011

VIA Facsimile Mail: 610 337-5269

TO: 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

ATTN: Thomas Thompson

FROM: John P. Seibyl

RE: Amendment to License Number 06-30624-01
Mail Control No. 576256

03035657

The following is in response to NRC questions from 9 November 2011.


- 1) Did you only want to have the one Authorized User on the license? If not then additional information should be provided to support the training of any proposed Supervisors of byproduct materials use on the license. The cGMP training described would focus on manufacturing processes but not necessarily radiation safety.

At this time we are moving forward with having one authorized user on the license. If we decide in the future to have include additional authorized users we will provide information supporting the appropriate training of such individuals.

- 2) The quantity of I-125 requested in your application should be supported with additional information on monitoring for air activity released to the environment and the breathing air zone of the worker. Information should be provided that either limits the quantity and form to preclude any expected significant releases or describe your means of assuring the releases will be in compliance with the regulations. ***The quantity (i.e., 50 mCi) requested in our application represents the total possession amount. Typically no more than 5 mCi is used for one radiolabeling operation. Due to the half-life of I-125 there may be several productions decaying in storage. Operations with radioiodine with the potential for releasing air-borne radioiodine are carried out in a hood exhausted to a Flanders filter housing activated carbon and HEPA filters. The breathing zone and stack effluent air are monitored for radioiodine.***
- 3) In your application you have indicated proposed uses of byproduct materials in animals. If you will be administering byproduct materials to animals at your facilities then please address the issues identified in NUREG-1556, Vol. 7, Appendix H. ***The materials will not be administered to animals at our facility.***

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

Sincerely,



John P. Seibyl, M.D.

MNI President