

**Jason von Ehr
Sr. Health Physicist
Medical and Licensing Assistance Branch,
Division of Radiological Safety and Security,
U.S. Nuclear Regulatory Commission, Region I
475 Allendale Road, Suite 102
King of Prussia, PA 19406-1415**

2 June 2025

Dear Mr. von Ehr,

Pursuant to our phone conversation of May 23rd , this letter is a follow up of a request for additional information in support of an amendment to NRC license number 06-35755-01 issued to Xingimaging,LLC.

Particular information is sought regarding human research studies performed at our facility. By way of background, clinical research studies of neurodegenerative disease are performed in humans using radiopharmaceuticals and PET imaging to interrogate brain pathophysiology. This is useful as a biomarker to enhance the phenotypic accuracy of the recruited cohorts, as a biomarker of disease progression, and for assessing treatment efficacy. All studies are done in accordance with research ethics as provided by the Declaration of Helsinki and other international standards. Every protocol requires approval of a certified, independent investigational review board (IRB) which includes additional radiation safety review.

We utilize the investigational new drug (IND) mechanism under the FDA for regulatory oversight of investigational radiopharmaceuticals. Every patient at Xingimaging is seen as either a research participant or in evaluation for participation in research. We do not charge participants or bill insurance for our clinical research activities. The great bulk of imaging is in the brain with focus on Alzheimer's disease and Parkinson's disease.

Please let me know if this information is adequate to your needs. I'm happy to provide additional information and thank you very much for your close and careful read of our license and the guidance you have provided.

Yours sincerely,



John P. Seibyl,MD
Radiation Safety Officer
Authorized User
Xingimaging, LLC,
New Haven, CT