



December 05, 2022

Region I, Materials Licensing Assistance Branch
U.S. Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, PA 19406-1415

RE: License No. 07-16199-01
Docket No. 030-10568
Control No. 610746

Subject: Response to stipulations for Amendment No. 23

Dear Ms. Ullrich,
Please see below our point-by-point response to your email dated November 3, 2022.

1. **The CV for Dr. Yue indicates that he has worked only with fluorine-18, and none of the other radionuclides on the licenses. Unless there is additional information supporting his training and experience handling the other radionuclides, I can only approve him as an authorized user of F-18.**

Response: Please find attached a record of Dr. Yue's previous isotope handling experience consisting of F-18, Cu-64, Ga-68, C-11, I-125 and I-123 from prior employment (Pages 1-3).

2. **The ABR Certification may be acceptable to approve Dr. Nikam for use under Part 35, but it does not provide me with any information regarding the training and experience in performing research with any of the radionuclides listed on the -01 license. Please provide that information.**

Response: Dr. Nikam is listed as an Authorized User under Nemours Children's Hospital's clinical license (No. 07-16199-02) that encompasses clinical research. We therefore withdraw our request to include Dr. Nikam as AU under -01 license.

3. **License No. 07-16199-01 authorizes research and development pursuant to 10 CFR 30.4, only with those materials and for the purposes listed on the license. This license does NOT include human use studies. Please explain the activities that Drs. Yue and Nikam will be performing under this license.**

Response: We affirm that human subjects' studies or research will NOT be conducted under License No. 07-16199-01. Please see attached document (Pages 4-5) detailing the use of radioactive material for preclinical research.



Sincerely,

Vicky L. Funanage, Ph.D.

Vicky L. Funanage, Ph.D.
Executive Director, Research
Nemours Children's Hospital, Delaware
1600 Rockland Road
Wilmington, DE 19803

cc. Sonali P. Barwe, Ph.D., Radiation Safety Officer