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February 1, 2016

Ms. Patricia Pelke
Materials Licensing Branch
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

RE: Materials License 21-11315-04
Request to amend license to remove all current authorized users and delegate new authorized users.

Dear Ms. Pelke,

MPI Research is requesting an amendment to Materials License 21-11315-04 as described below. The request addresses the removal of all current authorized users on our license and the addition of three new authorized users.

MPI Research has legally dissolved its partnership with 3D Imaging, the company that until recently handled operation of our Siemens Eclipse RDS cyclotron and holds four authorized user positions on our materials production license. In light of this partnership dissolution, MPI wishes to remove Dr. Marc Berridge, Mr. Scott Apana, Ms. Christina Carpenter Brown, and Ms. Destiny Weems as authorized users on our license. Concurrently, we also request to add Dr. Gwendolyn Marriner and Mr. Jason Roe as authorized users on our production license. Dr. Marriner and Mr. Roe were 3DI employees but are now MPI employees. A summary of their qualifications, training, and experience is included as Attachment 1.

Please contact me at 269-668-3336 extension 2050 if there are any questions, or if further information is required.

Best regards,

A handwritten signature in black ink, appearing to read "R. Granberg", with a long horizontal stroke extending to the right.

Richard Granberg
Radiation Safety Officer
MPI Research, Inc.

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Attachment 1

Gwendolyn Marriner, B.S., Ph.D.

Dr. Marriner holds a B.S. in chemistry from University of Illinois at Urbana-Champaign and earned a Ph.D. in organic chemistry at the University of Texas at Austin. Dr. Marriner received a post-doctoral appointment at the National Institutes of Health in Bethesda, MD where she completed radiation safety training and continued her studies in tuberculosis selective radiotracer development. She worked for 6 years under the direct supervision of NIH authorized users, handling the same quantities, types, and forms of radioactive material for the same or similar uses that she will be supervising as an authorized user at MPI. She joined MPI Research in October 2015 as an employee of 3D Imaging, where she completed radiation safety training courses through both companies. Between her years at NIH, 3DI, and now having been hired in by MPI as a senior radiochemist, Dr. Marriner has more than the required 40 hours of job-specific radiation safety training in radioisotope production, safe handling of large quantities of high-energy radioactive material, and other authorized user activities and responsibilities. She has advanced training and experience with radioactivity, radioactive materials, and synthesis and radiolabeling of small molecules using C-11 and F-18 in quantities of up to several Curies at a time. Additionally, she has basic training and experience in Zr-89 and NaI-124 labeling of large biomolecules; she has also observed techniques using Cu-64 and Zr-89 radiolabeling of large molecules and RGD-type peptides. Until the dissolution of our partnership with 3DI, she was completing basic cyclotron operator training on MPI's Siemens Eclipse RDS cyclotron under the direction of Dr. Marc Berridge and other named authorized users; to date, she has operated our cyclotron under authorized supervision for a period of 3 months and totaling 25 cyclotron run-hours.

Jason Roe, A.S., B.S.

Mr. Roe holds an A.S. in chemical process technology from Delta College and a B.S. in biochemistry from Central Michigan University. He joined MPI Research in June 2015 upon receiving a post-baccalaureate appointment with 3D Imaging. He completed radiation safety training at both MPI and 3DI. Mr. Roe has training and experience with synthesis of PET isotopes such as C-11 and F-18 in quantities of up to several Curies at a time. He also has training and experience with radiolabeling small molecules using Cu-64, NaI-124, and Zr-89. He completed a 2-week basic and advanced training course on the Siemens Eclipse 11 MeV proton-only cyclotron at 3D Imaging in Little Rock, AR in June 2015, which meets MPI's license stipulation for authorized users of at least 40 hours of radiation safety training specific to cyclotron operations, radiosyntheses, and other activities for which authorized users are responsible. He has worked with our Siemens Eclipse RDS cyclotron here at MPI under the supervision of our currently-named authorized users for 7 months totaling over 500 cyclotron run-hours. Mr. Roe meets the training and experience requirements of the State of Michigan for an authorized operator of radiation-producing machines and is an MPI authorized operator of our Siemens Eclipse RDS cyclotron.

MPI
RESEARCH

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