



DANIELLE SHEEN, EXECUTIVE DIRECTOR

May 14, 2018

Bryan A. Parker  
Senior Health Physicist  
Materials Licensing Branch  
U.S. Nuclear Regulatory Commission, Region III  
2443 Warrenville Road, Suite 210  
Lisle, IL 60532-4352

RE: **Additional Information for the Amendment to Materials License No. 21-00215-04  
(Ac-225)**

Dear Mr. Parker:

Per our conference call on Friday, April 27, 2018, below are responses to your questions regarding the requested addition of actinium-225 (Ac-225) to the University of Michigan (U-M) broad scope license.

**Q1:** Where will the Ac-225 come from?

**A1:** Currently, either Oak Ridge National Labs or TRIUMF in Canada (<http://www.triumf.ca/home/about-triumf>)

**Q2:** Will the Ac-225 be obtained as a 'unit dose' or will there be manipulation of it in a Nuclear Pharmacy or laboratory setting?

**A2:** For animal use, the U-M will obtain the Ac-225 and will have to radiolabel a proper precursor (ex: PSMA-617) in one of our Nuclear Medicine research labs.

**Q3:** Will a specific activity (uCi or mCi) be administered to an animal or human? If so, what activity to an animal or human is expected to be administered?

**A3:** The Nuclear Medicine physician researcher is planning on using Ac-225 in animals (tumor bearing mice) as Ac-225 (PSMA). The doses are not certain at this time as it will be determined in planned experiments. Generally speaking, the doses will likely be up to about 20 nCi/g, thus 600 nCi per 30 gram mouse. Ten mice are expected to be treated at any one point in time. At this time, the researcher intends to have an order limit of 0.5 mCi; and, a maximum amount per year of 2 mCi for animal research

There is no immediate intent to administer Ac-225 to humans; although, that will likely be the end goal in the future.

Thank you again for your time, effort, and consideration of this amendment request. Please do not hesitate to contact me at Radiation Safety Service / EHS (734) 647-2251 or (734) 764-6200 or [drisc@umich.edu](mailto:drisc@umich.edu) should you have any questions or comments regarding this correspondence.

Sincerely,

Mark L. Driscoll  
Director / Radiation Safety Officer  
Radiation Safety Service / EHS