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DANIELLE SHEEN, INTERIM EXECUTIVE DIRECTOR

April 11, 2018

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

Materials Licensing:

The University of Michigan (U-M) is requesting an amendment to Materials License No. 21-00215-04 (Broad Scope License) to add Actinium-225 (Ac-225) for medical and other research uses.

The U-M proposes to amend Sections 6, 7, 8, and 9 of the current license to include:

6. Byproduct Material	7. Chemical/Physical Form	8. Maximum Possession
Actinium-225	Any	20 millicuries

Section 9 - Authorized Use

For use in medical diagnosis, therapy, and research in humans. Research and development as defined in 10 CFR 30.4, including animal studies; instrument calibration; educational instruction or demonstration; dosimeter or instrument testing; and standardization and calibration.

Section 10 - Location of Use

U-M Ann Arbor medical campus or at other currently licensed locations as approved by the Radiation Policy Committee (RPC) in terms of adequacy for intended and proposed uses.

Intended Uses

The principal reason for the amendment request is to receive and use Ac-225 (Atomic # 89) to initiate studies on the use and efficacy of Ac-225 radiopharmaceuticals including Ac-225 PSMA-617. The material will be used in accordance with approvals from the U-M Radioactive Drug Research Committee / Subcommittee of the Human Use of Radioisotopes (RDRC / SHUR) or RPC as appropriate. Clinical uses may develop as an outcome of these studies. All therapeutic medical uses on patients or subjects will be under the supervision of Authorized Users in accordance with the requirements of 10 CFR 35.300.

In addition, the U-M may initiate other research efforts using Ac-225 for medical and non-medical uses, including general biological studies in animals or other potential research uses. Finally, the U-M may receive and use Ac-225 for testing or assessing instrumentation used incidental to other research or as part of other uses relevant to the safe handling and detection of such material.

Licensee Resources

Actinium-225 is an alpha emitter with a half-life of 10 days. Radioactive progeny are short-lived and possession of the progeny will be inherent to the possession of the parent radionuclide. The U-M has substantial experience in the receipt, safe handling, and disposal of alpha-emitting radionuclides under its other NRC license (Materials License No. SNM-179), including existing provisions of Materials License No. 21-00215-04. The U-M is adequately equipped to monitor and survey for alpha contamination and has a radiation safety staff experienced in preparing safety assessments and evaluations for alpha-emitting materials for review and approval by the Radiation Safety Officer, RPC, and RDRC/SHUR. The U-M has trained and experienced responders capable of addressing and remediating any radiological incident that may arise from the use of Ac-225.

Training and Use

U-M authorized users and personnel involved in the handling and/or administration of vendor-supplied radiopharmaceuticals containing Ac-225 will complete radiopharmaceutical-specific training as coordinated by the clinical sponsor/vendor or will complete training provided by the radiation safety staff in the appropriate handling and use of alpha-emitting radionuclides. This will include instruction on techniques to minimize contamination, general radiation safety precautions, and drug handling and administration practices. U-M personnel handling Ac-225 will use standard safety precautions, follow sponsor/vendor instructions, and comply with existing license conditions and U-M policies concerning the use of unsealed radioactive materials, including the completion of any additional radiation safety training deemed necessary by the RSO or RPC.

Dosage will be in accordance with sponsor/vendor instructions and verified in the manner recommended by the sponsor/vendor. After the radiopharmaceutical is administered, the external exposure hazard will be minimal and the patient/subject may be released in accordance with 10 CFR 35.75. Instructions will be provided to patients/subjects and their caregivers regarding radiological safety and hygiene precautions. Equipment and materials used in the preparation and administration of the radiopharmaceutical will be treated as radioactive waste and held for decay prior to disposal in accordance with 10 CFR 35.92.

Other medical and non-medical uses will be evaluated and approved by the RDRC/SHUR and/or RPC as appropriate with due consideration to safety precautions for handling, use, and disposal.

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

Sincerely,

Mark L. Driscoll

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

MLD/mld
NRCLicenseAmendmentAc-225

cc: Danielle Sheen, CIH, Interim Executive Director, Environment, Health & Safety
Ruthann Nichols, Ph.D., Chair, Radiation Policy Committee
Materials License (Broad Scope) No. 21-00215-04 Files

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