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DANIELLE SHEEN, EXECUTIVE DIRECTOR

February 6, 2025

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

RE: **Amendment Request**
University of Michigan, Byproduct Materials License No. 21-00215-04
Docket No. 030-01988

Materials Licensing:

The University of Michigan (U-M) requests to amend the subject broad scope license to add Astatine-211 (At-211) for medical and other research use:

6. Astatine-211
7. Any
8. 120 mCi
9. 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.

There is no change in location of use; the material will be used and stored only at facilities located on the U-M campus or other licensed locations, as approved for the proposed use by the U-M Radiation Policy Committee (RPC).

Intended Uses

At-211 (atomic number 85) is an alpha emitter with half-life ($T_{½}$) of 7.2 hours. Depending on the manner of production, trace At-210 contaminant ($T_{½}$ = 8.1 hours) may be present in the product received (estimated by one supplier to be <1% of total At-211 activity). Possession of At-210 is covered by Subitem 6AG.

The principal reason for this amendment request is to use At-211 to initiate studies on the use and efficacy of At-211 radiopharmaceuticals, including but not limited to ZA-001 (At-211 [YF2]). Radiopharmaceuticals will be used in accordance with approvals by the RPC's Radioactive Drug Research Committee / Subcommittee on the Human Use of Radioisotopes (RDRC/SHUR), as appropriate. Clinical uses may develop as an outcome of these studies. All medical uses on patients or research subjects will be under the supervision of an RPC-approved Authorized User physician, in accordance with 10 CFR 35.300 and 35.27.

U-M may initiate other research efforts using At-211 for medical and non-medical uses, including general biological studies in animals. U-M may also use At-211 for testing or assessing instrumentation used incidental to other research or as part of other uses relevant to the safe handling and detection of the material.

Licensee Resources

U-M has substantial experience in the safe handling and disposal of alpha-emitting radionuclides under existing provisions of the subject license. U-M is equipped to monitor for alpha contamination, has nuclear medicine staff experienced in preparation, safe handling, and administration of alpha-emitting radiopharmaceuticals, and has radiation safety staff experienced in preparing safety assessments and evaluations for alpha-emitting radionuclides for review and approval by the Radiation Safety Officer (RSO) and RPC. U-M also has trained and experienced hazardous materials responders capable of addressing and remediating any incident that may arise from the use of At-211.

Training and Use

General information about training for individuals working in restricted areas, facilities and equipment, the U-M radiation safety program, waste management, and decommissioning is provided in the license application document (February 24, 2011).

Nuclear medicine Authorized User physicians and other personnel involved in the handling and administration of At-211 radiopharmaceuticals will complete radiopharmaceutical-specific training as required by the clinical sponsor/vendor and/or training in the safe handling and use of alpha-emitting radionuclides provided by radiation safety staff. This will include instruction on techniques to minimize contamination, general radiation safety precautions, and drug handling and administration practices. Personnel handling At-211 will use standard safety precautions, follow sponsor/vendor instructions, and comply with existing license conditions and U-M policies governing the use of radioactive materials, including the completion of any safety training deemed necessary by the RSO or RPC.

Administered dosages will be in accordance with sponsor/vendor instructions and verified in the manner recommended by the sponsor/vendor, to comply with 10 CFR 35.63. After administration, the external exposure hazard will be minimal and the patient/subject may be released in accordance with 10 CFR 35.75. Oral or written instructions will be provided to patients/subjects and their caregivers regarding radiological safety and hygiene precautions. Waste materials used in the preparation and administration of radiopharmaceuticals will be sent to a licensed radioactive waste broker.

Future medical and non-medical uses of At-211 will be evaluated and approved by the RPC or RDRC/SHUR, as appropriate, after consideration of adequate facilities and safety precautions for handling, use, and disposal.

Thank you for your consideration of this amendment request. Please contact me [(734) 647-2251 / kfisch@umich.edu] if you have any questions or comments.

Sincerely,

Digitally signed by Karl W. Fischer
Date: 2025.02.06 15:05:52 -05'00'

Karl W. Fischer, CHP
Director / Radiation Safety Officer
Radiation Safety Service / EHS

cc: Peter Scott, Ph.D., Chair, Radiation Policy Committee
Danielle Sheen, CIH, Executive Director, Environment, Health & Safety
Materials License No. 21-00215-04 Files

Martha Pavon

From: Tammy Tomczak
Sent: Thursday, February 6, 2025 2:31 PM
To: Martha Pavon
Cc: Sandy Pavon
Subject: FW: License amendment request (21-00215-04)
Attachments: Amendment 2025-02-06 At-211.pdf

Hi Martha 😊

Can you please add the attached to ADAMS?

Thank you!!

Tammy

From: Fischer, Karl <kfisch@med.umich.edu>
Sent: Thursday, February 6, 2025 2:10 PM
To: R3-DRSSMail Resource <R3-DRSSMail.Resource@nrc.gov>
Cc: Scott, Peter <pjhscott@med.umich.edu>; Danielle Sheen <drsheen@umich.edu>
Subject: [External_Sender] License amendment request (21-00215-04)

Materials Licensing:

Please see the attached amendment request. At your convenience, please confirm receipt.

Thank you,

Karl Fischer, CHP
Director / Radiation Safety Officer
Radiation Safety Service / EHS
kfisch@umich.edu
734·647·2251

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