UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

June 12, 2023

Patrick R. Wright, CHP
Radiation Safety Officer
Michigan State University
Office of Environmental Health & Safety
4000 Collins Rd.
Ste. B20
Lansing, MI 48910

SUBJECT: ADDITIONAL INFORMATION NEEDED REGARDING MICHIGAN STATE UNIVERSITY LICENSE AMENDMENT REQUEST FOR NRC LICENSE NO. 21-00021-29

Dear Patrick Wright:

Our office has reviewed the April 27, 2023 request for NRC to amend NRC License No. 21-00021-29. Upon review, our office has determined that additional information is required to issue the license as outlined below. Please provide your response by no later than Friday, June 30, 2023.

Request 1 – Removal of Materials Authorized by Items 6.N. – 6.P.

1. Provide copies of final leak test records for all sealed sources previously possessed under license material authorizations 6.N. – 6.P.

2. Provide final transfer or waste disposal records for all licensed material previously possessed under material authorizations 6.N. – 6.P.

3. Provide a confirmatory statement affirming that the records provided in response to the previous two questions account for all licensed material previously possessed under the above referenced licensed authorizations.

Request 2 – Amendment of Materials Authorization 6.F. to allow for increased quantities of licensed materials with half-lives exceeding 120 days.

4. Provide an originally signed version of the Statement of Intent. The Statement of Intent may be submitted to our Region III office through regular mail.

5. Decommissioning Funding Plans (DFP) should provide specific facility descriptions for areas where long-lived radioisotopes are used and stored. Your application lists the radiochemistry wing of the chemistry building and portions of the biochemistry building as the most likely locations for long-lived contamination. Please provide more detailed information for these locations, as well as any other locations considered in your

analysis, to include the facility addresses, room numbers, and facility diagrams of the areas where long-lived radioisotopes are used and stored.

I understand from our conversation today that the submitted decommissioning funding plan accounts for all licensed material with a half-life of greater than 10 days. Your response to this item does not need to include information on facilities where radionuclides with half-lives of less than 120 days are exclusively used.

6. This amendment application includes a request for a Germanium-68/Gallium-68 generator, but the provided DFP does not appear to account for the cost of returning the generator to the manufacturer as described. Please provide a DFP that accounts for the expenses associated with return of the generator system to the manufacturer.

7. The provided outline of normal operations use in Section 2.2 of the DFP highlights the use of controlled and in some cases filtered exhaust systems and describes the isolation features of these systems for use in an emergency event. The provided DFP does not allocate any staff time to be spent characterizing, surveying, decontaminating, or performing other associated tasks for these exhaust and filtration systems. Exhaust and filtration components also do not appear to be accounted for in the evaluation of facility components that will require disposal as contaminated waste. Please describe why these exhaust and filtration systems were not accounted for when determining the cost inputs into the DFP, or revise the DFP to include these components in the cost evaluation.

8. Please clarify if all costs associated with offsite shipping, compaction, and disposal of contaminated waste in a near-surface waste facility are accounted for in the $14.30/kg assumed expense for low level waste and the described fixed costs associated with drum waste as described in Table 3.3.1b: “Waste Disposal Costs.”

Request 3 – Addition of Ge-68/Ga-68 Generators

9. Please clarify that the requested use for the Ge-68/Ga-68 generator is for preparation of Ga-68 for use in research and development as defined in 10 CFR 30.4, including animal studies. Please confirm that Ge-68 will not be used in animal studies.

10. Please review the attached Appendix A and provide the described commitments regarding use of the Ge-68/Ga-68 generator for research and development activities.

Request 4 – Addition of Byproduct Material to be Authorized in License Items 6.V. – 6.Z.

11. Please confirm that the long-lived radioisotopes requested in Items 6.V. - 6.Z. will not be used in animal studies.

12. Please describe the significance of the different colored spaces on the facility diagram provided.

In accordance with Title 10 Code of Federal Regulations 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Sincerely,

Laura B. Cender Digitally signed by Laura B. Cender
Date: 2023.06.12 15:58:19 -05'00'

Laura B. Cender
Health Physicist
Materials Licensing Branch

License No. 13-35179-02
Docket No. 030-38841

Attachment A – Germanium-68/Gallium-68 Generator Use

Provide response statements committing to the following:

- Providing instructions and/or training on the manufacturer's procedures to all individuals involved in Ge-68/Ga-68 generator use, commensurate with the individual's duties to be performed;

- Not opening, breaching, or physically modifying the Ge-68/Ga-68 generator in any way;

- Following the manufacturer's procedures, including: generator set-up; generator elution; Ge-68 breakthrough testing and frequency when in use; and final disposition;

- Eluting the generator in accordance with the manufacturer's stated frequency and procedures to minimize the concentration of Ge-68 in the eluate;

- Not using an expired generators for preparation of materials that will be used in research and development activities, including animal studies;

- Only using a generator that has a clearly marked expiration date;

- After installation, performing the conditioning procedure following the manufacturer's instructions properly disposing of the conditioning eluates prior to the first use of eluate for testing or research and development use;

- Developing and implementing written procedures for the determination of breakthrough that will detect whether the eluate exceeds the manufacturer's recommended breakthrough limit;

- During the course of breakthrough testing, if the eluate exceeds the manufacturer's breakthrough limits, the eluate will not be administered in animal studies;

- Maintaining a record of the breakthrough tests for at least 3 years. These tests should include the ratio of the measured activity of Ge-68 per Ga-68 corrected for the time of elution, time and date of the elution, time and date of the measurement, and the name of the individual who made the measurement;

- Notifying by telephone the NRC Operations Center (301-816-5100) and the manufacturer/distributor of the generator within 7 calendar days after discovery of a generator that is unable to meet the manufacturer's stated Ge-68 breakthrough limits. A failed generator effective date will be when the breakthrough calculation was performed, which should be no more than 7 days from the date of the previous breakthrough calculation;

- Include in the report to the NRC Operations Center the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects; when the manufacturer/distributor was notified; and the action taken;

- Sending a written report to the appropriate NRC Regional Office within 30 days after discovery of a generator that is unable to meet the manufacturer's stated breakthrough limits of Ge-68 on multiple occasions rendering the generator unusable;

- Include in the written report the action taken by the licensee; probable cause and assessment of failure in the licensee's equipment, procedures or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination, and the information in the telephone report made as described above;

- Conduct surveys of all areas of licensed material use, including the generator storage and kit preparation areas, for contamination each day of use; and

- Developing and implementing written emergency procedures for leaking or damaged generators;