UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

September 16, 2022

John A. Zehner, R.Ph.
Radiation Safety Officer
NukeMed Inc., dba Spectron Rx
9550 Zionsville Rd.
Indianapolis, IN 46268

SUBJECT: AMENDMENT NO. 12 TO RADIOACTIVE MATERIALS LICENSE FOR NUKEMED INC. DBA SPECTRON RX, NRC LICENSE NO. 13-32726-01MD

Dear Mr. Zehner:

Enclosed is Amendment No. 12 to NukeMed Inc., dba Spectron Rx's (your) U.S. Nuclear Regulatory Commission (NRC) Materials License No. 13-32726-01MD, in accordance with your August 17, 2022 letter, requesting to add a new location of use, with some limitations. First, the authorization for the new 3358 W 800 S, Bunker Hill, Indiana location (3358 W 800 S location) of use has been limited to research and development as defined in Title 10 of the *Code of Federal Regulations* (10 CFR) Section 30.4 and for the calibration and checking of the licensee's instruments. In addition, the location of use has been limited to possession and use of licensed materials below quantities requiring decommissioning financial assurance.

Your letter is available electronically from the NRC's Agencywide Documents Access and Management System (ADAMS) at Accession No. ML22230B894. The NRC's ADAMS is accessible from the NRC Web site at https://www.nrc.gov/reading-rm/adams.html.

Additional information is needed to expand the authorizations for the new 3358 W 800 S location of use to include radiopharmacy use, including submission of an application for a license to possess and transfer accelerator-produced materials to the radiopharmacy, as shown in the diagram attached to your letter. A description of information needed is outlined in this letter.

Additional information is also needed, in accordance with 10 CFR 30.35, regarding your decommissioning cost estimate and funding plan for the new 3358 W 800 S location of use. We will contact you separately regarding our review of the decommissioning cost estimate and funding plan for this new location as well as for the other locations of use authorized, under your license.

Please note that, if the pharmacy to be added is to be associated with transfer lines from an accelerator production area, an application for a new accelerator production possession license should be submitted concurrent with any request to amend your license to include transfer lines and receiving hot cells. In the alternative, if no accelerator production license application will be submitted, updated facility diagrams and described uses of radioactive materials submitted should clarify that any references to transfer lines and an accelerator production facility are for future use only, and not meant to be authorized at this time.

**The enclosure to this letter contains sensitive security-related information.
When separated from this cover letter this letter is uncontrolled.**

Regarding your NRC License No. 13-32726-01MD, please provide the following information regarding authorized uses for the proposed new 3358 W 800 S location:

RADIOACTIVE MATERIAL AND PURPOSE OF USE:

The application is unclear as to the radioactive material to be used at the proposed location.

1. Please describe any proposed uses of fluorine-18, other accelerator-produced radionuclides, iodine-123, iodine-123, iodine-131, lutetium-177, germanium-68, thorium-228, actinium-225, other alpha-emitting radionuclides, and any other potentially volatile radionuclides, for the proposed new 3358 W 800 S location.

2. Please describe any chemical synthesis or radioiodination use of licensed materials that will be conducted at the proposed new 3358 W 800 S location, and the maximum possession limit for iodine-131.

3. Please clarify any use of thorium-228 at the proposed new 3358 W 800 S location.

4. Please clarify whether germanium-68/gallium-68 generators will be prepared or distributed, and the maximum possession limit for the proposed new 3358 W 800 S location.

5. In accordance with 10 CFR 30.35(i), if overall maximum possession limits for the proposed new 3358 W 800 S location will exceed quantities in excess of 10 CFR 30.72, “Schedule C—Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release,” please provide either, specifically for the proposed new 3358 W 800 S location: (a) an evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials would not exceed 1 rem effective dose equivalent or 5 rems to the thyroid or (b) an emergency plan for responding to the release of radioactive material. If actual possession limits for the proposed new 3358 W 800 S location are lower than those exceeding 10 CFR 30.72 limits, please specify those. If actual possession limits exceed 10 CFR 30.72, but actual possession will be maintained below 10 CFR 30.72, please confirm the same.

FACILITIES AND EQUIPMENT:

The description of the licensee's facilities at the proposed new 3358 W 800 S location - including the facility diagram - lacks sufficient detail or is too small to assess shielding for areas of radioactive materials use and activities in areas contiguous to that use. Expanded descriptions of the area(s) assigned for the receipt, storage, preparation - including compounding of measurement, and distribution of (i) iodine-123, iodine-124, and iodine-131 (if any); (ii) lutetium-177; (iii) actinium-225; (iv) germanium-68/gallium-68 generators (if any); (v) thorium-228; (vi) fluorine-18; (vii) any other radionuclides to be received via transfer lines from an accelerator production facility; (viii) any other radionuclides; (ix) shipping and receiving; (x) QC labs on the first and second floors; and the (xi) location(s) for radioactive iodine-123, iodine-124, and iodine-131 waste storage and for waste storage and disposal of other radionuclides are needed, as noted below:

6. For iodine-123, iodine-124, iodine-131, lutetium-177, actinium-225, germanium-68/gallium-68 generators, thorium-228, fluorine-18, and any other significant radionuclides (or groups of radionuclides), if applicable, please provide updated facility diagram or diagrams, showing

locations of receiving, incoming transfer lines (from any attached accelerator production facility), hoods, glove boxes, storage cabinets, dispensing areas, waste storage, any sinks used for sewerage disposal, and disposal locations.

a. For ventilation systems, including glove boxes and fume hoods, please describe pertinent airflow rates, area differential pressures, filtration equipment, and monitoring systems for the use or storage of licensed radioactive materials that are likely to become airborne, such as compounding radioiodine capsules, dispensing radioiodine solutions, or other radionuclide manipulation and synthesis

b. If any specifications of equipment are identical to those at other authorized locations of use, it is acceptable to confirm the same, in lieu of a comprehensive description. In the alternative, for the proposed new 3358 W 800 S location, please provide specific safety equipment details for the new Indianapolis, Indiana facility.

c. For each glove box, fume hood, transfer line, or hot cell, etc., at the proposed new 3358 W 800 S location, please show or describe how and where it is connected to the main ventilation or other exhaust system.

d. For the proposed new 3358 W 800 S location, please show where filtration equipment will be placed and where the airborne radiation levels will be monitored.

e. For the proposed new 3358 W 800 S location, please show any additional details necessary to demonstrate that the ventilation system is adequate for all radionuclides to be used under the license

7. The revised facility diagram, or diagrams, for the proposed new 3358 W 800 S location should be drawn to the scale of 8 1/2 " x 11" sheets of paper, showing dimensions and details for areas where radioactive materials will be used or stored. The diagram or diagrams should clearly delineate areas to be authorized under the referenced license, or requested to be authorized under a new accelerator production possession license, if any. The facility diagram also should show what is above, below and adjacent to the area where the radioactive materials will be compounded, dispensed, and stored.

8. The facility diagram for the proposed new 3358 W 800 S location should show sufficient detail to show shielding specifically for the compounding of radioiodine or other radiation safety items.

9. The facility diagram or the proposed new 3358 W 800 S location should be in sufficient detail to indicate locations of shielding and the proximity of radiation sources- to unrestricted areas.

10. Please describe any key safety equipment and security features or show those in the diagrams for the use areas at the proposed new 3358 W 800 S location.

VENTILATION SYSTEMS/EXHAUST:

The description of the licensee's facilities for the proposed new 3358 W 800 S location - including the facility diagram - lacks sufficient detail or is too small to assess adequacy of ventilation systems, etc. In addition, verification (e.g., calculation or other evaluation

demonstrating that flow rates are adequate for procedures as' proposed) that the ventilation systems ensure that effluents are ALARA, are within the dose limits of 10 CFR 20.1301, and are within constraints for air emissions established under 10 CFR 20.1101(d).

11. Please provide an updated facility diagram of ventilation system for the proposed new 3358 W 800 S location, drawn to scale and to fit on an 8.5-inch by 11-inch sheet of paper, showing details and additional information as requested in NUREG 1556, Vol. 13, rev. 2, pp. 8-26 to 8-29 and Appendix B, pp. B-14 to B-15. The diagram should show locations of sampling for radioiodine and other radionuclides, and whether any locations for particulate or other filtering are prior to or subsequent to the sampling location.

12. Please include a calculation using either MicroShield or the U.S. EPA's COMPLY code, clearly indicating the stack height and any other assumptions, and the calculated maximum emissions for each radionuclide expected to be used, under the license. If the previously submitted calculation contains sufficient detail for the proposed new 3358 W 800 S location, it may be resubmitted as part of your resubmitted request.

13. Please provide the stack height for the proposed new 3358 W 800 S location, and describe whether the release would be expected to be less than 10 mrem, at the release point, given any and all uses to be authorized. If the 10 mrem requirement cannot be demonstrated in the calculation, please state the distance of the nearest air intake from the stack. Please also describe the area adjacent to the release stack, including any nearby facilities, parking areas, or other locations with potential occupancy.

14. If the proposed new 3358 W 800 S location will be associated with an area authorized for possession of accelerator-produced radionuclides, please clarify how the ventilation systems are separate or combined.

15. For the proposed new 3358 W 800 S location, please indicate the maximum allowable concentration – as a percentage of the Derived Air Concentrations (DACs) – for licensed material to be used under the license, in the event of an accidental release. In the event of such release, please confirm that the licensee will wait the necessary amount of time – determined based on a calculation of time required to reduce the concentrations using all necessary inputs – prior to allowing people to reenter the area of use.

SAFETY EQUIPMENT FOR ALPHA-EMITTING RADIONUCLIDE DETECTION:

The description of equipment to be maintained at the proposed new 3358 W 800 S location was unclear as to whether equipment suitable for detecting alpha-emitting radionuclides will be available.

16. For the proposed new 3358 W 800 S location, please describe equipment to be available for the detection of actinium-225 or other alpha-emitter contamination. Please confirm that the alpha detection equipment on hand will have adequate sensitivity to detect actinium-225 in air or on surfaces. If a gamma detector is used, please confirm that an adequate correction factor will be used for alpha activity measurements.

PHARMACY LICENSE:

In accordance with 10 CFR 32.72(a)(2), evidence of the applicant's ability to operate as a commercial radiopharmacy, at a specific location, must be included with an application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing byproduct material for use by persons authorized pursuant to 10 CFR Part 35. No such documentation for the proposed new 3358 W 800 S location was included with the request.

17. For the proposed new 3358 W 800 S location to be authorized for radiopharmacy use in Condition No. 10 to the licensee's commercial radiopharmacy radioactive materials license, in accordance with 10 CFR 32.72, please provide a copy of the licensee's registration or license from a State Board of Pharmacy as a pharmacy, as requested in NUREG 1556, Vol. 13, rev. 2, pp. 8-26 to 8-27 and Appendix B, p. B-14. If such license is not available, please explain.

Please review the enclosed document carefully, and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. NRC Region III Office at 630-829-9892 so that we may provide appropriate corrections and answers.

An environmental assessment for this action is not required because this action is categorically excluded under 10 CFR 51.22(c).

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation; or imposition of a civil penalty; or an Order suspending, modifying, or revoking your license as specified in the NRC Enforcement Policy. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance that NRC expects of its licensees.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's expectations for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at https://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

NRC's Regulatory Issue Summary (RIS) RIS 2005-31 provides criteria to identify security-related sensitive information and guidance for handling and marking of such documents. This ensures that potentially sensitive information is not made publicly available through NRC's ADAMS, the NRC's electronic document system. Pursuant to NRC's RIS 2005-31 and in accordance with 10 CFR 2.390 of the NRC's "Rules of Practice and Procedure," the enclosed license document is exempt from public disclosure because its disclosure to unauthorized individuals could present a security vulnerability. The RIS may be located on the NRC's Generic Communications Web page under "Regulatory Issue Summaries" at https://www.nrc.gov/reading-rm/doc-collections/gen-comm/, and the link for frequently asked questions regarding protection of security-related sensitive information may be located at https://www.nrc.gov/reading-rm/sensitive-info/faq.html.

A copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's ADAMS.

Sincerely,

Sara A. Forster

Digitally signed by Sara A. Forster
Date: 2022.09.16 14:33:17 -05'00'

Sara A. Forster, M.S.
Health Physicist
Materials Licensing Branch
Division of Nuclear Materials Safety

Docket No.: 030-38044
License No.: 13-32726-01MD

Control No.: 632185

Enclosure: Amendment No. 12 to NRC
License No. 13-32726-01MD