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

November 17, 2022

John A. Zehner, R.Ph.
CEO and Radiation Safety Officer
NukeMed Inc.
d/b/a SpectronRx
9550 Zionsville Rd.
Indianapolis, IN 46268

Dear Dr. Zehner:

This letter is in reference to your request dated September 21, 2022, to amend your U.S. Nuclear Regulatory Commission (NRC) Materials License No. 13-32726-01.

The U.S. NRC's guidance document for your type of license, which I refer to below as "the guidance," is NUREG-1556, Volume 13, Rev. 2, dated March 2019, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses." This guidance is available on the U.S. NRC website at: https://www.nrc.gov/docs/ML1907/ML19079A207.pdf

Upon review of the request, I identified the following areas requiring additional or clarifying information:

1. Section 8.5.1, "Sealed and Unsealed Byproduct Material," of the guidance, identifies that the applicant must specify each radionuclide requested, the form, and the maximum activity to be possessed at any one time.

   Your amendment request identified additional radionuclides, including tungsten-188, rhenium-188, lead-203, lead-212, neptunium-237, americium-241 and curium-244, which you would like to add to your license.

   Identify the facilities where these additional radionuclides will be possessed and used.

2. Section 8.5.1, "Sealed and Unsealed Byproduct Material," of the guidance, identifies that the applicant must specify each radionuclide requested, the form, and the maximum activity to be possessed at any one time.

   Your request does not clearly identify the radionuclides, form and quantities to be possessed and used at the proposed additional facility.

   Please identify the radionuclides, including types and quantities, that will be utilized at the proposed additional facility. For potentially volatile materials (e.g., iodine-123, I-131), identify whether the materials will be manipulated at the proposed facility and if so, depict where the manipulation occurs (i.e., a fume hood or a hot cell).

3. Section 8.7.2, “Authorized Nuclear Pharmacist (ANP),” of the guidance specifies that the Authorized Nuclear Pharmacist must be licensed by the applicable state pharmacy licensing board.

   A check with the Connecticut Department of Consumer Protection’s Commission of Pharmacy revealed that the license for Beth M. Kraemer, R.Ph., is currently pending.

   Please identify when the proposed Authorized Nuclear Pharmacist’s license has been reviewed and approved by the state licensing board.

4. Section 8.9.1, “Facilities and Equipment for Radiopharmacies,” of the guidance states that a commercial radiopharmacy must be licensed by the applicable state pharmacy licensing board.

   You have requested authorization for an additional pharmacy facility in Danbury, Connecticut. A check with the Connecticut Department of Consumer Protection’s Commission of Pharmacy was not successful in verifying that your additional facility is appropriately licensed.

   Submit a copy of the state pharmacy license issued by the state pharmacy licensing board. If the pharmacy license has not been issued, you may provide it later, but before the requested licensed amendment is issued.

5. Section 8.9.1, “Facilities and Equipment for Radiopharmacies,” of the guidance, identifies that applicants must provide the NRC with documentation demonstrating that their facilities and equipment provide sufficient engineering controls and barriers to protect the health and safety of the public and their employees.

   Your application does not identify the safety equipment that will be available at the proposed additional facility.

   Please identify the safety equipment that will be available at the proposed additional facility (e.g., including survey meters and probes, hand and foot monitors, breathing zone air sampling equipment, etc.). Note that radiation detection instruments must have adequate detection efficiency for the types of radionuclides, including alpha emitters, to be used.

6. Section 8.9.1, “Facilities and Equipment for Radiopharmacies,” of the guidance specifies that a sufficient facility description must be provided to demonstrate that the proposed facility and equipment provide adequate engineering controls and barriers to protect the health and safety of the public and your workers.

   An adequate facility diagram and description must include the following:

   - descriptions of the area(s) assigned for the production or receipt, storage, preparation, measurement, and distribution of radioactive materials and the location(s) for radioactive waste storage;

- sufficient detail in the diagram to indicate locations of shielding, the shielding thickness, and the materials used for shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety;

- a general description of any ventilation system that is used when handling radionuclides, including representative equipment such as glove boxes or fume hoods;

- confirmation that such ventilation systems will be employed for the use or storage of radioactive materials likely to become airborne, such as compounding radioiodine capsules and dispensing radioiodine solutions; and

- verification that ventilation systems ensure that effluents are ALARA, are within the dose limits of Title 10 of the *Code of Federal Regulations* (10 CFR) §20.1301 and are within the ALARA constraints for air emissions established under 10 CFR §20.1101(d).

The submitted facility diagram and description included with your application did not include adequate detail.

Please resubmit the facility diagram and description, identifying the scale and/or dimensions of the facility. Include additional detail in the diagrams or drawings of your facility, identifying receiving, preparation and storage areas and label available sinks, shielding, fume hoods, glove boxes, hot cells, refrigerators, storage cabinets and waste containers. The facility diagram should depict all areas above, below and adjacent to areas where radioactive materials are compounded, dispensed and stored.

Include a detailed ventilation diagram, identifying the location of all supply, return and exhaust vents and the flow rate in cubic feet per minute. Describe all available inlet and exhaust filtration (e.g., high efficiency particulate air and carbon filters) and/or containment systems.

Further, identify the continuous “real-time” effluent (stack) monitor(s) installed at the proposed facility. Describe how the performance of the effluent monitoring systems will be monitored and maintained. Please also provide a photograph of the area surrounding the release stack.

7. Section 8.10.6, “Safe Use of Radionuclides and Emergency Procedures,” identifies that licensees should establish written procedures for responding to radiation emergencies and accidents.

One such radiation emergency is the release of volatile radionuclides, which would require the evacuation of personnel.

Indicate the maximum allowable concentrations – as a percentage of the Derived Air Concentrations (DACs) – for licensed material to be used at the proposed additional facility, in the event of an accidental release. In the event of such release, please confirm that personnel 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 reentry into the area of use.

8. 10 CFR §20.1101, "Radiation Protection Program," requires licensees to develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the regulations.

   Submit any applicable revisions to your Radiation Protection Program accounting for the additional licensed materials to be used at your licensed facilities and the proposed additional licensed facility. For additional information and instruction, you may refer to Section 8.10, "Item 10: Radiation Safety Program," of the guidance.

In accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be made 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 https://www.nrc.gov/reading-rm/adams.html.

To continue review of your request, please submit your response to this letter within 15 calendar days from the date of this letter. In your response, please refer to the license, docket, and control number specified below. I will assume that you do not wish to further pursue this licensing action if I do not receive a reply within the specified timeframe noted above.

If you have questions, require additional time to respond, or require clarification on any of the information stated above, I encourage you to contact me at (630) 829-9737 or via e-mail at Jason.Kelly@nrc.gov.

Sincerely,

Digitally signed by Jason M. Kelly
Date: 2022.11.17 15:37:01 -06'00'
Adobe Acrobat version: 2022.003.20263

Jason M. Kelly, MPH
Health Physicist
Materials Licensing Branch

Docket No.: 030-38044
License No.: 13-32726-01
Control No.: 632523