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

July 18, 2020

John A. Zehner, R.Ph.
Chief Executive Officer and
Radiation Safety Officer
NukeMed Inc., dba Spectron Rx
17490 Dugdale Dr.
South Bend, IN 46635

E-mail to: jzehner@spectronrx.com
SUBJECT: SPECTRONRX REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 618729

Dear Mr. Zehner:

We have reviewed your letters dated April 24, 2020 and May 8, 2020. Your letters may be found in the NRC's Agencywide Document and Management System (ADAMS) at ML20118C132 and ML20129K058. Additional information is needed to complete our review. Accordingly, as discussed, in accordance with NUREG 1556, Vol. 13, rev. 2, please provide responses to the items below:

Facilities & Equipment at proposed 9550 Zionsville Rd., Indianapolis, IN 46268 Location of Use:

1. The description of the licensee's facilities - 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, (ii) lutetium-177; (iii) actinium-225; (iv) any other radionuclides; (v) shipping and receiving; (vi) QC labs on the first and second floors; and the (vi) location(s) for radioactive iodine-123, iodine-124, and iodine-131 waste storage and for waste storage and disposal of other radionuclides are needed;

    i. Please provide an updated facility diagram or diagrams, showing locations of receiving, hoods, glove boxes, storage cabinets, dispensing areas, waste storage, any sinks used for sewerage disposal, and disposal locations.
    ii. The revised facility diagram should be drawn to the scale of an 8 1/2 " x 11" sheet of paper, showing dimensions and details for areas where radioactive materials will be used or stored
    iii. The facility diagram should show sufficient detail to show shielding specifically for the compounding of radioiodine or other radiation safety items
    iv. The facility diagram should be in sufficient detail to indicate locations of shielding and the proximity of radiation sources- to unrestricted areas.
    v. The facility diagram should show what is above, below and adjacent to the area where the radioactive materials will be compounded, dispensed, and stored.
    vi. In lieu of a site visit, please include photographs showing each radioactive materials use area including any key safety equipment and security features of those areas.

2. Descriptions of the ventilation systems, including gloveboxes or fume hoods, with 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;

    i. Either confirm that any glove box or hood in which compounding or other handling will occur is identical (manufacturer, model, etc.) to those at the South Bend, Indiana facility, or provide specific safety equipment details for the new Indianapolis, Indiana facility.
    ii. Describe how each glove box or hood is connected to the main ventilation or other exhaust system.
    iii. Show where filtration equipment will be placed and where the airborne radiation levels will be monitored
    iv. Show additional details sufficient to demonstrate ventilation system is adequate for all radionuclides to be used under the license.

3. For authorization for radioactive materials use at the Indianapolis, Indiana location listed in Condition No. 10 to the licensee's commercial radiopharmacy radioactive materials license, 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.

4. The description of the licensee's facilities - including the facility diagram - lacks sufficient detail or is too small to assess adequacy of ventilation systems, etc. Accordingly, please provide an updated facility diagram of ventilation system, 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.

VENTILATION/EXHAUST:

5. Verification (e.g. calculation or other evaluation demonstrating that flow rates are adequate for procedures as' proposed) that the Indianapolis, Indiana radiopharmacy 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). 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.

6. Please provide the stack height, and describe whether the release would be expected to be less than 10 mrem, at the release point. If the 10 mrem requirement cannot be demonstrated in the calculation, please state the distance of the nearest air intake from the stack.

7. Please provide a photograph of the area surrounding the release stack, for the Indianapolis, Indiana pharmacy.

8. For both the Indianapolis, Indiana and South Bend, Indiana radiopharmacies, please indicate the maximum allowable concentrations – 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 ACTINIUM-225 DETECTION:

9. Please describe equipment to be available at the Indianapolis, Indiana, and Southbend, Indiana, locations of use, 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.

Sincerely,

Sara A. Forster

Digitally signed by Sara A. Forster
Date: 2020.07.18 15:31:50 -05'00'

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

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

cc: Christopher Ritter, Senior Radiochemist, Spectron Rx (via e-mail)