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

April 11, 2020

John A. Zhener, 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 SECOND REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 617986

Dear Mr. Zehner:

This letter is in reference to your letter and application dated February 10, 2020, requesting to amend NRC License No. 13-32726-01MD, and to your response March 24, 2020 response to our March 18, 2020 request for additional information. In order to continue our review, and to expedite our amendment to your license, we need responses the following items within the next 5 business days (on or before April 17, 2020):

FACILITIES AND EQUIPMENT

1. Your response to our previous request for information, as described in item No. 7.d.iv. of your March 24, 2020 letter indicated a MicroShield evaluation of the adequacy of ventilation using:

   (i) external exposure, to assure that effluent release doses do not exceed the public dose limits outlined in Title 10 of the *Code of Federal Regulations* (CFR) Section 20.1301. However, no MicroShield evaluation of the adequacy of ventilation – using effluent concentration – was provided to demonstrate that the effluent release does not exceed the 10 millirem per year limit required by 10 CFR 20.1101(d). Accordingly, a MicroShield evaluation using effluent concentration to evaluate compliance with 10 CFR 20.1101(d) limits is needed;

   (ii) an effective exhaust plume height of at least 30 feet, to demonstrate the extent to which the exhaust fan (Air Canon) dilutes the effluent by mixing in outside air at a high velocity. However, the basis – exhaust velocity, diameter of the stack, wind velocity, etc. – for concluding an effective exhaust height of at least 30 feet is unclear. A demonstration of how that stack height was arrived at is needed; and

   (iii) a highest anticipated iodine-131 source to be handled of 6 curies, with a worst-case scenario of 8 curies. However, the evaluation was unclear as to the maximum iodine-131 activity to be handled in a single year. Accordingly, to evaluate

compliance with annual limits, the maximum activity of iodine-131 to be handled in a given year is needed.

To further clarify that effluent release does not exceed limits stated in 10 CFR 20.1101(d), please provide the following:

- ***A MicroShield evaluation of the adequacy of ventilation using effluent concentration, to demonstrate that the effluent release does not exceed 10 millirem per year.***

- ***A demonstration that the effective stack height is 30 feet based on velocity, diameter of the stack, and wind velocity, etc.***

- ***Maximum total iodine-131 activity to be handled in a given year.***

RADIATION SAFETY PROGRAM

Bioassay Program for iodine-123, iodine-124, and iodine-131

2. Your response to our previous request for information as described in item No. 8 of your March 24, 2020 letter was unclear as to:

(i) the minimum detectable activity (MDA) and how intakes of less than 10% of the Annual Limit on Intake (ALI) will be detected; and

(ii) following evacuation of the area as described in subitem No. 8.c.i., the length of time required to reenter the room based on the concentration in the room, such as less than a small percentage of the Derived Air Concentration (DAC).

To further assess the adequacy of your bioassay program, please provide the following:

- ***A demonstration of how intakes of less than 10% of the ALI will be detected, including a determination of the MDA.***

- ***The time required to reenter a room, following detection of an accidental airborne release of iodine-123, iodine-124, or iodine-131. The time should be justified based on a maximum allowable concentration of the radionuclide in the room, such as a small percentage of DAC. This maximum allowable concentration and the percentage of DAC should be specified in your response.***

Air Sampling for iodine-123, iodine-124, and iodine-131

3. Your responses to our previous request for information as described in item Nos. 10.a.ii.2., 10.c.i., and 7.d.ii. of your March 24, 2020 letter were unclear as to:

(i) the correct formula for calculating the MDA and MDC, and how that relates to an air sampling duration of four half-lives but to checking on and/or replacing charcoal sampler

filters at least monthly, sufficient to demonstrate that MDCs meet fractions of 10 CFR Part 20 limits for both workers and the general public. This includes a need to adjust the MDC formula to include a decay correction factor during the period of continuous monitoring; and

(ii) the decay correction factor for the iodine trapped during the period of continuous air sampling, including its use in Attachment No. 4.

To further assess the adequacy of your air sampling program, please provide the following:

- ***The correct formula for the MDA calculation, and an adjustment to the MDC calculation to include a decay correction factor during the period of continuous sampling. Include an evaluation demonstrating that the MDCs meet fractions of the 10 CFR Part 20 limits for workers and for the general public.***

- ***The decay correction factor for iodine trapped during the period of continuous air sampling. Please also update Attachment No. 4, as contained in your previous response to our first request for information.***

Safety Program for expanded use of actinium-225

4. The description of your actinium-225 safety program as described in item No. 11 of your March 24, 2020 letter was unclear and/or incomplete.

To further assess the adequacy of your actinium-225 safety program, please provide the following:

- ***A demonstration that the MDC of breathing zone air sampling will be less than 10% of DAC; the decay correction factor should also be provided, if needed.***

- ***An efficiency calibration procedure for the Wizard gamma counter and determination of the MDC for urine samples; also, a demonstration that the intake of less than 10% of the ALI will be detected.***

- ***The time required to reenter the room after a spill based on the concentration in the room, such the value for the maximum allowable percentage of DAC.***

- ***A demonstration that, for contamination wipes to be assayed by liquid scintillation counting, that the MDC will not exceed 20 dpm per hundred square centimeters.***

- ***A suitable alpha detector – such as gas proportional, zinc sulfide, etc., that will be required for the contamination survey. Generally, the NRC expects that using only beta-gamma detectors – due to a much lower detection sensitivity than the suggested alpha detectors –for the detection of actinium-225 daughters would be inadequate to determine the actinium-225 activity. Please consider that the Scan MDC of alpha detector is expected to be much lower than beta-gamma detector. Accordingly, any evaluation procedure including a beta-gamma detector for the detection of daughters of actinium-225 should address NRC concerns that the***

method may be insufficient to determine whether the surface contamination is below the limit of alpha contamination. The evaluation procedure also should address the NRC concern that the evaluation of the contamination survey may be delayed for several hours until the decay chain reaches equilibrium.

Flexibility for Updating of Procedures

5. Attachments to your March 24, 2020 letter included procedures for (i) Thyroid Bioassays; (ii) Obtaining the Efficiency of Instruments Used for Bioassays; (iii) Obtaining the Efficiency of the Instrument for Air Monitoring; (iv) Air Monitoring; (v) Ion Chamber Calibration for Geometry; (vi) Urine Analysis Testing for 225-Actinium; and (vii) Urine Test Order Form. Please note that without an allowance to update procedures without amending the license, adherence to these procedures – as written – would be required.

   As discussed via phone on April 10, 2020, please note that you may wish to request flexibility to update procedures without amendment to the license. To request flexibility to update procedures without amendment to the license, please provide the following:

   - ***A description of the process that will be used to revise and implement these submitted procedures; and***

   - ***A confirmation of the statement:***

     "Changes may be made to submitted procedures as long as:

     (1) The revision is not contrary to regulations contained in Title 10 of the Code of Federal Regulations;
     (2) The revision does not require a license amendment under 10 CFR Part 30;
     (3) The revision has been reviewed and approved by the licensee's Radiation Safety Officer and management;
     (4) The affected individuals are instructed on the revised procedures before the changes are implemented;
     (5) The licensee shall retain a record of each change for 5 years; and
     (6) The record will include a copy of the old procedure, the new procedure, the date of the change, and the signature of the licensee management representative who reviewed and approved the change."

We will continue our review upon receipt of this information. Please submit your reply to my attention as soon as possible. As discussed by phone, for responses that cannot be provided in full by April 17, 2020, please provide a confirmation that such responses will be provided within 30 days of this letter (on or before May 11, 2020). For fastest processing, please submit your response as a pdf file of a signed and dated letter attached to an email at sara.forster@nrc.gov or as a signed and dated facsimile letter at 630-515-1078.

In accordance with 10 CFR 2.390, a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Document and Management System (ADAMS). ADAMS is accessible from the NRC's website at http://www.nrc.gov/reading-rm/adams.html.

If you have any questions regarding this request for additional information, please contact me at 630-829-9892 or sara.forster@nrc.gov.

Sincerely,

Sara A. Forster

Digitally signed by Sara A. Forster
Date: 2020.04.11 08:53:54 -05'00'

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

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