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

April 27, 2023

John A. Zehner, RPh.
Chief Executive Officer and Radiation Safety Officer
NukeMed Inc. dba SpectronRx
9550 Zionsville Rd.
Indianapolis, IN 46268

SUBJECT: ADDITIONAL INFORMATION NEEDED REGARDING AMENDMENT REQUESTS FOR NUKEMED INC. DBA SPECTRONRX, NRC MAIL CONTROL NO. 634860

Dear John:

Our office has reviewed NukeMed Inc. dba SpectronRx's (your) March 6, 2023, request to remove the location of use listed in Condition No. 10.C. to Amendment No. 14 to your license. We have also reviewed your March 8, 2023, request to increase your iodine-131 possession limit listed in Subitem No. 8.E. to the same license amendment. Finally, we have noted that we have not yet received all additional information requested in our letter dated March 29, 2021, which is needed to remove letters listed in Condition Nos. 25.A. through 25.C., 25.E. through 25.H., 25.J., and 25.K. of that prior amendment. This letter addresses deficiencies in your April 14, 2020 renewal request, and subsequent letters. Upon review, our office has determined that additional information is needed to increase the iodine-131 possession limit listed on the license, regarding the materials to be authorized, the purpose of use to be authorized, your training program, your facilities & equipment, your radiation safety program, and your waste management program.

Our review of your previously submitted decommissioning cost estimates and funding plans, and your resubmitted January 10, 2023 request to add a Connecticut location of use are ongoing. I or another NRC staff member will contact you separately, regarding those reviews.

Your letters are available electronically from NRC's Agencywide Documents Access and Management System (ADAMS) at accession numbers ML23067A036, ML23079A004, ML20105A439, and ML23012A020. Our previous request for information is available electronically from NRC's ADAMS at accession number ML21089A251. The NRC's ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

In preparing your responses according to NUREG 1556, Volume 13, rev. 2, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Licenses," please refer to the following sections: 8.5, "Radioactive Material," pp. 8-4 to 8-10; 8.6, "Purpose(s) for Which Licensed Material Will Be Used," pp. 8-10 to 8-15; 8.7, "Individual(s) Responsible for Radiation Safety Program and Their Training and Experience," pp. 8-15 to 8-18; 8.9, "Facilities and Equipment," pp. 8-26 to 8-33; 8.10, "Radiation Safety Program," pp. 8-34 to 8-61; and 8.11, "Radiation Safety Program," pp. 8-62 to 8-69.

NUREG 1556, Volume 13, rev. 2, is available electronically at the NRC's ADAMS accession number ML19079A207. The volume may be found at the NRC website: https://www.nrc.gov/docs/ML1907/ML19079A207.pdf.

RADIOACTIVE MATERIAL TO BE AUTHORIZED ON THE LICENSE (Item 5 of the Request):

1. The uses of iodine-123, iodine-124, iodine-125, and iodine-131 to be authorized at each of the four facilities (Bunker Hill, IN; Danbury, CT; Indianapolis, IN; and South Bend, IN) is unclear.

   Please indicate the following for each of these four radionuclides, for each of the four locations of use, including:

   a. maximum overall possession limit
   b. maximum per-use possession limit
   c. typical quantity and form to be received at the facility
   d. uses to be authorized at the facility (including but not limited to research and development, distribution for human use, distribution for non-human use, radioiodination, and chemical synthesis, etc.)
   e. handling equipment, spill containment, air monitoring, and effluent release monitoring procedures, as appropriate to the location and uses

2. Title 10 of the *Code of Federal Regulations* Section 32.210 specifies that sealed sources must be listed in the Sealed Source and Device Registry. The April 14, 2020, renewal application and subsequent submissions were unclear as to whether sealed sources will be listed in the SSDR.

   Please confirm that each 10 CFR 35.65 sealed source listed authorized in Subitem No. 6.AB. is registered as an approved sealed source and will be used in accordance with conditions specified in the registration certificate. If this cannot be confirmed, please describe.

3. The April 14, 2020, renewal application and subsequent submissions were unclear as to how materials will be transferred or distributed to mobile medical licensees.

   Please describe how materials will be transferred or distributed to mobile medical licensees, where there is no permanent structure for byproduct material storage, as applicable. In the alternative, please indicate that materials will not be transferred or distributed to facilities unless the transferees have a permanent structure for byproduct material storage.

4. The April 14, 2020, renewal application and subsequent submissions were unclear as to how generators authorized as stated in Subitem No. 9.AQ. will be received, repackaged, relabeled, or redistributed, for both unused and used generators, at each of the four facilities (Bunker Hill, IN; Danbury, CT; Indianapolis, IN; and South Bend, IN) to be authorized on the license:

Please provide the following information regarding germanium-68/gallium-68 generators for each location of use, including:

a. **maximum overall possession limit**
b. **maximum per-generator possession limit**
c. **Confirmation that unused generators will be redistributed without opening or altering the manufacturers packaging. In the alternative, a description of how generators may be opened, repackaged, or relabeled for redistribution.**
d. **Description of procedures and instructions for repackaging generators**
e. **Confirmation that generator manufacturer's packaging and labeling will not be altered**
f. **Confirmation that generators will not be distributed beyond the expiration date shown on the generator label**

RADIATION SAFETY OFFICER:

5. The April 14, 2020, renewal application and subsequent submissions were unclear as to the duties, responsibilities, and authority of the Radiation Safety Officer (RSO).

   Please provide a statement delineating the RSO's duties and responsibilities.

FACILITIES AND EQUIPMENT AND WASTE MANAGEMENT PROGRAM:

6. Facilities authorized for distribution of radiopharmaceuticals for medical use must be licensed with the State Board of Pharmacy. We have not received documentation showing that one or more of the locations of use authorized on the license are licensed with either the Connecticut or Indiana Boards of Pharmacy, as appropriate.

   For any of the four pharmacy facilities (Bunker Hill, IN; Danbury, CT; Indianapolis, IN; and South Bend, IN) for which documentation was not previously provided, please submit a copy of the registration or license from a State Board of Pharmacy.

7. For some facilities (Bunker Hill, IN; Danbury, CT; Indianapolis, IN; and South Bend, IN), the ventilation system and equipment for actinium-225, lutetium-177, and iodine-131 were not fully described in either the April 14, 2020, renewal application or subsequent submissions.

   For each location, where not provided previously, please provide the following information regarding ventilation systems:

   a. **A general description of any ventilation system that is used when handling radionuclides, including representative equipment such as glove boxes or fume hoods for areas where actinium-225, lutetium-177, or iodine-131 will be used or stored.**
   b. **A confirmation that such ventilation systems will be used for any materials likely to become airborne, whenever those materials are stored or used**
   c. **A verification (comply code or other analysis) that ventilation systems are ALARA, are within the dose limits of 10 CFR 20.1301, and are within the constraint for air emissions established under 10 CFR 20.1101(d), if not provided previously**

8. For facilities where iodine-131 will be used or stored, the adequacy of the ventilation and alarm systems cannot be fully evaluated.

   For each location, where not provided previously, please provide the following information regarding ventilation systems:

   a. A confirmation that radionuclide emission during the year is based on sampling results from the effluent releases, not just on a theoretical calculation
   b. A description of the total uses of iodine-131 per year based on the overall possession limit of 50 Ci. Based on the total uses, an estimate of the potential effluent release
   c. A diagram of stack height related to the release building dimensions

RADIATION SAFETY PROGRAM:

SAFE USE OF RADIONUCLIDES AND EMERGENCY PROCEDURES

9. The April 14, 2020, renewal application and subsequent submissions were unclear as to whether you "have developed and will implement and maintain procedures for the safe use of radioactive materials that address items outlined in NUREG 1556, Vol. 13, rev. 2." (refer to referenced volume for specific issues to be included in the response.)

   Please provide confirmations and descriptions for safe use and emergency procedures to address items outlined in NUREG 1556, Vol. 13, rev. 2, pp. 8-45 to 8-50. Please address specific issues as outlined in the NUREG, as applicable.

10. Regarding the request to increase the iodine-131 possession limit, procedures for cases where a spill occurs are unclear.

    Please, provide the time of re-entry for spills occurring in the warehouse or operations area where there is no localized ventilation system providing dedicated exhaust of the building air outside. If the re-entry time varies from location to location, please explain.

11. Regarding the request to increase the iodine-131 possession limit, the stated re-entry time following an airborne release is inconsistent with the NRC's evaluation. Based on the NRC's review, the formulas provided in Attachment V to your January 27, 2023 letter, and Appendix III to your March 8, 2023 letter may be incorrect. Our review indicates that the formula below could be a better choice for conducting your evaluation:

$$t = -\frac{\ln\left(\frac{C_2}{C_1}\right)}{Q/V}$$

    For each location of use, please provide the room volume, not the area of the room, and re-evaluate the re-entry times, based on the adjustment. If the evaluation varies from location to location, please explain.

DOSAGE MEASUREMENT SYSTEMS:

12. Applicants must describe the types of systems (measurement or combination of measurement and calculation) to be used for the measurement of alpha-, beta-, gamma-, and photon-emitting radioactive drugs.

    Please provide confirmations and sample calculations for dosage measurement systems to address items outlined in NUREG 1556, Vol. 13, rev. 2, pp. 8-54 to 8-55. Please address specific issues as outlined in the NUREG, as applicable.

Please provide a response via a signed and dated letter within 14 days (on or prior to May 11, 2023). For quickest processing, please submit your response as a pdf file attached to an email message. You may also submit a response via fax or via regular mail. If you have any questions regarding this message, please do not hesitate to reach out to me at 630-829-9892.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice and Procedure," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's ADAMS, accessible from the NRC Web site at https://www.nrc.gov/reading-rm/adams.html.

Sincerely,

Sara A. Forster

Digitally signed by Sara A. Forster
Date: 2023.04.27 13:20:58 -05'00'

Sara A. Forster, MS
Health Physicist
Materials Licensing Branch
Division of Radiological Safety and Security

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

Control No.: 634860

Martha Pavon

From: Sara Forster
Sent: Tuesday, May 2, 2023 12:10 PM
To: Sandy Pavon; Martha Pavon
Cc: Tammy Tomczak
Subject: FW: Additional Information Request for NukeMed dba SpectronRx, Lic. 13-32726-01MD, Dkt. 030-38044, CN634860
Attachments: CN634860.Lic13-32726-01MD Additional Information Request signed public 20230427 sf.pdf

Good afternoon, Sandy & Martha…

Could you please add the attached letter to ADAMS and let me know the accession number.

Thank you,

Sara

From: Sara Forster
Sent: Thursday, April 27, 2023 1:41 PM
To: Jon Bolen <jbolen@spectronrx.com>; Christopher Ritter <critter@spectronrx.com>; John Zehner <jzehner@spectronrx.com>
Subject: Additional Information Request for NukeMed dba SpectronRx, Lic. 13-32726-01MD, Dkt. 030-38044, CN634860

Good afternoon, John, Jonathan, and Christopher…

Our office has reviewed your March 6, 2023, and March 8, 2023 letters. Additional information as described in the attached letter is needed to complete our review.

To complete our review, please provide the requested information within the next 14 days (on or before May 11, 2023). You may submit your information electronically as a signed and dated letter attached in pdf format, to an email message.

If you have any questions regarding this request, including any need for additional time, please do not hesitate to call or email me.

Sincerely,

Sara A. Forster, Health Physicist
U.S. Nuclear Regulatory Commission - Region III
Division of Radiological Safety & Security
Materials Licensing Branch
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