



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

July 27, 2021

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

SUBJECT: ADDITIONAL INFORMATION NEEDED REGARDING REQUEST TO AMEND
NUKEMED INC., DBA SPECTRON RX, NRC LICENSE NO. 13-32726-01MD

Dear Mr. Zehner:

Our office has reviewed the April 28, 2021 request for NRC to amend NukeMed Inc., dba Spectron Rx's (your) U.S. Nuclear Regulatory Commission (NRC) Materials License including to add radionuclides and facilities subject to decommissioning financial assurance requirements. Upon review, our office has determined that additional information is needed to amend the license, regarding revisions to the mailing address, addresses where licensed material will be used or stored, the radionuclides to be authorized under the license, financial assurance required for decommissioning, the purpose of radioactive materials use under the license, your facilities & equipment, your radiation safety program, and your radioactive waste program. Your initial amendment request and the June 21, 2021 revision are available electronically from NRC's Agencywide Documents Access and Management System (ADAMS) at accession numbers ML21120A018 and ML21179C059. The NRC's ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

For additional guidance, please refer to NUREG 1556 Volume 13, revision 2, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Commercial Radiopharmacy Use Licenses," Section 8.2, "Name and Mailing Address of Applicant," p. 8-2, Section 8.3, "Address(es) Where Licensed Material Will Be Used or Possessed," pp. 8-2 to 8-3, Section 8.5.1, "Unsealed and Sealed Byproduct Material," pp. 8-4 to 8-8, "Financial Assurance and Recordkeeping for Decommissioning," pp. 8-8 to 8-9, Section 8.6, "Purpose(s) for Which Licensed Material Will Be Used," pp. 8-10 to 8-15, Section 8.9, "Facilities and Equipment," pp. 8-26 to 8-32, Section 8.10, "Radiation Safety Program," pp. 8-33 to 8-60, and Section 8.11, "Waste Management," pp. 8-62 to 8-69.

LICENSEE MAILING ADDRESS:

1. The mailing address on the license is listed as 17490 Dugdale Dr., South Bend, IN 46635, while the amendment request lists the mailing address as 9550 Zionsville Rd., Indianapolis, IN 46268. It is unclear which address you wish to have listed in Item 2, on the first page of the new license. **Please indicate the mailing address to be listed on the license.**

LOCATIONS OF USE:

2. In our June 15, 2021 phone conversation, it was the NRC's understanding that you would be adding the Arizona Isotope Science Research Corp. dba AZIsotopes Corp., 7796 S Innovation Way, Bunker Hill, IN 46914 location of use to the license, for radiopharmacy and for research and development use. **Please indicate all locations of use which you wish to list on the license. For each location, please indicate which radionuclides and purposes of use will be authorized.**

RADIOACTIVE MATERIAL TO BE AUTHORIZED ON THE LICENSE:

3. The list of elements with mass numbers to be added to Item 6 of the license includes both radionuclides which may trigger financial assurance requirements and some that do not. In addition, based on our June 15, 2021 phone conversation, it is the NRC's understanding that the long-lived radionuclide use will be limited to the Indianapolis location and that additional radionuclides may be requested for use at the Bunker Hill location. **Please update the list of radionuclides to include all radionuclides, chemical/physical form, and possession limits to be added to or increased, under the license. For each added radionuclide, please indicate all locations where the radionuclide may be used or stored. For the Bunker Hill location of use, please indicate all radionuclides to be authorized.**
4. The request to add an authorization for germanium-68/gallium-68 included two distinct types of use. The two different uses may require different possession limits and financial assurance criteria. **As discussed by phone on July 15, 2021, please separate the germanium-68/gallium-68 authorization request by purpose of use, with one line item for generators to be received and re-distributed and second and third line items – specific to germanium-68 and gallium-68 - for any generator manufacturing planned under this license.**

PURPOSES OF USE AUTHORIZED ON THE LICENSE:

5. For any uses other than those listed in Item Nos. 1, 2, and 3 of your application, please clarify the requested authorized use. For example, for the germanium-68 generators to be manufactured by the licensee, the purpose of use is not clear. **Please describe the process, from receipt of material through final disposal, for any new purposes of use to be authorized under the license. Please also update any purposes of use with other information needed to add new uses for the Bunker Hill location of use.**

DECOMMISSIONING FINANCIAL ASSURANCE:

6. The decommissioning financial assurance provided in support of the request to add multiple radionuclides was limited to a decommissioning cost estimate and funding plan. **Please either provide the date by which one or more financial instruments will be provided to cover the decommissioning funding for both Indianapolis and Bunker Hill, or confirm that such an instrument will be provided within 30 days of NRC's approval of the submitted decommissioning cost estimate.**

FACILITIES AND EQUIPMENT:

7. The facility diagrams do not clearly describe the areas of use and storage at the Indianapolis and Bunker Hill locations of use. The application also omitted an analysis as to how the ventilation adequacy for the authorized facilities is verified. **Please provide updated facility diagrams – including sinks, hoods, refrigerators, and waste – for new authorizations at the Indianapolis location and for the Bunker Hill areas of use. Please also include a copy of the Comply Analysis of building ventilation, for the new Bunker Hill area of use, under the signed and dated response. Finally, please describe how ventilation adequacy will be monitored via real-time management and oversight of effluent release and radionuclide levels.**
8. The application omits any additional detector survey instrumentation for the Bunker Hill location of use. **Please describe the detector that will be used to measure effluent release, for each of the Bunker Hill and the and provide sample calculations using the detector geometry and efficiency to explain how effluent release concentrations are determined.**

RADIATION SAFETY PROGRAM:

9. Based on our June 15, 2021 conversation, it is the NRC's understanding that there will be no changes to the Radiation Safety Program for the addition of the Bunker Hill facility. **Please either confirm that the existing Radiation Safety Program also will apply for the added Bunker Hill facility or provide any updates to the Radiation Safety Program as applicable.**

WASTE MANAGMENT:

10. The application is unclear as to how waste may be received, stored, and dispositioned from the Arizona Isotope Science Research Corp. dba AZIsotopes Corp. accelerator production license at the Bunker Hill facility. It is also unclear as to how returned germanium-68/gallium-68 generators will be dispositioned. **Please describe how waste will be managed at the Bunker Hill location of use. Please also describe how returned germanium-68/gallium-68 generators will be accounted for and dispositioned.**

As discussed in our June 15, 2021 conversation we are expecting that you will provide a response via a signed and dated letter in the next day or two. 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 Title 10 of the *Code of Federal Regulations* (10 CFR) Section 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, M.S.
Health Physicist
Materials Licensing Branch
Division of Nuclear Materials Safety

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

Control No.: 625535