

~~Official Use Only – Security Related Information~~



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

December 21, 2022

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

SUBJECT: AMENDMENT NO. 13 TO RADIOACTIVE MATERIALS LICENSE FOR NUKEMED INC., D/B/A SPECTRONRX, U.S. NRC LICENSE NO. 13-32726-01MD

Dear Dr. Zehner:

Enclosed is Amendment No. 13 to your U.S. Nuclear Regulatory Commission (NRC) Materials License No. 13-32726-01MD in accordance with your request dated September 21, 2022.

Your license is amended to account for the requested addition of lead-203, neptunium-237, americium-241 and curium-244, and the increase in the authorized possession limits for rhenium-188, tungsten-188 and lead-212.

Please continue to ensure that your total license possession of all radionuclides continues to remain below the limits for Decommissioning Financial Assurance and Emergency Planning as specified in Condition 13, 14 and 24 of your license.

I am unable to proceed with your request to add Emilia Klimek, Pharm.D., as the request lacked a written attestation, signed by a preceptor authorized nuclear pharmacist, identifying that the applicant has satisfactorily completed the requirements in Title 10 of the *Code of Federal Regulations* (10 CFR) §35.55(b)(1) and is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist.

Further, I am unable to proceed with your request to add the additional facility in Danbury, Connecticut. A request for additional information was sent on November 17, 2022. The response letter dated December 9, 2022, signed by Jon Bolen, Administrative RSO & EHS Officer, did not satisfactorily respond to all items requiring additional or clarifying information. Further, the response letter was not signed by a management representative as is required. I also understand that proposed facility is not currently equipped with all of the safety equipment and the facility's state-issued Board of Pharmacy license is still pending issuance.

You may resubmit your request addressing all items requested. You may refer to Control Number 632523 to reference correspondence previously submitted.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. NRC Region III office at (630) 829-9887 so that we may provide appropriate corrections and answers.

The enclosed document contains sensitive security-related information.
When separated from this cover letter this letter is uncontrolled.

~~Official Use Only – Security Related Information~~

J. Zehner

-2-

An environmental assessment for this action is not required because this action is categorically excluded under 10 CFR §51.22(c).

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation; or imposition of a civil penalty; or an Order suspending, modifying, or revoking your license as specified in the NRC Enforcement Policy. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance that NRC expects of its licensees.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at <https://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

NRC's Regulatory Issue Summary (RIS) RIS 2005-31 provides criteria to identify security related sensitive information and guidance for handling and marking of such documents. This ensures that potentially sensitive information is not made publicly available through NRC's ADAMS, the NRC's electronic document system. Pursuant to NRC's RIS 2005-31 and in accordance with 10 CFR 2.390 of the NRC's "Rules of Practice and Procedure," the enclosed license document is exempt from public disclosure because its disclosure to unauthorized individuals could present a security vulnerability. The RIS may be located on the NRC's Generic Communications Web page under "Regulatory Issue Summaries" at <https://www.nrc.gov/reading-rm/doc-collections/gen-comm/>, and the link for frequently asked questions regarding protection of security-related sensitive information may be located at <https://www.nrc.gov/reading-rm/sensitive-info/faq.html>.

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,

Jason M. Kelly, MPH
Health Physicist
Materials Licensing Branch

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

Enclosure: Amendment No. 13 to U.S. NRC Materials License No. 13-32726-01MD