



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

March 29, 2021

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

SUBJECT: RENEWAL OF RADIOACTIVE MATERIALS LICENSE FOR NUKEMED INC., DBA SPECTRONRX, NRC LICENSE NO. 13-32726-01MD

Dear Mr. Zehner:

Enclosed is Amendment No. 9 renewing your U.S. Nuclear Regulatory Commission (NRC) Materials License No. 13-32726-01MD in accordance with NukeMed Inc. dba Spectron Rx's (your) April 24, 2020 request to add an Indianapolis, Indiana location of use, your September 30, 2020 renewal application, with the exceptions of removing all previous letters referenced in Subitems to Condition No. 24, and to add an authorization for germanium-68/gallium-68 generators to your license. renewal request is available electronically from NRC's Agencywide Documents Access and Management System (ADAMS) at accession number ML20274A212. The NRC's ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Please note that, to remove previous letters referenced in Subitems to Condition No. 24, additional information is needed from you updating your:

- (1) description of uses of radioiodines including handling equipment, spill containment, air monitoring, and effluent release monitoring procedures;
- (2) for 10 CFR 35.65 sealed sources, a confirmation that each sealed source is registered as an approved sealed source and will be used in accordance with conditions specified in the registration certificate;
- (3) description of how materials will be transferred or distributed to mobile medical licensees, where there is no permanent structure for byproduct material storage, as applicable;
- (4) confirmation that unused generators will be redistributed without opening or altering the manufacturers packaging;
- (5) description of procedures and instructions for repackaging generators;
- (6) confirmation that generator manufacturer's packaging and labeling will not be altered;
- (7) confirmation that generators will not be distributed beyond the expiration date shown on the generator label;
- (8) statement delineating the duties of the Radiation Safety Officer (RSO);
- (9) a copy of the registration or license from a State Board of Pharmacy for the South Bend, Indiana pharmacy;

- (10) 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;
- (11) confirmation that such ventilation systems will be used for any materials likely to become airborne, whenever those materials are stored or used;
- (12) 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);
- (13) confirmation that 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.)
- (14) Confirmation and sample calculations for dosage measurement systems to address items outlined in NUREG 1556, Vol. 13, rev. 2. (refer to referenced volume for specific issues to be included in the response.)

Please note that to add an authorization for germanium-68/gallium-68 generators, a description of generator use specifications as well as financial assurance are needed, for each location where such generators may be used or stored.

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 630-829-9892 so that we may provide appropriate corrections and answers.

An environmental assessment for this action is not required, since this action is categorically excluded under Title 10 of the *Code of Federal Regulations* (10 CFR) Section 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 General Statement of Policy and Procedure for NRC Enforcement Actions. 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 which 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 <http://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.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice and Procedure," a copy of this letter and its enclosure 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

Docket No.: 030-38044
License No.: 13-32726-01MD
Control No.: 623256

Enclosure: Amendment No. 9 to NRC License No. 13-32726-01MD