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

August 2, 2022

EA-22-065

Mr. John Zehner, R.Ph
CEO/RSO
NukeMed Inc., dba SpectronRx
9550 Zionsville Rd.
Indianapolis, IN 46268

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03038044/2022001(DNMS) – NUKEMED INC., DBA SPECTRONRX

Dear Mr. Zehner:

On April 26, 2022, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your Indianapolis, Indiana, with continued in-office review through July 14, 2022. The purpose of the inspection was to review activities performed under your NRC license to ensure that activities were being performed in accordance with NRC requirements. The in-office review included a review of shipping records not available at the time of the inspection. The enclosed inspection report presents the results of the inspection.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. Additionally, the staff examined your compliance with the Commission's rules and regulations as well as the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, one apparent violation of NRC requirements was identified and is being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The apparent violation concerned the licensee's failure to confine their possession of material to what is approved on their NRC license, as required by Title 10 of the *Code of Federal Regulations* (CFR) Part 30.3(a).

Because the NRC has not made a final determination in this matter, the NRC is not issuing a Notice of Violation for this inspection finding at this time. Mr. Luis Nieves of my staff discussed the circumstances surrounding this apparent violation, the significance of the issue, and the need for lasting and effective corrective action with you at the inspection exit meeting on July 14, 2022.

Before the NRC makes its enforcement decision, we are providing you an opportunity to either: (1) respond in writing to the apparent violations addressed in this inspection report within 30 days of the date of this letter; or (2) request a Predecisional Enforcement Conference (PEC).

If a PEC is held, it will be open for public observation and the NRC will issue a press release to announce the time and date of the conference. **Please contact Mr. Michael Kunowski, Chief of the Materials Inspection Branch, at Michael.Kunowski@nrc.gov or 630-829-9618 within ten days of the date of this letter to notify the NRC of your intended response.** NRC website at: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html.

If you choose to provide a written response, it should be clearly marked as "Response to the Apparent Violation in Inspection Report No. 03038044/2022001(DNMS); EA-22-065," and should include, for the apparent violation: (1) the reason for the apparent violation, or, if contested, the basis for disputing the apparent violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations; and (4) the date when full compliance was or will be achieved. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violation. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be useful in preparing your response. You can find the information notice on the NRC website at: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. Your response should be sent to the NRC's Document Control Desk, Washington, DC 20555-0001, with a copy mailed to the NRC Region III Office, 2443 Warrenville Road, Suite 210, Lisle, Illinois 60532, within 30 days of the date of this letter. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a pre-decisional enforcement conference (PEC).

If you choose to request a PEC, it will afford you the opportunity to provide your perspective on the apparent violations and any other information that you believe the NRC should take into consideration before making an enforcement decision. The topics discussed during the PEC may include the following: information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned to be taken. If a PEC is held, it will be open for public observation, and the NRC will issue a press release to announce the time and date of the conference.

As your facility has not been the subject of escalated enforcement action within the last two years or two inspections, a civil penalty may not be warranted in accordance with Section 2.3.4 of the Enforcement Policy. In addition, based upon NRC's understanding of the facts and your corrective actions, it may not be necessary to conduct a PEC in order to enable the NRC to make a final enforcement decision. Our final decision will be based on your confirming on the license docket that the corrective actions previously described to the staff have been or are being taken.

In addition, please be advised that the number and characterization of the apparent violations described in the enclosed inspection report may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

In accordance with the NRC's "Rules of Practice" in 10 CFR 2.390, a copy of this letter, its enclosure, and any response you provide will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents

Access and Management System (ADAMS), accessible from the NRC's website at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, any response should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction.

Please feel free to contact Mr. Nieves of my staff if you have any questions regarding this inspection. Mr. Nieves can be reached at 630-829-9571.

Sincerely,

Heck, Jared signing on behalf
of Curtis, David
on 08/02/22

David Curtis, Director
Division of Nuclear Materials Safety

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

Enclosure:
Inspection Report No. 03038044/2022001(DNMS)

cc (w/encl): State of Indiana

Letter to J. Zehner from David Curtis, dated August 2, 2022.

SUBJECT: NRC INSPECTION REPORT NO. 03038044/2022001(DNMS) – NUKEMED INC., DBA SPECTRONRX

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DATE	7/27/2022		7/27/2022		8/1/2022		8/2/2022	

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U.S. Nuclear Regulatory Commission
Region III

Docket No.	030-38044
License No.	13-32726-01MD
Report No.	03038044/2022001(DNMS)
EA No./NMED No.	EA-22-065
Licensee:	NukeMed Inc., dba SpectronRx
Facility:	9550 Zionsville Rd. Indianapolis, IN
Inspection Dates:	April 26, 2022 - July 14, 2022
Exit Meeting Date:	July 14, 2022
Inspector:	Luis Nieves, Health Physicist
Approved By:	Michael Kunowski, Chief Materials Inspection Branch Division of Nuclear Materials Safety

Enclosure

EXECUTIVE SUMMARY

NukeMed Inc., dba SpectronRx
NRC Inspection Report 03038044/2022001(DNMS)

This was a routine inspection of a contract radiopharmaceutical manufacturer in Indianapolis, Indiana, authorized to prepare and distribute radioactive drugs and radiochemicals for medical and non-medical use, to use radioactive material for R&D purposes, to produce and distribute radioactive material using a cyclotron, and to possess incidentally-activated products. The licensee has three locations of use in Indiana.

As a result of this inspection, the NRC identified one apparent violation of regulatory requirements, the failure to confine their possession of material to what is approved on their NRC license, as required by Title 10 of the *Code of Federal Regulations* (CFR) 30.3(a). The licensee had taken possession of sealed sources containing Radium-226 (Ra-226) but was not authorized by its NRC license for this radioisotope.

The circumstances surrounding this apparent violation, as well as a discussion of root causes, contributing factors, and the licensee's corrective actions, are discussed in more detail in the following report.

REPORT DETAILS

1 Program Overview and Inspection History

This was an announced routine inspection of a radiopharmaceutical manufacturer in Indianapolis, South Bend, and Bunker Hill, Indiana, authorized to prepare and distribute radioactive drugs and radiochemicals for medical and non-medical use, to use radioactive material for R&D purposes, to produce radioactive material using a cyclotron and to distribute that material, and to possess incidentally-activated products. At the time of the inspection, the licensee routinely prepared and distributed radiolabeled monoclonal antibodies containing Iodine-131 (I-131), Lutetium-177 (Lu-177), and Actinium-225 (Ac-225) and diagnostic radiopharmaceuticals containing Indium-111 (In-111) to support clinical trials and new investigational drugs for brain and prostate cancer treatments. At the main location in Indianapolis, the licensee employed two pharmacists, six labeling technologists, six quality control technologists, and five quality assurance technologists.

2 Radiation Safety Program

2.1 Inspection Scope

On April 26, 2022 through July 14, 2022, the inspector reviewed the elements of the licensee's radiation safety program, including the following: records of the physical inventories, leak tests, linearity, accuracy, geometry, waste, survey, audits, shipping documents, and dosimetry records.

2.2 Observations and Findings

On April 26, 2022, an NRC inspector performed a routine inspection at SpectronRx in South Bend, Bunker Hill, and the main location in Indianapolis, Indiana. During this inspection and through additional email communications, the inspector learned that SpectronRx had taken possession of approximately 22 sealed sources containing Ra-226, totaling approximately 254 mCi, from about December 2021, to April 6, 2022. Based on the transfer records, these sources were acquired from five agreement state licensees in California, Wisconsin, Pennsylvania, Tennessee, and Texas. The licensee, however, was not authorized to receive, possess or use Ra-226 per their NRC license. As of the date of the inspection, the licensee had no radium sources in its possession, having transferred the sources back to individuals authorized to possess the material.

The root cause of the violation appears to be erroneous assumption/conclusion by the licensee. The licensee representative asserted that he mistakenly assumed that a registration letter from Indiana for the possession of Ra-226, dated December 7, 2021, was all that was needed.

As corrective actions on April 15, 2022, SpectronRx submitted a license amendment request to add Ra-226 (10 Ci) to their license. This request was approved by the NRC on July 14, 2022 (amendment 11). During the inspection, the inspector was told that this amendment request was submitted as a result of the State of Indiana informing the licensee that the December 2021 letter did not authorize the licensee for possession of Ra-226 as that authorization would need to come from the NRC. This communication

from the State of Indiana was also the reason that SpectronRx divested itself of the radium sources it had acquired.

2.3 Other Areas Inspected

The inspector toured all three locations of the licensee and observed radiolabeling of different isotopes, packaging and surveying of doses, pig and package surveys and wipes, verification of package contents, preparation of labels and shipping papers, and waste disposal. Licensee personnel demonstrated and described daily area surveys and wipes, package receipt surveys, spill procedures, waste disposal, and other procedures. The inspector noted no concerns with these activities. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings.

The inspector reviewed a selection of records, including internal audits, dose calibrator constancy, dose calibrator linearity, dose calibrator accuracy, survey meter calibration certificates, waste disposal of activated parts, well counter constancy, area surveys, and dosimetry reports.

2.4 Conclusions

The inspector identified an apparent violation of 10 CFR 30.3(a) for the failure of the licensee to confine their possession of material to what is approved on their NRC license.

3 Exit Meeting Summary

The NRC inspector presented preliminary inspection findings following the onsite inspection on July 14, 2022. The licensee did not identify any documents or processes reviewed by the inspector as proprietary. The licensee acknowledged the findings presented.

LIST OF PERSONNEL CONTACTED

John Zehner, CEO and RSO

Attended exit meeting on July 14, 2022.

INSPECTION PROCEDURES USED

87128: Radiopharmacy Programs
87126: Industrial/Academic/Research Programs