



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

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

November 10, 2022

EA-22-065

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

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

Dear Mr. Zehner:

This letter refers to the US Nuclear Regulatory Commission (NRC) inspection conducted on April 26, 2022, at your Indianapolis, Indiana facility 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. A final exit briefing was conducted by telephone with you on July 14, 2022, and the inspection report was issued on August 2, 2022, (Agencywide Document Access and Management System (ADAMS) Accession No. ML22207B850).

In the letter transmitting the inspection report, we provided you with the opportunity to address the apparent violation identified in the report by either attending a predecisional enforcement conference or by providing a written response before we made our final enforcement decision. In a non-publicly available letter dated September 1, 2022, you provided a response to the apparent violation. In the response, you agreed that a violation occurred involving the failure to amend your license for the possession of radium-226, but disputed the severity level of the violation, believing the violation should be categorized at Severity Level IV and dispositioned as a non-cited violation. The NRC's understanding of your basis for your disputing the severity level of the violation are: (1) there was no adverse impact to public health and safety for possessing the material prior to obtaining NRC authorization; (2) your staff protected, held, and accounted for the sources in the same manner as other NRC-licensed material you possessed; (3) no risk to public health and safety was present from the incorrect belief that the radium-226 was held under a State license versus an NRC license; and (4) the material was all in sealed sources and amounted to less than 3 percent of what is now authorized on your NRC license.

The NRC's Enforcement Policy, Section 6.3.c.11.(c) lists an example of a Severity Level III violation as a violation where the licensee fails to seek required NRC approval before the implementation of a significant change in licensed activities that has radiological significance, such as an increase in the quantity or type of radioactive material being processed or used. You had a significant change to licensed activities by acquiring radioactive material not approved on your license. Furthermore, the radiological significance for this violation goes beyond just acquiring the radioactive material as NukeMed had plans to open the radium-226 sources and make cyclotron targets which would then be used to make actinium-225. If not for the State of Indiana informing you that an NRC license was needed, your staff would have opened the

sources without the necessary NRC review and approval to ensure the materials were being processed safely. Unencapsulated radium-226 presents a significant radiological hazard through contamination and exposure.

Based on the information developed during the inspection, the information that you provided in your response to the inspection report dated September 1, 2022, and our response above, the NRC has determined that a violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in the subject inspection report. Therefore, this violation has been categorized in accordance with the NRC Enforcement Policy at Severity Level III. In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$8000 is considered for a Severity Level III violation.

Because your facility has not been the subject of escalated enforcement actions within the last two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy. NukeMed implemented the following corrective actions: (1) returning the radium-226 to properly authorized individuals; (2) requesting an amendment to your NRC license for the possession of radium-226, which was subsequently approved by the NRC; (3) radiation safety officer's acknowledgement of awareness and understanding of the licensing requirements for radium-226; (4) hiring a law firm to review the circumstances surrounding the violation and provide advice regarding the difference between radioactive materials licensed by a State and those licensed by the NRC; and (5) planning to seek information from the NRC when pursuing to add any new radioactive materials to confirm whether NRC or State licensing is required. Based on the above corrective actions, credit for *Corrective Action* is warranted.

Therefore, to encourage prompt and comprehensive correction of violations and in recognition of the absence of previous escalated enforcement action, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this Severity Level III violation constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding: (1) the reason for the violation; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance was achieved is already adequately addressed on the docket in Inspection Report No. 03038044/2022001(DNMS) and your letter dated September 1, 2022. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response will be made available electronically for public inspection in the NRC Public Document Room and in the NRC's ADAMS, accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such information, you must specifically identify the portions of your response that you seek to have withheld and provide in

detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). The NRC also includes significant enforcement actions on its Web site at (<http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>).

If you have any questions concerning this matter, please contact Diana Betancourt-Roldan, Enforcement Officer of my staff, at 630-829-9653 or diana.betancourt@nrc.gov.

Sincerely,



Signed by Giessner, Jack
on 11/10/22

John B. Giessner
Regional Administrator

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

Enclosure:
Notice of Violation

cc: State of Indiana

NOTICE OF VIOLATION

NukeMed Inc., dba SpectronRx
Indianapolis, Indiana

Docket No. 030-38044
License No. 13-32726-01MD
EA-22-065

During a US Nuclear Regulatory Commission (NRC) inspection conducted on April 26, 2022, at your Indianapolis, Indiana facility with continued in-office review through July 14, 2022, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

Title 10 of the *Code of Federal Regulations* (10 CFR) 30.3(a) states, in part, that except for person exempted, no person shall receive, acquire, or possess byproduct material except as authorized in a specific or general license issued in accordance with the regulations in this chapter (Chapter I – Nuclear Regulatory Commission).

Contrary to the above, from December 21, 2021, to March 23, 2022, the licensee received, acquired, and possessed byproduct material that was not authorized in a specific or general license and was not exempted from the requirements for a license. Specifically, the licensee possessed 22 sealed sources of radium-226, totaling 254 millicuries, that were not authorized in its license.

This is a Severity Level III violation (NRC Enforcement Policy Section 6.3.c.11.(c)).

The NRC has concluded that information regarding the reason for the violation the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 03038044/2022001(DNMS) and the licensee's letter dated September 1, 2022. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, EA-22-065," and send it to the US Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region III, 2443 Warrenville Road, Suite 210, Lisle, IL 60532 within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 10th day of November 2022

Enclosure

NOTICE OF VIOLATION; NRC ROUTINE INSPECTION REPORT NO. 03038044/2022001(DNMS) –
NUKEMED, INC., DBA SPECTRONRX DATE November 10, 2022

DISTRIBUTION: EA-22-065

RidsSecyMailCenterResource, SECY

DDorman, OEDO/EDO

CHaney, OEDO/DEDM

MLombard, OE

TMartinezNavedo, OE

JPeralta, OE/EB

LSreenivas, OE/EB

DLew, R-I

LDudes, R-II

SMorris, R-IV

JLubinski, NMSS

RLewis, NMSS

KWilliams, NMSS/MSST

MBurgess, NMSS/MSST/MSEB

RSun, NMSS/MSST/MSEB

RMcKinley, R-I/EAGLT

MKowal, R-II/ORAEICS

JGroom, R-IV/ACES

DBetancourt-Roldan, R-III/DRP/B3/BRO

HHarrington, OPA

THiggs, OI

MBlair, OCFO/DOC/LAFBB

JQuichocho, NSIR/DPR/RLB

LMcKown, R-II/DRP/RPB5

SLewman, R-III

DCurtis, R-III/DRS

JHeck, RIII/DNMS

MKunowski, R-III/DNMS/MIB

ABarker, R-III

HLogaras, R-III

DPiccirillo, R-III/DNMS

VMitlyng, OPA/OPA-RIII

PChandrathil, OPA/OPA-RIII

KLambert, R-III/EICS

SBakhsh, R-III/EICS

RidsOeMailCenterResource, OE
 LBaer, OGC/GCHA/AGCMLE/NLO
 RWilliams, R-II/DFFI/PB1
 MGarza, R-III/DRS/OB

OE-001

OFFICE	R-III/EICS	R-III/DNMS/MIB	R-III/DNMS	NMSS/MSST
NAME	KLambert <i>KL</i>	MKunowski <i>MK</i>	JHeck <i>JH</i>	KWilliams <i>KW</i>
DATE	Oct 20, 2022	Oct 21, 2022	Oct 26, 2022	Nov 2, 2022
OFFICE	OE/EB	R-III/DRP/B3/BRO	R-III	
NAME	JPeralta <i>JP</i>	DBetancourt-Roldan <i>DB</i>	JGiessner <i>JG</i>	
DATE	Nov 8, 2022	Nov 9, 2022	Nov 10, 2022	

OFFICIAL RECORD COPY