UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

June 24, 2016

EA-16-127

Mr. Damien Shriver
Environmental Specialist
Paragon Medical, Inc.
8 Matchett Drive
Pierceton, IN 46562

SUBJECT: NRC SPECIAL INSPECTION REPORT NO. 99990003/2016002(DNMS) AND NOTICE OF VIOLATION – PARAGON MEDICAL, INC.

Dear Mr. Shriver:

On June 1, 2016, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted an in-office review of the circumstances surrounding the loss of two generally licensed devices. The NRC initiated this review after Paragon Medical, Inc. contacted the State of Indiana, Medical Radiology Services which in-turn contacted the NRC Region III office on June 1, 2016, to report that the Paragon Medical, Inc. could no longer account for two polonium-210 sources with a nominal activity of 10 millicurie (mCi) each. According to your report, the first device was shipped to Paragon Medical Inc., on October 4, 2011, and it was noted missing on January 24, 2013. The second device was shipped on January 7, 2013, and was noted missing on February 17, 2014. Mr. Zahid Sulaiman of my staff presented the findings of this review to you via telephone on June 13, 2016.

During this in-office review, the NRC staff examined activities conducted under your general license related to public health and safety. Additionally, the staff examined your compliance with the Commission's rules and regulations. The in-office review consisted of interviews with personnel and examination of information provided by you to the NRC.

Based on the results of this in-office review and the information you provided, the NRC has determined that two Severity Level IV violations of NRC requirements occurred. The violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The first violation concerned the licensee's failure to properly dispose or transfer the devices, as required by Title 10 of the *Code of Federal Regulations* (CFR) 31.5(c)(8)(i). The second violation concerned the licensee's failure to immediately notify the NRC after it becomes aware of the loss of the device, as required by 10 CFR 31.5(c)(10) and 10 CFR 20.2201(a). The violations are cited in the enclosed Notice of Violation (Notice). The NRC is citing the violations in the Notice because the inspector identified the violation. The NRC is citing the violations at Severity Level IV (very low safety significance), because the loss of the decayed sources did not present a hazard to public health and safety. Although the amount of material was greater than 1,000 times the 10 CFR Part 20 Appendix C quantity, this case involves generally licensed material that is not required to be registered. The

calculated activity of each source at the time the devices were found missing was at 1.07 millicuries (mCi) and 1.32 mCi, respectively. As such, the loss of these devices does not present a risk to public health and safety. In addition, the activity of both sources has since decayed to levels that would be indistinguishable from background radiation levels.

The inspector determined that the root cause of the violations was a lack of full understanding of NRC's requirements for generally licensed devices. This is of concern to the NRC because it increases the chance for the devices to be lost, stolen, or improperly handled, which could result in adverse impacts to the health and safety of the general public, and it impairs the NRC's ability to evaluate the impact of the lost material on public health and safety in a timely manner. As corrective actions to address recurrence of the event and to prevent similar violations in future, Paragon Medical, Inc. created a gauge calibration tracking program, through which each device will be numbered with an assigned location, and the licensee will conduct monthly visual inspections. Additionally, the licensee will ensure that each device is exchanged annually and returned to vendor within 12 months of their original shipment date.

The NRC has concluded that information regarding the root cause of the violation, the corrective actions planned to correct the violation and address its recurrence, and the date when full compliance was achieved is already adequately addressed on the docket in this letter. Therefore, you are not required to respond to this letter unless the description herein 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, if you choose to provide one, 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). ADAMS is accessible from the NRC's website 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 publicly available without redaction.

Please feel free to contact Mr. Sulaiman of my staff if you have any questions regarding this inspection. Mr. Sulaiman can be reached at 630-829-9752.

Sincerely,

/RA/

Aaron T. McCraw, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 999-90003
License No. 10 CFR 31.5

Enclosure:
Notice of Violation

cc w/encl: State of Indiana

Please feel free to contact Mr. Sulaiman of my staff if you have any questions regarding this inspection. Mr. Sulaiman can be reached at 630-829-9752.

Sincerely,

/RA/

Aaron T. McCraw, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 999-90003
License No. 10 CFR 31.5

Enclosure:
Notice of Violation

cc w/encl: State of Indiana

DISTRIBUTION w/encl:
Darrell Roberts
John Giessner
Christine Lipa
Richard Skokowski
Carole Ariano
Paul Pelke
MIB Inspectors

ADAMS Accession Number: ML16176A185
☒ Publicly Available ☐ Non-Publicly Available ☐ Sensitive ☒ Non-Sensitive
To receive a copy of this document, indicate in the concurrence box "C" = Copy without attach/encl "E" = Copy with attach/encl "N" = No copy

OFFICE	RIII-DNMS		RIII-EICS		RIII-DNMS		RIII	
NAME	ZSulaiman:ps AMcCraw for		RSkokowski		AMcCraw			
DATE	6/24/2016		6/22/2016		6/24/2016			

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Paragon Medical Inc.
Pierceton, Indiana

License No. 10 CFR 31.5
Docket No. 999-90003
EA-16-127

During a U.S. Nuclear Regulatory Commission (NRC) in-office review conducted on June 1, 2016, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

Title 10 of the *Code of Federal Regulations* (CFR) 31.5(c)(8)(i) requires, in part, that any person who acquires, receives, possesses, uses or transfers byproduct material in a device pursuant to a general license shall transfer or dispose of the device containing byproduct material only by export as provided by paragraph (c)(7) of this section, by transfer to another general licensee as authorized in paragraph (c)(9) of this section, or to a person authorized to receive the device by a specific license.

Contrary to the above, as of January 24, 2013, and February 17, 2014, Paragon Medical, Inc. (the licensee) failed to transfer or dispose of byproduct material in a generally licensed device by export, by transfer to another general licensee, or by transfer to a person authorized by a specific license. Specifically, the licensee discovered that two generally licensed devices, each containing a nominal 10 millicuries polunium-210 source, were missing. The devices were suspected to have been discarded as normal trash.

This is a Severity Level IV violation (Section 6.7.d).

Title 10 CFR 31.5(c)(10) requires, in part, that the licensee shall comply with the provisions of 10 CFR 20.2201, and 10 CFR 2202 of this chapter for reporting radiation incidents, thefts or loss of licensed material.

Title 10 CFR 20.2201(a)(1)(i) states that each licensee shall report by telephone, immediately after its occurrence becomes known to the licensee, any lost, stolen, or missing licensed material in aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix C to Part 20 under such circumstances that it appears to the licensee that an exposure could result to persons in unrestricted areas.

Contrary to the above, on January 24, 2013, and February 17, 2014, the licensee failed to report the loss of generally licensed devices containing licensed material greater than 1,000 times the Appendix C quantities at the time of loss to the NRC immediately after the losses became known to the licensee. Specifically, the first device, containing 1.07 mCi of polonium-210 at the time of loss – a quantity greater than 1,000 times the Appendix C quantity for polonium-210 – was noted missing by the licensee on January 24, 2013, and the second device, containing 1.32 mCi, was noted missing by the licensee on February 17, 2014.

This is a Severity Level IV violation (Section 6.7.d).

The NRC has concluded that information regarding the reason for the violation, the corrective actions planned to correct the violation and prevent recurrence, and the date when full

compliance was or will be achieved is already adequately addressed on the docket in the letter transmitting this Notice of Violation (Notice). Therefore, you are not required to respond to this letter unless the description herein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, IR 99990003/2016002(DNMS)" and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice.

If you choose to respond, your response 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, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction.

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, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

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

Dated this 24th day of June, 2016.