UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
1600 EAST LAMAR BOULEVARD
ARLINGTON, TEXAS 76011-4511

January 14, 2022

NMED No. 210539

Mr. James McKee, Radiation Safety Officer
Monument Health, Inc.
353 Fairmont Boulevard
Rapid City, SD 57701

SUBJECT: NRC INSPECTION REPORT 030-03231/2021-002; AND NOTICE OF VIOLATION

Dear Mr. McKee:

This letter refers to the Event Notification (EN 55643) reported to the U.S. Nuclear Regulatory Commission's (NRC) on December 14, 2021, as a medical event at your facility in Rapid City, South Dakota. An in-office review of this event was performed by the NRC from December 15, 2021 through January 5, 2022. The in-office review was an examination of activities conducted under your license as they relate to public health and safety, to confirm compliance with the U.S. Nuclear Regulatory Commission's (NRC's) rules, regulations, and with the conditions of your license. Within these areas, the in-office review was limited to documents associated with the administration of iodine-125 to a patient on November 11, 2021, that was determined by the licensee to have resulted in a medical event. The inspector discussed the preliminary findings with you at the conclusion of the in-office review of the documentation submitted as part of EN 55643. A final exit briefing was conducted telephonically with you on January 5, 2022.

Based on the results of this review, the NRC has determined that a Severity Level IV violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy which can be found at the NRC's Web site at https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The violation is being cited in the enclosed Notice of Violation (Notice) because it was identified by the NRC during the in-office review. The violation involved the failure to include all information required on a written directive for permanent implant brachytherapy that was signed and dated on September 30, 2021, for an administration that occurred on November 11, 2021.

Additionally, it was determined that the licensee reported this medical event based on previous reporting criteria of radiation dose delivered that has since been superseded by reporting criteria based on activity/source strength for permanent implant brachytherapy, as described in 10 CFR 35.3045. Based in part on this misunderstanding of the current reporting criteria, the licensee reevaluated this event and determined that it did not meet the new reporting requirements in 10 CFR 35.3045 that are based on source strength, and the medical event report, EN 55643, was subsequently retracted.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful in preparing your response. You can find the Information Notice on the

NRC website at: https://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html. 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 will be (was) achieved should be addressed. The NRC review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

To the extent possible, your response should not include any personal privacy or proprietary 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).

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter, its enclosure, and your response, will be made available electronically for public inspection in the NRC Public Document Room or from ADAMS, accessible from the NRC website at http://www.nrc.gov/reading-rm/adams.html.

Should you have any questions regarding this letter or the enclosed Notice, please contact Mr. James Thompson at (817) 200-1538, or the undersigned at (817) 200-1455.

Sincerely,

Lizette Roldán Otero Signed by Roldan-Otero, Lizette on 01/14/22

Lizette Roldán-Otero, PhD, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-03231
License No. 40-00238-04

Enclosure:
Notice of Violation (Notice)

cc w/Enclosure:
John Priest, Sr. Health Facilities Surveyor
Office of Health Care Facilities
Licensure and Certification
4101 West 38th Street, Suite 102
Sioux Falls, SD 57106

SUBJECT: NRC INSPECTION 030-03231/2021-002; AND NOTICE OF VIOLATION – DATED JANUARY 14, 2022

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ADAMS ACCESSION NUMBER: **ML22013B267**

☒SUNSI Review: ADAMS: ☐ Non-Publicly Available and Sensitive
By: JLT ☒ **Yes** ☐ No ☒ **Publicly Available and non-sensitive**

OFFICE	SHP:MIB	C:MIB				
NAME	JLThompson	LRoldanOtero				
SIGNATURE	***/RA/***	LRO				
DATE	1/12/2022	1/14/2022				

OFFICAL RECORD COPY

NOTICE OF VIOLATION

Monument Health, Inc.
Rapid City, South Dakota

Docket No. 030-03231
License No. 40-00238-04

During an NRC in-office review that began on December 15, 2021, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

> 10 CFR 35.40(b)(6) requires, in part, that a written directive must be dated and signed by an authorized user before the administration of any therapeutic dose of radiation from byproduct material. The written directive must contain the patient or human research subject's name and, for permanent implant brachytherapy, the following information: before implantation, the treatment site, the radionuclide, and the total source strength; and after implantation but before the patient leaves the post-treatment recovery area, the treatment site, the number of sources implanted, the total source strength implanted, and the date.
>
> Contrary to the above, on September 30, 2021, an authorized user signed and dated a written directive before the administration of a therapeutic dose of radiation from byproduct material that failed to contain the patient or human research subject's name and, for permanent implant brachytherapy, the following information: before implantation, the treatment site, the radionuclide, and the total source strength; and after implantation but before the patient leaves the post-treatment recovery area, the treatment site, the number of sources implanted, the total source strength implanted, and the date.
>
> Specifically, a written directive was prepared on September 30, 2021, for the administration of iodine-125 permanent implant brachytherapy seeds to a patient, and the written directive failed to contain, before implantation, the total source strength; and, after implantation but before the patient left the post-treatment recovery area, the total source strength implanted.

This is a Severity Level IV violation (NRC Enforcement Policy, Section 6.3.d.1).

Pursuant to the provisions of 10 CFR 2.201, Monument Health, Inc. is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Regional Administrator, Region IV, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation; 030-03231/2021-002" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued requiring information as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

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.

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. To the extent possible, your response should not include any personal privacy or proprietary 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, then 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 material, 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).

In accordance with 10 CFR 19.11, you may be required to post this Notice within 2 working days of receipt.

Dated this 14th day of January 2022