



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION IV
1600 EAST LAMAR BOULEVARD
ARLINGTON, TEXAS 76011-4511

November 17, 2022

Nathan Dykstra
Radiation Safety Officer
DMS Health Technologies
109 South Petro Avenue
Sioux Falls, South Dakota 57107

SUBJECT: NRC INSPECTION REPORT 030-36404/2022-001; AND NOTICE OF VIOLATION

Dear Nathan Dykstra:

This letter refers to the announced routine inspection conducted September 15–16, 2022, at your facility in Sioux Falls, South Dakota, and at a temporary jobsite in Yankton, South Dakota. The inspection 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 inspection consisted of a selected examination of procedures and representative records, observation of licensed activities, independent radiation measurements, and interviews with personnel. The preliminary inspection findings were discussed with you on September 15, 2022, following the completion of inspection activities at your location in Sioux Falls. During a virtual meeting on November 1, 2022, the inspectors discussed the final inspection findings with you and Angela Van Hill.

Based on the results of this inspection, 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 which can be found at the NRC's Web site at <https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The violations are cited in the enclosed Notice of Violation (Notice) because they were identified by the NRC during the inspection. The violations involved the failure to (1) monitor packages received at the licensee's facility as required by Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1906 and (2) obtain a letter signed by the management of each client for which mobile medical services are rendered as required by 10 CFR 35.80.

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's 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 Allyce Bolger, at (817) 200-1197, or the undersigned at (817) 200-1455.

Sincerely,



Signed by Roldan-Otero, Lizette
on 11/17/22

Lizette Roldán-Otero, PhD, Chief
Materials Inspection Branch
Division of Radiological Safety and Security

License No. 40-32477-01

Docket No. 030-36404

Enclosure:
Notice of Violation (Notice)

cc w/Enclosure:
John Priest, Director
South Dakota Department of Health

NRC INSPECTION REPORT 030-36404/2022-001; AND NOTICE OF VIOLATION
 DATED NOVEMBER 17, 2022

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OFFICAL RECORD COPY

NOTICE OF VIOLATION

DMS Health Technologies
Sioux Falls, South Dakota

Docket No. 030-36404
License No. 40-32477-01

During an NRC inspection conducted on September 15–16, 2022, at the licensee’s facility in Sioux Falls, South Dakota and at a temporary jobsite in Yankton, South Dakota, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 20.1906(c) requires, in part, that the licensee shall perform the monitoring required by 10 CFR 20.1906(b) after the package is received at the licensee’s facility.

Contrary to the above, on September 15–16, 2022, the licensee failed to perform the monitoring required by 10 CFR 20.1906(b) after packages were received at the licensee’s facility. Specifically, after receiving radioactive packages (labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations) at its facility in Sioux Falls, South Dakota, the licensee did not perform the monitoring required by 10 CFR 20.1906(b) prior to reoffering those packages for transport to their clients’ locations.

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

- B. 10 CFR 35.80(a)(1) requires that a licensee providing mobile medical service shall obtain a letter signed by the management of each client for which services are rendered that permits the use of byproduct material at the client’s address and clearly delineates the authority and responsibility of the licensee and the client.

Contrary to the above, on September 16, 2022, the licensee provided mobile medical services and failed to obtain a letter signed by the management of the client for which services were rendered that permitted the use of byproduct material at the client’s address. Specifically, the licensee rendered mobile medical services (administration of radiopharmaceuticals containing fluorine-18) at a client location in Yankton, South Dakota, but had not obtained a letter signed by the management of the client permitting the use of byproduct material at the client’s address.

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

Pursuant to 10 CFR 2.201, DMS Health Technologies 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 Director, Division of Radiological Safety and Security, U.S. Nuclear Regulatory Commission Region IV, 1600 E. Lamar Blvd., Arlington, Texas 76011, and emailed to Lizette.Roldan-Otero@nrc.gov 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” 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 was or 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

Enclosure

received within the time specified in this Notice, the NRC may issue an order or a demand for information requiring you to explain why your license should not be modified, suspended, or revoked, or why the NRC should not take other action as may be proper. Consideration may be given to extending the response time for good cause shown.

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 website at <http://www.nrc.gov/reading-rm/adams.html>. Therefore, to the extent possible, the 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 17th day of November 2022