



UNITED STATES
NUCLEAR REGULATORY COMMISSION

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

June 9, 2023

EA-22-138

Dr. Gary Bailey, Director of Imaging
St. James Healthcare
400 South Clark Street
Butte, MT 59701

SUBJECT: ST. JAMES HEALTHCARE - NOTICE OF VIOLATION, NRC INSPECTION
REPORT 030-12143/2022-001

Dear Dr. Gary Bailey:

This letter refers to the unannounced inspection performed on November 8, 2022, at your facility in Butte, Montana, with continued in-office review through January 19, 2023. The inspection was conducted to examine activities conducted under your license as they relate to public health and safety and to confirm compliance with the U.S. Nuclear Regulatory Commission (NRC) rules and regulations and with the conditions of your license. A final exit meeting was conducted with you and your Radiation Safety Officer on February 27, 2023. The results of the inspection and one apparent violation were provided to you in the subject inspection report, dated March 14, 2023, Agencywide Documents Access and Management System (ADAMS) Accession No. ML23054A168.

In the letter transmitting the inspection report, we provided you with the opportunity to address the apparent violation by either attending a predecisional enforcement conference, requesting alternative dispute resolution mediation, or providing a written response before we made our final enforcement decision. In a letter dated April 10, 2023 (ML23115A425), you provided a written response to the apparent violation.

Based on the information developed during the inspection and the information you provided in your April 10, 2023, written response to the inspection report, 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 the violation are described in detail in the subject inspection report. The violation involved the administration of iodine-131 sodium iodide to patients with written directives that were not signed or dated by an authorized user listed on the license.

The NRC considers this to be a significant violation because the failure to have the written directives signed by a physician trained and authorized for the administration of iodine-131 sodium iodide could have resulted in an adverse medical event. Therefore, this violation has been categorized in accordance with the NRC Enforcement Policy at Severity Level III. The Enforcement Policy can be found on the NRC's website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$8,750 is considered for a Severity Level III violation.

Because your facility has not been the subject of an escalated enforcement action within the last two routine 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 NRC Enforcement Policy. The NRC has determined that *Corrective Action* credit is warranted based on the prompt and comprehensive corrective actions you implemented. Your corrective actions to address the violation are documented in NRC Inspection Report 030-12143/2022-001 and in your letter dated April 10, 2023.

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 NRC Inspection Report 030-12143/2022-001 and in your letter dated April 10, 2023. 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 "Agency Rules of Practice and Procedure," a copy of this letter, the enclosure, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room and from the NRC's ADAMS, accessible from the NRC website 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. The NRC also includes significant enforcement actions on its website at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions>.

If you have any questions concerning this matter, please contact Dr. Lizette Roldán-Otero of my staff, at 817-200-1455.

Sincerely,



Monninger, John signing on behalf
of Lewis, Robert
on 06/09/23

Robert J. Lewis
Regional Administrator (Acting)
Region IV

Docket No. 030-12143
License No. 25-13173-02

Enclosure:
Notice of Violation

cc w/enclosure:
Ross Barnes, Director (Interim)
Radiation Control Program, Office Inspector General
Montana Department of Public Health & Human Services
Ross.Barnes@mt.gov

ST. JAMES HEALTHCARE - NOTICE OF VIOLATION, NRC INSPECTION
 REPORT 030-12143/2022-001 - DATED JUNE 9, 2023

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ADAMS: **ML23136A582**

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|-------------------------|------------------|--|---|------------|---|-----------------------|
| SUNSI Review By: ACR | | ADAMS <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No | <input checked="" type="checkbox"/> Publicly Available <input type="checkbox"/> Non-Publicly Available | | <input checked="" type="checkbox"/> Non-Sensitive <input type="checkbox"/> Sensitive | Keyword: EA-22-138 |
| OFFICE | ES:ACES | C:MIB | TL:ACES | RC | OE | NMSS |
| NAME | ARoberts | LRoldan-Otero | RKumana | DCylkowski | JPeralta | MBurgess |
| SIGNATURE | /RA/ E | /RA/ E | /RA/ E | /RA/ E | /RA/ E | /RA/ E |
| DATE | 05/11/23 | 05/17/23 | 05/17/23 | 05/18/23 | 05/23/23 | 05/26/23 |
| OFFICE | D:DRSS | RA: RIV | | | | |
| NAME | AXR1 for GMiller | RLewis | | | | |
| SIGNATURE | /RA/ E | /JDM for/E | | | | |
| DATE | 05/30/23 | 06/09/23 | | | | |

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

St. James Healthcare
Butte, MT

Docket No. 030-12143
License No. 25-13173-02
EA-22-138

During an NRC inspection conducted on November 8, 2022, with continued in-office review through January 19, 2023, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 35.40(a) requires, in part, that a written directive must be dated and signed by an authorized user before the administration of iodine-131 (I-131) sodium iodide greater than 30 microcuries (μCi).

Contrary to the above, from June 2019 to November 2022, the licensee implemented written directives that were not dated and signed by an authorized user before administration of I-131 sodium iodide greater than 30 μCi . Specifically, four written directives that prescribed I-131 sodium iodide with activity greater than 30 μCi (2000 μCi , 4000 μCi , 10,000 μCi , and 20,000 μCi) were not dated and signed by an authorized user, but by an individual who was not authorized to sign and date written directives for administrations of I-131 sodium iodide.

This is a Severity Level III violation (Enforcement Policy Section 6.3.c.2).

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 NRC Inspection Report 030-12143/2022-001 and in your letter dated April 10, 2023.

However, if the description therein does not accurately reflect your position or your corrective actions, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 within 30 days of the date of the letter transmitting this Notice of Violation. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation; EA-22-138," 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, U.S. Nuclear Regulatory Commission, Region IV, 1600 East Lamar Blvd., Arlington, Texas 76011-4511, and email it to R4Enforcement@nrc.gov.

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.

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 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

Enclosure

request that such material is withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (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).

Dated this 9th day of June 2023