



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

December 15, 2021

EA-21-034

James Adamson, Chief Executive Officer
Mountain View Hospital
2325 Coronado Street
Idaho Falls, ID 83404

SUBJECT: MOUNTAIN VIEW HOSPITAL - NOTICE OF VIOLATION, NRC INSPECTION
REPORT 030-38701/2020-001

Dear Mr. Adamson:

This letter refers to the routine inspection that commenced on November 9, 2020, as a remote inspection. An onsite inspection was performed at your facilities in Idaho Falls, Idaho from November 16-19, 2020. The inspection continued with in-office review through September 2, 2021. The purpose of the inspection was 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 briefing was conducted by videoconference with representatives of your staff on September 2, 2021. Details of the inspection and six apparent violations were provided to you in the subject inspection report, dated September 12, 2021, Agencywide Documents Access and Management System (ADAMS) Accession No. ML21250A165.

In the letter transmitting the inspection report, we provided you with the opportunity to address the apparent violations by either attending a predecisional enforcement conference, requesting alternative dispute resolution mediation session, or providing a written response before we made our final enforcement decision. In a letter dated October 6, 2021 (ADAMS Accession No. ML21286A187), you provided a written response to the apparent violations.

Based on the information developed during the inspection and the information you provided in your written response to the inspection report dated September 12, 2021, the NRC has determined that six violations of NRC requirements occurred. These violations are cited in the enclosed Notice of Violation (Notice), and the circumstances surrounding them are described in detail in the subject inspection report. The violations involved: (A) failure to develop, implement, and maintain written procedures for the administration of lutetium-177 (Lu-177); (B) release of individuals who had been administered Lu-177 and had radiation dose rates that exceeded your release criteria; (C) failure to retain a record of safety instructions provided to individuals caring for patients administered Lu-177; (D) failure to document radiation surveys to demonstrate that rooms used for Lu-177 patients could be released for unrestricted use; (E) discharge to the sanitary sewer of Lu-177 contaminated materials that were not readily soluble in water or biological materials; and (F) failure to label a Lu-177 radioactive waste storage container and its contents to indicate that they contained radioactive material.

The NRC considers Violations A and B above to be significant violations because of the programmatic failures associated with your Lu-177 administration program. Therefore, these two violations have been categorized collectively in accordance with the NRC Enforcement Policy as a Severity Level III problem. The Enforcement Policy can be found on the NRC's website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>.

The NRC considers Violations C, D, E, and F to be of low safety significance and thus has categorized them in accordance with the NRC Enforcement Policy as Severity Level IV violations. These violations are being formally cited as Severity Level IV rather than as a non-cited violations because they were identified by the NRC during an inspection.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$7,500 is considered for a Severity Level III problem.

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 violations are documented in your letter dated October 6, 2021, and NRC Inspection Report 030-38701/2020-001.

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 for the Severity Level III problem. However, significant violations in the future could result in a civil penalty. In addition, issuance of this Severity Level III problem constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding: (1) the reason for the violations; (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 030-38701/2020-001 and in your letter dated October 6, 2021. 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 or in 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 Ms. Lizette Roldán-Otero of my staff, at 817-200-1455.

Sincerely,



Signed by Morris, Scott
on 12/15/21

Scott A. Morris
Regional Administrator

Docket No: 030-38701
License No: 11-35120-01

Enclosure:
Notice of Violation

cc w/ enclosure:

Mark Dietrich, PE, State Liaison Officer
Idaho Department of Environmental Quality
1410 N. Hilton St.
Boise, ID 83706

MOUNTAIN VIEW HOSPITAL - NOTICE OF VIOLATION, NRC INSPECTION REPORT
030-38701/2020-001 - DATED DECEMBER 15, 2021

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NOTICE OF VIOLATION

Mountain View Hospital
Idaho Falls, Idaho

Docket No. 030-38701
License No. 11-35120-01
EA-21-034

During an NRC inspection conducted November 9-19, 2020, with continued in-office review through September 2, 2021, six violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 35.41(a)(2) requires, in part, that for any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.

Contrary to the above, from September 4, 2018, to November 16, 2020, the licensee failed to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. Specifically, the licensee failed to develop, implement, and maintain written procedures for the administration of lutetium-177 (Lu-177) that would provide high confidence that each administration is in accordance with the written directive.

- B. 10 CFR 35.75(a) requires, in part, that a licensee may authorize the release from its control of any individual who has been administered byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 500 mrem.

Contrary to the above, on October 24, 2019, March 12, 2020, and May 14, 2020, the licensee authorized the release from its control individuals who had been administered byproduct material where the total effective dose equivalent to any other individual from exposure to the released individual was likely to exceed 500 mrem. Specifically, the licensee's criteria for the release of patients administered Lu-177 was that if the radiation dose rate at 1 meter from the patient was less than or equal to 2.5 millirem/hour, then the total effective dose equivalent to any other individual was not likely to exceed 500 millirem. However, on October 24, 2019; March 12, 2020, and May 14, 2020, the licensee authorized the release from its control individuals who had been administered byproduct material with resultant radiation dose rates at 1 meter that were 13.0 millirem/hour, 6.5 millirem/hour, and 6.5 millirem/hour, respectively.

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

- C. 10 CFR 35.310(b) requires, in part, that the licensee shall retain a record of individuals receiving instruction in accordance with 10 CFR 35.2310.

10 CFR 35.2310 requires, in part, that the licensee shall maintain a record of safety instructions required by 10 CFR 35.310 for 3 years. The record must include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

Contrary to the above, from September 4, 2018, to November 16, 2020, the licensee failed to retain a record of individuals receiving instruction in accordance with 10 CFR 35.2310. Specifically, the licensee failed to retain a record of safety instructions that were provided as

Enclosure

required by 10 CFR 35.310, including failing to maintain a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

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

- D. 10 CFR 20.2103(a) requires, in part, that each licensee shall maintain records showing the results of surveys required by 10 CFR 20.1501. The licensee shall retain these records for 3 years after the record is made.

Contrary to the above, for patients admitted on March 12, 2020, and May 14, 2020, the licensee failed to maintain records showing the results of surveys required by 10 CFR 20.1501. Specifically, for patients admitted on March 12, 2020, and May 14, 2020, the licensee performed surveys required to release rooms for unrestricted use after the rooms were used to house patients that had been administered licensed material, Lu-177, and the licensee failed to maintain records showing the results of the surveys.

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

- E. 10 CFR 20.2003(a)(1) requires, in part, that a licensee may discharge licensed material into sanitary sewerage if the material is readily soluble (or is readily dispersible biological material) in water.

Contrary to the above, from September 4, 2018, to November 16, 2020, the licensee discharged licensed material into sanitary sewerage that was not readily soluble (or is readily dispersible biological material) in water. Specifically, the licensee discharged wipes into the sanitary sewerage that had been used to decontaminate surfaces that were radioactively contaminated with Lu-177, a licensed material, and the wipes were not readily soluble in water and were not readily dispersible biological material.

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

- F. 10 CFR 20.1904(a) requires, in part, that the licensee shall ensure that each container of licensed material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL."

Contrary to the above, from August 2019 to November 16, 2020, the licensee failed to ensure that each container of licensed material bore a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL." Specifically, neither the licensee's rooftop Lu-177 radioactive waste storage container nor the individual radioactive waste containers inside of it had a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL."

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

The NRC has concluded that information regarding: (1) the reason for the violations; (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 030-38701/2020-001 and in your letter dated October 6, 2021. 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-21-034," 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 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 15th day of December 2021