WEST VALLEY MEDICAL CENTER
1717 Arlington Avenue | Caldwell, Idaho 83605 | (208) 459-4641

ADAMS Accession# ML23073A105

March 9, 2023

Dear Ms. Roldan-Otero:

Enclosed is West Valley Medical Center's response to the two Severity level IV violations identified during the NRC inspection on October 18, 2022. The Notice of Violation included deficiencies surrounding those requirements of 10 CFR 35.41 (a) (2) and 10 CFR 35.67 (g).

This letter and attachments describe the numerous actions West Valley Medical Center has taken to ensure compliance with 10 CFR 35.41 (a) (2) and 35.67 (g), and provides credible evidence of full compliance with all of the U.S. NRC regulations related to the before mentioned violations.

The concerns of the NRC have been taken very seriously by the West Valley administration, the Medical Executive Committee of the medical staff, and the Board of Trustees. You can be assured that the highest priority has been assigned to correcting and clarifying policies and procedures relating to the 10 CFR, 35.41 (a) (2) and 35.67 (g), at West Valley Medical Center.

> Immediately on receipt of survey findings, a team met and initiated intensive review into nuclear medicine services, and began formulating a plan of correction to fully address all regulations identified as out of compliance, resulting in system changes as identified within the attached report.

Based on the explanations herein and the actions of the West Valley Medical Center, we believe the Nuclear Medicine Department has ensured appropriate safety and quality care for all patients that are treated at West Valley Medical Center.

Subsequent to the review of the attached materials, West Valley Medical Center kindly requests a determination by the U.S. NRC of having achieved compliance.

If you require additional information or if we may be of assistance, please do not hesitate to call me at 208-455-3752.

Sincerely,

Jason Demke
Chief Operations Officer

cc: Jake Nancolas, BSRT(R)(CT), Director of Medical Imaging
Teri Steele, BS, CNMT, RT(N), NCT, NMTCB(RS), Radiation Safety Officer
Sandra Sprong-Burns, BSRT(N)(R)(CT), Nuclear Medicine Coordinator

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Reply to Notice of Violation

U.S. NRC, ATTN: Document Control Desk

Director, Division of Radiological Safety and Security, US NRC, Region IV

Lizette Roldan-Otero, Ph.D.,

This letter is in reply to two Severity Level IV violations identified at West Valley Medical Center, Inc during an NRC inspection done on October 18, 2022.

West Valley Medical Center, Inc. License number 11-27087-01 Docket number 030-32242

Violation of 10 CFR 35.41 (a)(2):

Reason for the violation: A written directive was flagged by an inspector on 10/18/2022 as being written for 20 uCi I-131 instead of the intended and dosed 20 mCi I-131 for a hyperthyroid therapy.

On 11/16/2018, an Authorized User prescribed a I-131 therapy dose for hyperthyroidism. He consulted the patient and was present when the therapy dose of 21.1 mCi I-131 was given to the patient as he intended.

What actions have been taken to prevent recurrence: As suggested by the inspector, the written directive prescription form and the written directive checklist form previously used at West Valley Medical Center were combined into one single form. To ensure the written directive is clear and unambiguous, the Authorized User now has to circle the word "millicuries" or "microcuries" and initial the selection for the radiopharmaceutical prescription. This is in addition to writing out the radiopharmaceutical, route of administration and dosage and signing the prescription.

An additional line was added to the radiopharmaceutical dosage verification section to include the technologist's verification that the dose to be administered is the dose ordered by the Authorized User. He or She will have to initial date and time on that verification line.

An in-service to all Nuclear Medicine technologists on our written directive procedure to include the updated I-131 Written Directive, Checklist and Verification form was held on 10/28/2022. In-service to be repeated annually.

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Corrective action that will be taken: The RSO will be notified and review the Written Directive Checklist and Verification form following administration of a therapeutic dose. This will be documented at the bottom of the I-131 Written Directive, Checklist and Verification form.

As an additional measure to ensure a medical event has not occurred, a technologist and the RSO will perform the annual audit together. Previously, the annual audit was done by a technologist and presented to the RSO and RSC.

Date when full compliance will be achieved: As of 10/28/2022, all the stated changes are in place for our next written directive patient. As of today, we have not done a written directive therapy patient.

Violation of 10 CFR 35.67 (g):

Reason for the violation: During the NRC inspection on 10/18/22, the Sealed Source Inventory record listed five sources. Three of the sealed sources did not match the information listed on the Sealed Source Inventory record. The sources included a barium-133 vial, cesium-137 rod and europium-152 rod. These three sources were replaced in 2016, but were not updated on the SSI form. Immediate proof of disposal of the old sources in 2016 was not readily available to the inspectors.

What actions have been taken to prevent recurrence: On October 20, 2022 a physical inventory was performed. All information on the SSI form was updated to include model number, serial number, radionuclide, activity, location of each source. Henceforth, this form will be completed by two technologists. All information to be read by one technologist and verified by another technologist. Both technologists to sign the form as an attestation to the correct information.

Proof of the disposal of the old sources from 2016 was provided to the inspectors on October 28, 2022

Corrective action that will be taken: RSO will do a physical check of all sources quarterly. A technologist will read the information on the actual sources and the RSO will verify on the SSI form and document this verification.

Nuclear Medicine Coordinator is responsible for the receipt and documentation of any new sources. This includes disposal of any old sources, updating new source on all forms and in BioDose.

Date when full compliance will be achieved: October 20,2022