



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BLVD.
KING OF PRUSSIA, PA 19406-2713

February 6, 2019

Robert Adcock
Chief Executive Officer
Alecto Healthcare Services Fairmont, LLC
d/b/a Fairmont Regional Medical Center
1325 Locust Avenue
Fairmont, WV 26554-1435

SUBJECT: ALECTO HEALTHCARE SERVICES FAIRMONT, LLC D/B/A FAIRMONT
REGIONAL MEDICAL CENTER - NRC INSPECTION NO. 03013661/2018001
NOTICE OF VIOLATION

Dear Mr. Adcock:

This letter refers to the inspection conducted on March 29, 2018 at your Fairmont, West Virginia facility. This inspection examined activities conducted under your license as they relate to public health and safety, and to confirm compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel. Additional information received September 17, 19, and 21, 2018, was also reviewed as part of the inspection. The results of the inspection were discussed with you and other members of your organization during a telephonic exit meeting on January 24, 2019.

Based on the results of this inspection, the NRC has determined that four Severity Level IV violations of NRC requirements occurred. These violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on 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 the violations were identified by the NRC.

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 and include: revising your "Radiopharmaceutical and Adjunct Medication Doses" protocol to include the revised dosages for Myocardial SPECT rest and stress studies, retraining the Nuclear Medicine (NM) staff on the revised prescribed dose chart, amending the license to include the cardiac stress lab, implementing a new policy that all IV waste from the cardiac stress lab will be transferred to the NM hot lab, retraining staff on the new IV policy, retraining NM staff on the policy for package receipt wipes, and retraining NM and cardiology staff that all radioactive materials are to be stored only in the hot lab and surveyed by appropriate NM staff prior to disposal.

Therefore, you are not required to respond to this letter unless the description herein 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 "Rules of Practice," a copy of this letter and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC document 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, proprietary, or safeguards information so that it can be made available to the Public without redaction.

If you have any questions regarding this matter, please contact Janice Nguyen of my staff at (610) 337-5006 or via electronic mail at janice.nguyen@nrc.gov.

Thank you for your cooperation.

Sincerely,

/RA/

Donna M. Janda, Chief
Medical and Licensing Assistance Branch
Division of Nuclear Materials Safety
Region I

Docket No. 030-13661
License No. 47-17929-01

Enclosure:
Notice of Violation

cc w/ encl: Mark Perna, Radiation Safety Officer
State of West Virginia

ALECTO HEALTHCARE SERVICES FAIRMONT, LLC D/B/A FAIRMONT REGIONAL
MEDICAL CENTER - NRC INSPECTION NO. 03013661/2018001 NOTICE OF VIOLATION
DATED FEBRUARY 6, 2019

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NOTICE OF VIOLATION

Alecto Healthcare Services Fairmont, LLC
d/b/a Fairmont Regional Medical Center
Fairmont, West Virginia

Docket No. 03013661
License No. 47-17929-01

During an NRC inspection conducted on March 29, 2018, with additional information received on September 17, 19, and 21, 2018, and telephonic exit on January 24, 2019, four violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 35.63(d) requires, in part, that unless otherwise directed by the authorized user, a licensee may not use the dosage if the dosage does not fall within the prescribed dosage range.

Contrary to the above, on March 29, 2018, and other various dates after December 2015, a licensee used a dosage that did not fall within the prescribed dosage range without direction by an authorized user. Specifically, the Chief Nuclear Medicine Technologist revised the "Myocardial SPECT Rest/Stress (SESTAMIBI) with Ultraspect 3" procedure manual in December 2015, which changed the Tc-99m Myocardial SPECT Rest dosage range from 12-15 mCi to 6-8 mCi, and the Tc-99m Myocardial SPECT Stress dosage range from 30-45 mCi to 15-27 mCi, without direction and approval from an authorized user. The new dosage range was administered during the December 2015 through March 2018 time period.

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

- B. 10 CFR 30.34(c) requires, in part, that each licensee shall confine his possession and use of the byproduct material to the locations and purposes authorized in the license.

Contrary to the above, as of March 29, 2018, the licensee did not confine his possession and use of the byproduct material to the locations and purposes authorized in the license. Specifically, the licensee was using Technetium-99m (Tc-99m) and storing Tc-99m waste in a cardiac stress lab, which was not a location authorized by the license.

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

- C. 10 CFR 20.1906(b)(1) states, in part, that each licensee shall monitor the external surfaces of a labeled package for radioactive contamination.

Contrary to the above, on March 29, 2018 and other various dates, the licensee did not monitor the external surfaces of labeled packages received in the Nuclear Medicine Department. Specifically, the ammo boxes containing radioactive dosages were monitored with a survey instrument, but not wiped for radioactive contamination.

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

- D. 10 CFR 35.92(a)(1) requires, in part, that a licensee may hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if it monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding.

Contrary to the above, as of March 29, 2018, the licensee was holding byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity, but did not monitor the byproduct material at the surface before disposal to determine if its radioactivity could be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding. Specifically, Tc-99m waste that was being stored in the cardiac stress lab was being disposed of by the cardiology staff, without being surveyed prior to disposal.

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

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence and the date when full compliance will be achieved is already adequately addressed on the docket. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

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

Dated This 6th day of February 2019