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June 21, 2024

By USPS (Priority Mail Express – Next Business Day)
U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555-0001

By Federal Express (Priority Overnight – Next Business Day)
U.S. Nuclear Regulatory Commission
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11555 Rockville Pike
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By Email
David Curtis, Director
Division of Radiological Safety and Security
Nuclear Regulatory Commission
Document Control Deck
Washington, DC 20555-0001
David.Curtis@nrc.gov

RE: Response to the Apparent Violation in Inspection Report No. 03035774/2024001(DRSS); EA-24-019

Dear Mr. Curtis:

Alliance HealthCare Services, Inc. d/b/a Akumin mobile PET/CT unit PET CT 142 ("the "Company") hereby submits the Company's response to the U.S Nuclear Regulatory Commission's ("NRC's" or the "Agency's") May 22 2024 correspondence, "NRC Non-Routine Inspection Report No. 03035774/2024001(DRSS) – Alliance Healthcare Services, Inc. EA-24-019/230352" (ML24122A520) regarding the Agency's inspection on August 21, 2023 through April 30, 2024 (the "Inspection"). The Inspection related to a self-reported event regarding certain sealed sources held by Alliance Healthcare Services, Inc. pursuant to NRC Materials License No. 47-25570-01.

We appreciate the opportunity to provide the enclosed written response, which further addresses the NRC's Inspection findings related to the self-reported event. This letter supplements my previous correspondence

transmitted to the NRC on August 23, 2023 and September 5, 2023 regarding the Company's immediate and proactive corrective actions since the Company's disclosure on August 23, 2023 (EN 56693).

Should you have any questions or require additional information, please do not hesitate to contact me, Kay Kassel Manager, Corporate Radiation Safety Officer at Kay.kassel@akumin.com or (561) 701-1311.

Sincerely,

Kay Kassel, MS CNMT NMTCB(RS)
Corporate Radiation Safety Officer
Kay.kassel@akumin.com
561-701-1311

Enclosure: Response to the Apparent Violation in Inspection Report No. 03035774/2024001(DRSS); EA-24-019

cc: **By Federal Express (Priority Overnight -- Next Business Day)**
NRC Region III Office
2443 Warrenville Road, Suite 210
Lisle, IL 60532

By Email
Rhex Edwards, Chief
Materials Inspection Branch
Division of Radiological Safety and Security
Rhex.Edwards@nrc.gov

Enclosure
Response to the Apparent Violation
in Inspection Report No. 03035774/2024001(DRSS); EA-24-019

Alliance HealthCare Services, Inc.
d/b/a Akumin mobile PET/CT unit PET CT 142 ("the "Company")
Response to the Apparent Violation
in Inspection Report No. 03035774/2024001(DRSS); EA-24-019

On May 22, 2024, the U.S. Nuclear Regulatory Commission ("NRC" or the "Agency") requested that a written response to "NRC Non-Routine Inspection Report No. 03035774/2024001(DRSS) – Alliance Healthcare Services, Inc. EA-24-019/230352"[1] address (1) the reason for the apparent violation, or, if contested, the basis for disputing the apparent violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations; and (4) the date when full compliance was or will be achieved. The Company responds as applicable to these four inquiries, and provides in Section 5 below, a discussion for the NRC's consideration of the self-reported event as a noncited violation. This response has been provided within the timeframe provided by the NRC.

(1) The Reason for the Apparent Violation

On August 21, 2023, the Company discovered that two germanium-68 sources were unable to be located. The two germanium-68 sources were located on a mobile PET CT imaging unit – Pet CT 142 that was sent for repair to TDC Trailer, LLC ("TDC's") facility located at 1065 N. US Highway 231 in Rensselaer, Indiana. The two germanium-68 sources were not removed from the Pet CT 142 unit prior to the unit's transportation for repair.

At the TDC facility, the TDC staff conducted a structural repair on the mobile unit, which required items in the camera room to be removed from their designated locations. The Company understands that TDC's trailer repairman removed the two germanium-68 sources and the source holder by unbolting the holder from the floor and moving it to the hot lab where it was placed in a radiopharmaceutical dose container.

On August 16, 2023, the Pet CT 142 unit returned to the route, and was not used for imaging until August 21, 2023. When the unit returned to its normal use on August 21, 2023, the nuclear medicine technologist ("NMT") discovered that the sources were missing from the radiopharmaceutical dose container.

Based on the Company's investigation of the event (as discussed below in Section 2), the Company believes that the two germanium-68 sources may have been picked up inadvertently by employees of PET NET Solutions Inc. ("PETNET") on August 16, 2023, as part of their routine pick up of empty radiopharmaceutical cases when there is a new delivery of radiopharmaceuticals.

[1] Letter from David Curtis, Dir., Div. of Radiological Safety & Sec., NRC Region III, to Kay Kassel, Corp. Radiation Safety Officer, All. Healthcare Servs., Inc. (May 22, 2024).

(2) Completed Corrective Actions

The Company has completed and directed third-party partners to complete the following immediate corrective actions.

#	Action	Status	Completed Date
1	Immediately upon discovery that the two germanium-68 sources were unable to be located, the NMT notified the Company's Manager of Operations and Corporate Radiation Safety Officer (RSO)	Completed	August 21, 2023
2	The Company's technologist team in Michigan conducted a physical search to locate the two germanium-68 sources, which included a thorough search of the entire Pet CT 142 unit, including all cabinets in the camera room, hot lab, and control room	Completed	August 21, 2023
3	The Company conducted an investigation, which involved interviews of the NMT, personnel working on Pet CT 142 unit, relevant repair personnel at TDC, and PETNET personnel	Completed	August 21-22, 2023
4	Action by PETNET to contact PETNET managers in Cleveland, Chicago and Detroit to query whether the sources were recovered in any of the return cases	Completed	August 22, 2023
5	Once the Company's investigation was complete, proactive notification of NRC Region III by telephonic call (EN 56693)	Completed	August 23, 2023
6	Submission of written event report regarding the two germanium-68 sources	Completed	August 23, 2023
7	Submission of physicist's estimation of the lifetime dose resulting from the two germanium-68 sources (ML23269A098)	Completed	September 5, 2023

(3) The Company's Pending Corrective Actions

The Company is currently undertaking the following corrective actions to prevent any future loss of control of licensed material.

1. Development and implementation of company-wide policy, which includes a set of procedures to outline the handling, security, and storage of licensed materials when mobile units are scheduled for repairs. The policy will incorporate specific directives and lessons learned from logistics team, operations team, and the corporate RSO.
2. Development and implementation of company-wide policy that requires the Company team to complete a source inventory immediately following the completion of a trailer repair.

(4) The Company's Full Compliance

At the time of this letter, the Company has achieved full compliance.

(5) Consideration of Event as Noncited Violation

Pursuant to the applicable criteria of the NRC's Enforcement Policy[2] and consistent with prior enforcement decisions by NRC Region III,[3] the self-reported event should be treated as a noncited violation. The Company outlines how the circumstances and immediate corrective actions related to the self-reported event meet the applicable criteria for a noncited violation.

Criteria 1: The licensee or nonlicensee identified the violation.

As acknowledged in the NRC's Inspection Report, "[the] apparent violation of 10 CFR 20.1801 was identified through a ***reported*** event."[4] Once the loss of the material was confirmed, the Company provided to the NRC telephonic notification, followed by a written report and written submission regarding dosage.

Criteria 2: The licensee or nonlicensee corrected or committed to correcting the violation within a reasonable period of time by specific corrective action committed to by the end of the inspection, including immediate corrective action and comprehensive action to prevent recurrence.

Within three business days, the Company took and directed third-party partners to take immediate action, including but not limited to:

1. A physical search to locate the two germanium-68 sources, which included a thorough search of the entire Pet CT 142 unit, including all cabinets in the camera room, hot lab, and control room;
2. An investigation, which involved interviews of the NMT, personnel working on Pet CT 142 unit, the relevant repair personnel at TDC, and PETNET personnel;
3. An action by PETNET to contact PETNET managers in Cleveland, Chicago and Detroit to query whether the sources were recovered in any of the return cases;
4. Proactive notification of NRC Region III by telephonic call made (EN 56693); and
5. Submission of written event report to NRC.

Additionally, the Company is currently in the process of completing the following corrective actions to prevent any future loss of control of licensed material:

1. Development and implementation of company-wide policy to improve the handling, security, and storage of licensed materials when mobile units are scheduled for repairs.
2. Development and implementation of company-wide policy to require the Company team to complete a source inventory immediately following the completion of a trailer repair.

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[2] NRC, NRC Enforcement Policy, at §§ 2.3.2 (b) (Jan. 12, 2024), https://www.nrc.gov/docs/ML2333/ML23333A447.pdf.
[3] Letter from Aaron T. McCraw, Chief, Materials Inspection Branch, Div. of Nuclear Materials Safety, NRC Region III, to Maha Srinivasan, MS, Radiation Safety Officer, Wayne State Univ. (Mar. 29, 2019).
[4] NRC Region III, NRC Non-Routine Inspection Report, No. 03035774/2024001 (DRSS) (Apr. 30, 2024).

Criteria 3: The violation is not repetitive as a result of inadequate corrective action.

The Company is not aware of any prior violations related to loss of sealed sources authorized for use by NRC Materials License No. 47-25570-01. The Company is currently undertaking additional corrective actions (as discussed above) to prevent any future loss of control of licensed material.

Criteria 4: The violation is not willful.

There is no indication that the loss of the material was the result of a willful action.