



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

May 22, 2024

EA-24-019
EN 56693
NMED No. 230352 (Closed)

Kay Kassel
Corporate Radiation Safety Officer
Alliance Healthcare Services, Inc.
18201 Von Karman Ave.
Ste. 550
Irvine, CA 92612

SUBJECT: NRC NON-ROUTINE INSPECTION REPORT NO. 03035774/2024001(DRSS) –
ALLIANCE HEALTHCARE SERVICES, INC.

Dear Kay Kassel:

On August 21, 2023, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a non-routine inspection, with continued in-office review through April 30, 2024. The purpose of the inspection was to review the circumstances surrounding the loss of two germanium-68 (Ge-68) line sources with current calculated activity of 0.312 mCi each, for a total of 0.624 mCi, from a mobile nuclear medicine unit while at a repair facility in Rensselaer, Indiana. The loss of the sources was discovered on August 21, 2023. The event was reported to the NRC on August 23, 2023, under Title 10 of the Code of Federal Regulations (10 CFR) 20.2201(a)(1)(ii). Zahid Sulaiman of my staff conducted a virtual exit meeting with you on April 30, 2024, to discuss the inspection findings.

This inspection examined activities conducted under your license as they relate to safety and compliance with the Commission's rules and regulations and with the conditions in your license. Within these areas, the inspection consisted of an examination of selected procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, one apparent violation of NRC requirements was identified and is being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The apparent violation concerned the failure to secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas, as required by 10 CFR Part 20.1801. The circumstances surrounding the apparent violation, the significance of the issue, and the need for lasting and effective corrective action were discussed with you at the exit meeting conducted by Zahid Sulaiman on April 30, 2024.

Since the apparent violation involves the loss of two germanium-68 (Ge-68) line sources with current calculated activity of 0.312 mCi each, for a total of 0.624 mCi, the NRC is considering proposing imposition of a civil monetary penalty. Consistent with Section 2.3.4, Civil Penalty, of the NRC Enforcement Policy, for violations where a licensee has lost required control of its regulated licensed material for any period of time, the NRC will normally impose at least a base civil penalty. The base civil penalty amount is based on approximately three times the expected

average cost of authorized disposal; however, the NRC may exercise its discretion to mitigate or escalate a civil penalty amount based on the merits of a specific case. Therefore, you may provide information regarding the actual expected cost of authorized disposal for the NRC to consider in making a final enforcement decision. However, the NRC will not normally decrease the civil penalty to an amount below the lowest base civil penalty for such cases.

Before the NRC makes its enforcement decision, we are providing you an opportunity to (1) respond to the apparent violation addressed in this inspection report within 30 days of the date of this letter, (2) request a Pre-decisional Enforcement Conference (PEC), or (3) request Alternative Dispute Resolution (ADR). If a PEC is held, it will be open for public observation and the NRC will issue a press release to announce the time and date of the conference. **Please contact Rhex Edwards at (630) 829-9722 or Rhex.Edwards@nrc.gov within 10 days of the date of this letter to notify the NRC of your intended response or request.** A PEC should be held within 30 days and an ADR session within 45 days of the date of this letter.

If you choose to provide a written response, it should be clearly marked as "Response to the Apparent Violation in Inspection Report No. 03035774/2024001(DRSS); EA-24-019," and should include, for the apparent violation: (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. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. Your response should be sent to the NRC's Document Control Desk, Washington, DC 20555-0001, with a copy mailed to the NRC Region III Office, 2443 Warrenville Road, Suite 210, Lisle, Illinois 60532, within 30 days of the date of this letter. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a PEC.

If you choose to request a PEC, the conference will afford you the opportunity to provide your perspective on these matters and any other information that you believe the NRC should take into consideration before making an enforcement decision. The decision to hold a pre-decisional enforcement conference does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference would be conducted to obtain information to assist the NRC in making an enforcement decision. The topics discussed during the conference may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned. In presenting your corrective action, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful in preparing your response. You can find the information notice on the NRC website at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html>.

You may also request ADR with the NRC in an attempt to resolve this issue. ADR is a general term encompassing various techniques for resolving conflicts using a neutral third party. The technique that the NRC has decided to employ is mediation. Mediation is a voluntary, informal process in which a trained neutral party (the "mediator") works with parties to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an

opportunity to discuss issues, clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues. Additional information concerning the NRC's program can be obtained at <http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html>. The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as a neutral third party. **Please contact ICR at 877-733-9415 within 10 days of the date of this letter if you are interested in pursuing resolution of this issue through ADR. In addition, if you choose ADR, please also contact Rhex Edwards at the telephone number or email address listed above.**

In addition, please be advised that the number and characterization of the apparent violations described in the enclosed inspection report may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

In accordance with the NRC's "Agency Rules of Practice and Procedure" in 10 CFR 2.390, a copy of this letter, its enclosure, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, any response should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction.

Please feel free to contact Zahid Sulaiman of my staff if you have any questions regarding this inspection. Zahid can be reached at 630-829-9752 or Zahid.Sulaiman@nrc.gov.

Sincerely,



Signed by Curtis, David
on 05/22/24

David Curtis, Director
Division of Radiological Safety and Security

Docket No. 030-35774
License No. 47-25570-01

Enclosure:
Inspection Report No. 03035774/2024001(DRSS)

cc w/encl: Kay Kassel, Corporate Radiation Safety Officer
State of California

Letter to K. Kassel from D. Curtis, dated May 22, 2024.

SUBJECT: NRC NON-ROUTINE INSPECTION REPORT NO. 03035774/2024001(DRSS) – ALLIANCE HEALTHCARE SERVICES, INC.

DISTRIBUTION w/encl:

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ADAMS Accession Number: ML24122A520

OFFICE	RIII-DRSS		RIII-DRSS		RIII-EICS		NMSS	
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DATE	5/2/24		5/2/24		5/2&21/24		5/3/24	
OFFICE	OE		OGC		RIII-DRSS			
NAME	JPeralta		MSimon		DCurtis			
DATE	5/8/24		5/15/24		5/22/24			

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**U.S. Nuclear Regulatory Commission
Region III**

Docket No. 03035774

License No. 47-25570-01

Report No. 03035774/2024001(DRSS)

EA No./NMED No. EA-24-019 / 230352

Licensee: Alliance Healthcare Services, Inc

Facility: 18201 Von Karman Ave
Irvine, CA

Inspection Dates: August 21, 2023 - April 30, 2024

Exit Meeting Date: April 30, 2024

Inspector: Zahid Sulaiman, Health Physicist

Approved By: Rhex Edwards, Chief
Materials Inspection Branch
Division of Radiological Safety and Security

Enclosure

EXECUTIVE SUMMARY

Alliance Healthcare Services, Inc NRC Inspection Report 03035774/2024001(DRSS)

This was a non-routine inspection of a mobile positron emission tomography/computed tomography (PET/CT) nuclear medicine service provider authorized to store byproduct material for diagnostic medical purposes at a base station in Owosso, Michigan, and use at temporary job sites throughout NRC jurisdiction. The licensee operated numerous PET/CT trailers across the country, including several in Michigan.

The scope of the inspection was limited to the review of the circumstances surrounding the loss of two germanium-68 (Ge-68) line sources from a mobile PET/CT imaging unit which was used for camera alignment checks. This mobile unit was sent to Rensselaer, Indiana, for a structural repair which required items in the camera room to be removed from their designated place. The licensee believes the sources were inadvertently picked up by the PetNet radiopharmacy as part of their routine pick up of empty radiopharmaceutical cases and were inadvertently thrown in the trash; the licensee determined that the sources do not pose a risk to the public if in a landfill. The calculated activity of the lost sources on August 21, 2023, was 0.312 mCi each, with a total activity of 0.624 mCi. The licensee's consultant physicist estimated the dose resulting from the two sources over their lifetime to be 31 mSv (3100 mrem) at 1 meter from the unshielded sources (ML23269A098). The whereabouts of the two Ge-68 line sources is unknown.

As a corrective action for the apparent violation, the licensee will develop a policy regarding the security of radioactive materials when the mobile PET/CT units are scheduled for repairs. The policy will include Team discussions with personnel from logistics, operations, and the Radiation Safety Officer to provide directives on steps to be taken to secure the radioactive materials onboard the unit and before the unit leaves for repair. Also, the licensee staff will complete a source inventory immediately following the completion of a mobile PET/CT unit repair.

REPORT DETAILS

1 Program Overview and Inspection History

Alliance Healthcare Services, Inc., doing business as Akumin, is a mobile PET/CT nuclear medicine service provider authorized under NRC Materials License No. 47-25570-01 to store byproduct material for diagnostic medical purposes at a base station in Owosso, Michigan, and use at temporary job sites throughout NRC jurisdiction. The licensee operated numerous PET/CT trailers across the country, including several in Michigan.

2 Radiation Safety Program

2.1 Inspection Scope

On August 21, 2023 through April 30, 2024, the inspector reviewed the circumstances surrounding an event involving the loss of two germanium-68 (Ge-68) line sources with calculated activity, as of August 21, 2023, of 0.312 mCi each, for a total of 0.624 mCi. The inspector interviewed licensee personnel, reviewed records, and reviewed radiation safety programs.

2.2 Observations and Findings

On August 21, 2023, the licensee discovered that two Ge-68 sources were lost (model PET-180/1, s/n S529, and model PET-180/1, s/n S530). The nominal activity, as of February 9, 2022, was 1.3 mCi each. The sources were stored on a mobile PET/CT imaging unit #142 in their designated shielded holder inside the normally locked camera room. The sources were used for PET/CT camera alignment checks. The calculated activity of the lost source on August 21, 2023, was 0.312 mCi each, with a total activity of 0.624 mCi.

This mobile unit was sent to TDC Trailer at 1065 N. US Highway 231 in Rensselaer, Indiana, for repair. While at TDC Trailer, the unit needed a structural repair which required items in the camera room to be removed from their designated place. According to the licensee's 30-day written report (ML23269A098), the trailer repairman removed the 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. After the repair was completed, the mobile unit was returned to the normal service route on Wednesday August 16, 2023. The licensee stated the mobile unit was not used for imaging until Monday August 21, 2023. At this time, the nuclear medicine technologist (NMT) working on the mobile PET/CT unit discovered that the sources were missing from their container.

Immediately upon discovery that the sources were missing, the technologist notified the Manager of Operations in the area and the Corporate Radiation Safety Officer (RSO). The corporate RSO then notified the NRC and Region III by telephone on August 23, 2023 (EN 56693). The licensee interviewed the NMT, the repair personnel at TDC Trailer, and personnel at the PetNet Radiopharmacies about the missing sources. The licensee's Michigan technologist team searched the entire mobile unit, all cabinets in the camera room, hot lab, and control room for the two sources.

The licensee believes the sources were inadvertently picked up by the PetNet radiopharmacy as part of their routine pick up of empty radiopharmaceutical cases on

Wednesday August 16, 2023. The licensee further believes the sources were inadvertently thrown in the trash and would not be an exposure risk to the public if in a landfill. The licensee's consultant physicist estimated the dose resulting from the two sources over their lifetime to be 31 mSv (3100 mrem) at 1 meter from the unshielded sources (ML23269A098).

The whereabouts of the two Ge-68 line sources with total activity of 0.624 mCi are unknown.

Title 10 of the Code of Federal Regulations (10 CFR) 20.1801 states the licensee shall secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

Contrary to the above, on or about August 16, 2023, the licensee failed to secure from unauthorized removal or access licensed materials that were stored in controlled or unrestricted areas. Specifically, the licensee failed to secure from unauthorized removal two germanium-68 line sources, model PET-180/1, s/n S529, and model PET-180/1, s/n S530, containing a total activity of 0.624 mCi.

This is an apparent violation of 10 CFR 20.1801 and is being considered for escalated enforcement action in accordance with sections 2.3.4 and 6.7 of the NRC's Enforcement Policy.

As a corrective action for the apparent violation, the licensee will develop a policy regarding the security of radioactive materials when the mobile PET/CT units are scheduled for repairs. The policy will include Team discussions with personnel from logistics, operations, and the Radiation Safety Officer to provide directives on steps to be taken to secure the radioactive materials on board the unit and before the unit leaves for repair. Also, the licensee staff will complete a source inventory immediately following the completion of a mobile PET/CT unit repair.

2.3 Conclusions

An apparent violation of 10 CFR 20.1801 was identified through a reported event when the licensee failed to secure from unauthorized removal or access licensed materials that were stored in controlled or unrestricted areas.

3. **Exit Meeting Summary**

The NRC inspector presented preliminary inspection findings upon completion of the in-office review, and a virtual exit meeting was held on April 30, 2024, with the licensee. The licensee committed to implementing actions to prevent recurrence of similar types of events.

LIST OF PERSONNEL CONTACTED

Kay Kassal, Corporate RSO
Brandon Boyd, Territory Operations Manager

Attended exit meeting on April 30, 2024.

INSPECTION PROCEDURES USED

IP 87130 – Nuclear Medicine Programs, Written Directive Not Required