



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

August 27, 2024

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

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

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY -
\$9,000, NRC NON-ROUTINE INSPECTION REPORT 03035774/2024001 (DRSS) -
ALLIANCE HEALTHCARE SERVICES, INC.

Dear Kay Kassel:

This letter refers to the U.S. Nuclear Regulatory Commission (NRC) inspection conducted on August 21, 2023, 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 from a mobile nuclear medicine unit while at a repair facility in Rensselaer, Indiana. During the inspection, one apparent violation of NRC requirements was identified. The circumstances surrounding the apparent violation, the significance of the issues, and the need for lasting and effective corrective actions were discussed with you during a virtual exit meeting on April 30, 2024. Inspection Report No. 03035774/2024001 (DRSS) was issued on May 22, 2024, and can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) at accession number ML24122A520. ADAMS is accessible from the NRC Web site at <https://www.nrc.gov/reading-rm/adams.html>.

In our May 22, 2024, letter transmitting the inspection report, we informed you that one apparent violation was being considered for escalated enforcement action, including a civil penalty. In the letter, we provided you the opportunity to address the apparent violation identified in the report by either attending a predecisional enforcement conference, engaging the NRC in Alternative Dispute Resolution (ADR) mediation, or by providing a written response before we made our final enforcement decision. In letters dated June 21, 2024 (ML24185A127), July 9, 2024 (ML24212A311), and July 10, 2024 (ML24212A311), you provided written responses to the apparent violation.

Based on the information developed during the inspection and the information that you provided in your responses to the inspection report, the NRC has determined that a violation of NRC requirements occurred and is proceeding with enforcement action. The violation is cited in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty. The violation involved the failure to secure from unauthorized removal or access to licensed materials that are stored in controlled or unrestricted areas, as required by Title 10 of the *Code of Federal Regulations* (10 CFR) Section 20.1801. This failure resulted in the loss of the two Ge-68 sources, which are still missing today. The NRC considers the loss of NRC-regulated material a significant safety

and security concern because of the potential for unauthorized individuals to gain control of the radioactive material, which could result in an unintended exposure to a member of the public. Therefore, this violation has been categorized in accordance with the NRC Enforcement Policy at Severity Level (SL) III. The current Enforcement Policy is included on the NRC's web site at <https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>.

In your response letter dated June 21, 2024, you requested that the NRC consider issuing a non-cited violation (NCV) for the failure to secure the sources since you met the conditions in Section 2.3.2 of the Enforcement Policy for issuing an NCV. However, Section 2.3.2 of the Enforcement Policy also provides that NCVs are issued only for SL IV violations. Therefore, issuing an NCV in this case is not appropriate.

In accordance with Section 2.3.4 of the NRC Enforcement Policy, the NRC considers civil penalties for violations associated with the loss of regulated material. A base civil penalty amount of \$7,000 is identified for the loss of regulated material in this case, as provided in Section 8, Table A, Item f.3 of the Enforcement Policy. However, Section 8, Table A, Item e together with Table B identifies a base civil penalty amount of \$9,000 for a SL III violation by a licensee of your type. The NRC normally does not issue civil penalties less than the base amount for the types of licensees listed in Section 8, Table A, Items a through e.

Therefore, to emphasize the importance of maintaining security and control of sealed sources, I have been authorized, after consultation with the Director, Office of Enforcement, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the base amount of \$9,000 for the SL III violation. In addition, issuance of this Notice constitutes escalated enforcement action that may subject you to increased inspection effort. The NRC also includes significant enforcement actions on its web site at <https://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/index.html>.

You may choose to pay the proposed civil penalty by submitting your payment, with the invoice enclosed to this letter, to the following address:

Office of the Chief Financial Officer
U.S. Nuclear Regulatory Commission
P.O. Box 979051
St. Louis, MO 63197

In addition, you may pay the proposed civil penalty in accordance with NUREG/BR-0254, which can be found on the NRC's web site at <https://www.nrc.gov/reading-rm/doc-collections/nuregs/brochures/br0254/index.html>. When using NUREG/BR-0254 to pay the civil penalty, the invoice number should be used as the "enforcement action identifier" when submitting your payment through one of the approved methods listed in the brochure. The NRC may consider a request for additional time to pay the proposed civil penalty, including the option to enter into an installment agreement, if payment of the civil penalty as a lump sum in the required timeframe would pose a financial hardship. To request additional time to pay, you must submit a written request, with appropriate justification explaining your financial hardship, to NRCCollections.Resource@nrc.gov. All requests should be submitted in sufficient time to allow the NRC the ability to review your request for additional time to pay before the 30-day payment period expires.

If you disagree with this enforcement sanction, you may deny the violation, as described in the Notice, or you may request alternative dispute resolution (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 (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 ADR program can be found 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. **If you are interested in pursuing this issue through the ADR program, please contact: (1) the ICR at 877-733-9415; and (2) Diana Betancourt-Roldan at 630-810-4373 within 10 days of the date of this letter.** You may also contact both ICR and Diana Betancourt-Roldan for additional information. Your submitted signed agreement to mediate using the NRC ADR program will stay the 30-day time period for payment of the civil penalty and the required written response, as identified in the enclosed Notice, until the ADR process is completed.

The NRC has concluded that information regarding: (1) the reason for the violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance was achieved is already adequately addressed on the docket in Inspection Report No. 03035774/2024001 (DRSS) and your letters dated June 21, July 9, and July 10, 2024. 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, its enclosures, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room and from the NRC's 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 or proprietary information so that it can be made available to the public without redaction.

K. Kassel

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If you have any questions concerning this matter, please contact Diana Betancourt-Roldan at 630-810-4373.

Sincerely,



Shuaibi, Mohammed signing on behalf
of Giessner, Jack
on 08/27/24

John B. Giessner
Regional Administrator

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

Enclosure: Notice of Violation and Proposed
Imposition of Civil Penalty
Civil Penalty Invoice No. EA-24-019

cc w/encl: State of California
State of Indiana

Letter to K. Kassel from J. Giessner dated August 27, 2024.

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - \$9000, NRC NON-ROUTINE INSPECTION REPORT 03035774/2024001 (DRSS) - ALLIANCE HEALTHCARE SERVICES, INC.

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ADAMS Accession Number: ML24214A142

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OFFICE	RIII-EICS		RIII-DRSS		RIII-DRSS		OE
NAME	GEdwards for KLambert:bw		REdwards		JFeibus for DCurtis		CRivera Diaz for JPeralta
DATE	8/5/2024		8/6/2024		8/6/2024		8/13/2024
OFFICE	NMSS		OGC-NLO		RIII-EICS		RIII-ORA
NAME	MBurgess		MSimon		DBetancourt-Roldan		MShuaibi for JGiessner
DATE	8/14/2024		8/8/2024		8/27/2024		8/27/2024

OFFICIAL RECORD COPY

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Alliance Healthcare Services, Inc.
Irvine, California

Docket No. 030-35774
License No. 47-25570-01
EA-24-019

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on August 21, 2023, with continued in-office review through April 30, 2024, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the NRC proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The violation and associated civil penalty are set forth below:

Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1801 requires that the licensee 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, 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 millicurie, were lost after they were removed from the licensee's mobile medical imaging unit while it was being repaired.

This is a Severity Level III violation (Enforcement Policy Section 2.3.4)
Civil Penalty - \$9,000 (EA-24-019)

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved is already adequately addressed on the docket in Inspection Report No. 03035774/2024001 (DRSS), and the letters from the licensee, dated June 21, July 9, and July 10, 2024. 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-24-019" and send it to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region III, 2443 Warrenville Road, Suite 210, Lisle, IL 60532-4352 and the Document Control Desk, Washington, DC 20555-0001.

The licensee may pay the civil penalty proposed above through one of the following two methods:

1. Submit the payment with the enclosed invoice for Civil Penalty EA-24-019, issued to Alliance Healthcare Services, Inc., to the following address:

Enclosure

Office of the Chief Financial Officer
U.S. Nuclear Regulatory Commission
P.O. Box 979051
St. Louis, MO 63197

OR

2. Submit the payment in accordance with NUREG/BR-0254.

The licensee may protest the imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice. Should the licensee fail to answer within 30 days of the date of this Notice, the NRC will issue an order imposing the civil penalty. Should the licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation listed in this Notice, in whole or in part; (2) demonstrate extenuating circumstances; (3) show error in this Notice; or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the response should address the factors addressed in Section 2.3.4 of the Enforcement Policy. Any written answer addressing these factors pursuant to 10 CFR 2.205 should be set forth separately from the statement or explanation provided pursuant to 10 CFR 2.201 but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the licensee is directed to the other provisions of 10 CFR 2.205 regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205 to be due, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The responses noted above, i.e., Reply to Notice of Violation, Statement as to payment of civil penalty, and Answer to a Notice of Violation, should be addressed to Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region III, 2443 Warrenville Road, Suite 210, Lisle, IL 60532-4352 and the Document Control Center, 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 Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response, if any, 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).

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

Dated this 27th day of August 2024.



08/26/2024

Address/Customer Information

Alliance HealthCare Services, Inc.
18201 Von Karman, Suite 600
Irvine, CA 92612

Customer Codes

Account Code: L00002839/1

Bill Information

Bill Number: EA-24-019
Amount Due: \$9,000.00
Due Date: 09/25/2024

Contact Us

Phone Number: 301-415-7554
Fax Number: 301-415-4135
Email Address: Fees.Resource@nrc.gov

Remit to Address

Office of the Chief Financial Officer
U.S. Nuclear Regulatory Commission
P.O. Box 979051
St. Louis, MO 63197

Bill Summary

Initial Charges	\$9,000.00
Discount	0.00
Surcharge	0.00
Interest Charges	0.00
Penalty Charges	0.00
Admin Charges	0.00
Bill Amount	\$9,000.00
Collected	0.00
Applied Credit	0.00
Adjustments	0.00
Amount Due	\$9,000.00

Credit Summary

Applied Credit	\$0.00
Unapplied Credit	0.00
Credit Total	\$0.00

Comments:For questions, contact the NRC Financial Services and Operations Branch at (301) 415-7554 or by email at Fees.Resource@nrc.gov. For NRC debt collection procedures, including interest and penalty provisions, see 31 U.S.C. 3717, 4 CFR 101-105 and 10 CFR 15.

If this invoice is related to an Order Imposing a Civil Penalty, Alliance HealthCare Services, Inc. is required to pay the Civil Penalty within 30 days of the Order date. If payment is in response to a Notice of Violation and Proposed Imposition of a Civil Penalty, please follow the instructions in the Notice. The NRC may consider a request for additional time to pay the Civil Penalty, including the option to enter into an installment agreement, if appropriate. All requests for additional time to pay an invoice must be submitted in writing, with appropriate justification, to NRCCollections.Resource@nrc.gov, and should be submitted sufficiently ahead of time to allow the NRC time to review the request for additional time to pay within the 30-day payment period. This Invoice is related to the Civil Penalty proposed or imposed under EA-24-019 issued to Alliance HealthCare Services, Inc. Please include this reference number on your payment method (see attached Payments Methods Brochure).

Please see the Payment Methods brochure for instructions on how to make payment. EFFECTIVE OCTOBER 1, 2024, THE NRC WILL ONLY ACCEPT ELECTRONIC PAYMENT METHODS. PAPER METHODS OF PAYMENT, INCLUDING CHECKS, WILL NO LONGER BE ACCEPTED. Please refer to the terms and conditions brochure for information on interest, penalties, and administrative fees associated with delinquent payments. Please reference the invoice number on the remittance.

Customer Information

L00002839/1
Alliance HealthCare Services, Inc.
18201 Von Karman, Suite 600
Irvine, CA 92612

Change of Address:

Phone:

Remittance Information

Office of the Chief Financial Officer
U.S. Nuclear Regulatory Commission
P.O. Box 979051
St. Louis, MO 63197

This Payment References the following Bill:

EA-24-019

Outstanding Amount Due:

\$9,000.00

Amount Enclosed:
