



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

December 3, 2018

EA-18-112
NMED No. 180259

Kert F. Anzilotti, MD, MBA
Chief Medical Officer Acute Care
Christiana Care Health Services
CH Management Suite 1218
4755 Ogletown-Stanton Road
Newark, DE 19718

SUBJECT: CHRISTIANA CARE HEALTH SERVICES, INC., NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF A CIVIL PENALTY - \$3,500 - NRC INSPECTION REPORT NO. 03001303/2018001

Dear Dr. Anzilotti:

This letter provides you the U.S. Nuclear Regulatory Commission's (NRC's) enforcement decision for the apparent violation identified during the reactive and routine inspections conducted on June 5 and July 9-12, 2018, at the Christiana Care Health Services, Inc. (CCHS) facilities in Newark, Smyrna, Middletown, and Wilmington, Delaware. The reactive inspection was conducted to review the circumstances surrounding the loss of 50 Iodine-125 (I-125) seeds as reported to the NRC on June 1, 2018 (Event Notification #53437). The routine 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. During the inspections, the NRC identified one apparent violation that was considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The NRC discussed the apparent violation during a telephonic exit meeting with you and other members of your staff on September 12, 2018. The apparent violation was also described in the NRC inspection report sent to you with a letter dated October 10, 2018 (ML18284A028).¹

In the NRC letter transmitting the inspection report, we provided you an opportunity to address the apparent violation before we made our final enforcement decision by attending a pre-decisional enforcement conference (PEC), providing a written response, or requesting alternative dispute resolution (ADR). In an electronic mail message dated October 17, 2018, and in a subsequent telephone conversation on October 19, 2018, with Farrah Gaskins of my staff, you indicated that CCHS accepted the violation and the proposed civil penalty. Therefore, based on the information developed during the inspection, the NRC determined that a violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it were described in detail in the subject inspection report.

¹ Designation in parentheses refers to an Agency-wide Documents Access and Management System (ADAMS) accession number. Documents referenced in this letter are publicly-available using the accession number in ADAMS.

The violation is related to the loss of 50 unused I-125 seeds. Specifically, on May 30, 2018, while preparing to return the unused I-125 seeds back to the manufacturer, it was discovered that the unused seeds were missing from the "hot lab." After further review, it was discovered that the unused seeds were likely inadvertently dropped in the universal waste trailer and either lost during transportation or disposed of with the metal trays as scrap metal. Although the seeds were not recovered, due to the encapsulation of the material, the relatively short half-life (~60 days) of I-125, and that the likely disposal location is not accessible to the public, the loss of control of this material likely had limited impact on the health and safety of the public.

The failure to control the I-125 seeds is contrary to Title 10 of the Code of Federal Regulations (CFR) Part 20.1802, which requires that licensees control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage. In assessing the significance of this violation, the NRC considered that the 50 unused seeds, as of March 16, 2018, had a combined total activity of 14.8 milli-Curies (mCi) (as calculated by CCHS), were not recovered and that the potential existed, although limited, for members of the public to receive unintended radiation exposure. Therefore, this violation has been categorized in accordance with the NRC Enforcement Policy at Severity Level (SL) III.

In accordance with Section 2.3.4 of the NRC Enforcement Policy, a base civil penalty is considered for any escalated violation. Under the normal civil penalty assessment process described in this section of the Enforcement Policy, your facility would not be subject to a civil penalty. Specifically, because your facility has not received escalated enforcement action within either the last two years or the two most recent inspections, the NRC would normally only consider whether credit was warranted for *Corrective Action*. The NRC notes that in response to this issue, CCHS implemented changes to its practices and procedures for handling unused seeds, including more clearly posting, and instituting monthly inspections of, the seed storage area, as well as increasing the shipment frequency of unused seeds and verifying such shipments occurred. The NRC concluded these measures to be sufficiently prompt and comprehensive to warrant granting corrective action credit.

However, as further described in Section 2.3.4 of the Enforcement Policy, the loss of regulated material is a significant regulatory and security concern because of the potential for overexposure to members of the public from its misuse. Therefore, notwithstanding the outcome of the normal civil penalty assessment process, in cases where the licensee has lost its regulated radioactive material, the NRC may exercise discretion and impose a civil penalty of at least the base amount. Therefore, to emphasize the importance of maintaining security and control of sealed sources and devices, 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 \$3,500 as listed in Section 8, Table A, Item f.3 of the Enforcement Policy. Issuance of this Notice constitutes escalated enforcement action that may subject you to increased inspection oversight.

If you disagree with this enforcement sanction, you may deny the violation, as described in the Notice, or you may 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 employs 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) Donna Janda, Chief, Medical Branch, Division of Nuclear Materials Safety, NRC Region I, at 610-337-5371 within 10 days of the date of this letter. You may also contact both ICR and Ms. Janda for additional information. Your submitted signed agreement to mediate using the NRC ADR program would stay the 30-day time period for payment of the civil penalties and the written response, as identified in the enclosed notice, until the ADR process is completed.

The NRC has concluded that information regarding: (1) the reasons 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 dates when full compliance was achieved is already adequately addressed on the docket in NRC Inspection Report No. 03001303/2018001. 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 "Rules of Practice," 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 or from the NRC's 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, or proprietary information so that it can be made available to the Public without redaction. The NRC also includes significant enforcement actions on its Web site at (<http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>). If you have any questions concerning this matter, please contact Donna Janda of my staff at 610-337-5371.

Sincerely,

Original Signed by /RA/

David C. Lew
Regional Administrator

Docket No. 03001303
License No. 07-12153-02

Enclosures:

1. Notice of Violation and Proposed Imposition of Civil Penalty
2. NUREG/BR-0254, "Payment Methods"

cc w/enclosures: C. Wen, Radiation Safety Officer
State of Delaware

SUBJECT: CHRISTIANA CARE HEALTH SERVICES, INC., NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF A CIVIL PENALTY - \$3,500 - NRC INSPECTION REPORT NO. 03001303/2018001

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 Region I OE Files (with concurrences)

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| X SUNSI Review/ CJC* | | X Non-Sensitive □ Sensitive | | | X Publicly Available □ Non-Publicly Available | |
|----------------------|----------------|--------------------------------|---------------|----------------|--|----------------|
| OFFICE | RI/ORA | RI/DNMS | RI/ORA | ORA | OE | OGC |
| NAME | C Crisden/CJC* | D Janda/DMJ* | B Klukan/BMK* | B Bickett/BAB* | J Peralta/JP* | L Baer/LB NLO* |
| DATE | 11/2/18 | 11/5/18 | 11/7/18 | 11/21/18 | 11/17/18 | 11/19/18 |
| OFFICE | RI/DNMS | | | | | RA |
| NAME | J Trapp/JMT* | | | | | D Lew/DCL |
| DATE | 11/21/18 | | | | | 11/27/18 |

* See previous concurrence page OFFICIAL RECORD COPY

ENCLOSURE 1

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Christiana Care Health Services, Inc.
Newark, Delaware

Docket No. 03001303
License No. 07-12153-02
EA-18-112

During NRC inspections conducted on June 5 and July 9-12, 2018, with continued in office review through September 12, 2018, 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 particular violation and associated civil penalty is set forth below:

10 CFR 20.1802 requires that the licensees control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

Contrary to the above, as of March 16, 2018, the licensee did not control and maintain constant surveillance of licensed material that was in a controlled or unrestricted area and that was not in storage. Specifically, on May 30, 2018, Christiana Care Health Services, Inc. (CCHS) discovered that 50 unused Iodine-125 seeds were missing. CCHS concluded that on March 16, 2018, the seeds were likely dropped in the universal waste trailer and either lost during transportation or disposed of with the metal trays as scrap metal. The seeds were not recovered.

This is a Severity Level III violation. (Enforcement Policy Section 6.7)
Civil Penalty - \$3,500 (EA-18-112)

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. 03001303/2018001. 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," and send it to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville, MD 20852-2738, with a copy to the Regional Administrator, U.S., Nuclear Regulatory Commission, Region I and the Document Control Desk, Washington, DC 20555-0001.

The Licensee may pay the civil penalty proposed above in accordance with NUREG/BR-0254 and by submitting to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, a statement indicating when and by what method payment was made, or may protest 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: Anne Boland, 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 I, 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 ADAMS. 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. 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. If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

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

Dated this 3rd day of December 2018