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

June 29, 2015

Docket No. 03001303 License No. 07-12153-02
EA-15-129

Patrick A. Grusenmeyer, ScD
President, Christiana Care Health Initiatives
Christiana Care Health Services, Inc.
Management Suite - Room 1270
4755 Ogletown-Stanton Road
Newark, DE 19718

SUBJECT: NRC INSPECTION REPORT NO. 03001303/2015001, CHRISTIANA CARE HEALTH SERVICES, INC., NEWARK, DELAWARE SITE AND THE SMYRNA AND MIDDLETOWN, DELAWARE SITES, NOTICE OF VIOLATION, AND EXERCISE OF ENFORCEMENT DISCRETION

Dear Dr. Grusenmeyer:

On March 16-20, 2015, Penny Lanzisera and John Nicholson of this office conducted a safety inspection at the above address and at the Smyrna and Middletown, Delaware sites of activities authorized by the above listed NRC license. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selective examination of representative records. Additional information provided in your correspondence dated May 19, 2015, with in-office review thru June 16, 2015, was also examined as part of the inspection. The findings of the inspection were discussed with you and other members of your staff of your organization at the conclusion of the inspection.

Based on the results of this inspection, the NRC has determined that three violations of NRC requirements occurred. The first violation involved 10 CFR 35.60 which requires, in part, that licensees calibrate the instrument used to measure the activity of the dosage before it is administered to each patient or human research subject. This calibration may either be performed in accordance with nationally recognized standards or calibration instructions provided by the manufacturer. Contrary to the above, Christiana Care Health Services, Inc. (CCHC) was unable to calibrate a Rubidium-82 (Rb-82) generator unit in accordance with the regulations because there are currently neither nationally recognized standards nor specific calibration procedures for calibrating detectors in a dynamic mode (i.e., while liquids are flowing past the detector). Until such standards or procedures are developed, compliance with 10 CFR 35.60 is not possible. The second violation involved 10 CFR 35.63 which requires, in part, that a licensee determine the activity of each dosage administered before medical use. Due to the 76 second half-life of Rb-82 and direct infusion of the Rb-82 into the patient, users of this generator system are unable to measure patient dosages of Rb-82 prior to administration.

Although violations of 10 CFR 35.60 and 10 CFR 35.63 were identified, which, in accordance with the NRC Enforcement Policy would normally be categorized at Severity Level IV, CCHC met all of the criteria in NRC Enforcement Guidance Memorandum (EGM) 13-003, “Interim

Guidance for Dispositioning Violations Involving 10 CFR 35.60 and 10 CFR 35.63 for the Calibration of Instrumentation to Measure the Activity of Rubidium-82 and the Determination of Rubidium-82 Patient Doses," dated April 18, 2013. Therefore, the NRC is exercising enforcement discretion and not pursuing any enforcement action for these violations. The NRC's decision is based on the criteria listed in EGM 13-003. Specifically: (1) CCHC has written test procedures to ensure that the infusion pump flow rate is consistent and accurate, and that the radiation detector meets the manufacturer's specifications; (2) CCHC has confirmed that the required infusion rate and radiation detector tests were performed within the last twelve months, on March 18, 2015, and has maintained records documenting the performance and results of these tests; (3) all authorized users for medical uses under 10 CFR Part 35.200 who are using the Rb-82 generator and infusion cart, as well as the Radiation Safety Officer and Temporary Radiation Safety Officer, have successfully completed training specific to the manufacturer and model of generator and infusion cart being used, and documentation of satisfactory completion of such training has been maintained; and (4) CCHC has recorded the activity of each dosage administered, as provided by the infusion cart. No further action or response is required on your part with regards to these issues.

The third violation involved the failure to secure the console keys of the remote afterloader unit located in the main hospital when not in use or unattended. Specifically, the keys were left in the remote afterloader unit's console after morning warm-up and prior to use for the day. The violation is cited in the enclosed Notice of Violation (Notice), because the violation was identified by the NRC.

In follow-up correspondence on May 19, 2015, you indicated that you revised the department procedure to clarify key control to remove and secure the keys after morning warm-up and retrained all radiation oncology staff on the revised procedure. You stated that you have taken corrective and preventative actions to address this violation and that CCHC is committed to radiation safety and to compliance with NRC regulations and licensed conditions.

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 is already adequately addressed in our records and in your correspondence dated May 19, 2015. Therefore, you are not required to respond to this letter unless the description of your corrective actions in this letter and your May 19, 2015, correspondence 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 enclosure, 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 website 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.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses;** then **Regulations, Guidance and Communications.** The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **About NRC, Organizations & Functions; Office of Enforcement;**

Enforcement documents; then **Enforcement Policy (Under 'Related Information').** You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at
1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

Please contact Penny Lanzisera at 610-337-5169 if you have any questions regarding this matter.

Sincerely,

/RA J. Nick for

Daniel S. Collins, Director
Division of Nuclear Materials Safety

Enclosure:
Notice of Violation

cc: Timothy Manzone, M.D.,
Temporary Radiation Safety Officer
State of Delaware

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Daniel S. Collins, Director
Division of Nuclear Materials Safety

Enclosure:
Notice of Violation

cc: Timothy Manzone, M.D.,
Temporary Radiation Safety Officer
State of Delaware

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NAME	PLanzisera/jpd f/	JNicholson/jpd f/	JDwyer/jd	BBickett/mmm f/	DCollins/jln f/
DATE	06/24/15	06/24/15	6/22/15	06/26/15	06/29/15

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Christiana Care Health Services, Inc.
Newark, DE

Docket No. 03001303
License No. 07-12153-02
EA-15-129

During an NRC inspection conducted on March 16-20, 2015, with in-office review until June 16, 2015, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

> 10 CFR 35.610(a)(1) requires, in part, that a licensee secure the console keys for remote afterloader units when not in use or unattended.
>
> Contrary to the above, on March 18, 2015, the licensee did not secure the console keys for the remote afterloader unit located at the main hospital when not in use and unattended. Specifically, the keys were left in the remote afterloader unit's console after morning warm-up and prior to use for the day and the console was left unattended. The remote afterloader unit was secured within the treatment room.
>
> This is a Severity Level IV violation (Section 6.3).

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 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 _29th_ day of _June_ 2015