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

July 28, 2016

Docket No. 03001303 License No. 07-12153-02
EA-16-142

Michael S. Eppehimer
Senior Vice President, Service
Line Operations
Christiana Care Health Services, Inc.
Management Suite - Room 1270
4755 Ogletown-Stanton Road
Newark, DE 19718

SUBJECT: NRC INSPECTION REPORT NO. 03001303/2016001, CHRISTIANA CARE HEALTH SERVICES, INC., NEWARK, DELAWARE SITE, NOTICE OF VIOLATION AND EXERCISE OF ENFORCEMENT DISCRETION

Dear Mr. Eppehimer:

On June 23-29, 2016, Robin Elliott of this office conducted a safety inspection at the above address and at the 501 West 14th Street and 3105 Limestone Road, Wilmington, 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 July 8, 2016, was also examined as part of the inspection. The findings of the inspection were discussed with you and other members of your staff at the conclusion of the inspection on June 29, 2016.

Based on the results of this inspection, the NRC has determined that five 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. (CCHS) 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 each medical use. Due to the short 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 35.63 were identified which, in accordance with the NRC Enforcement Policy, would normally be categorized at Severity Level IV, CCHS met all of the criteria listed 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. Specifically: (1) CCHS 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) CCHS has confirmed that the required infusion rate and radiation detector tests were performed within the last twelve months, on April 12, 2016, 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, 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) CCHS has recorded the activity of each dosage administered, as provided by the infusion cart. Therefore, the NRC is exercising enforcement discretion and not pursuing any enforcement action for these violations. No further action or response is required on your part with regards to these issues.

The three remaining violations involved the failure to: (1) conduct a full calibration of the high dose-rate remote afterloader (HDR) unit at the Helen F. Graham Cancer Center (HFGCC) that included a determination of timer linearity out to 12 minutes; (2) follow daily spot check procedures for the HDR at the HFGCC on June 13, 15, and 17, 2016, when patient treatments were conducted without a determination of source positioning accuracy to within $\pm$ 1mm; and (3) perform a quarterly linearity test on the dose calibrator that is used to measure the activity of PET doses at the HFGCC prior to patient administration. The three Severity Level IV violations are cited in the enclosed Notice of Violation (Notice) because the violations were identified by the NRC.

During our inspection exit meeting on June 29, 2016, you indicated that: (1) the timer linearity test for the HDR unit at the HFGCC was performed on June 27, 2016, and then again with the source exchange during the full calibration on June 28, 2016, (2) CCHS committed to conducting radiographs to determine source positioning accuracy to $\pm$ 1mm until a camera can be installed to perform this check daily as required by CCHS spot check procedures. This change was instituted with the patient treatment starting on June 27, 2016; and (3) the linearity for the dose calibrator in the HFGCC PET/CT department was calibrated on June 27, 2016. You stated that you have taken corrective and preventative actions to address each violation and that CCHS 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 violations, the corrective actions taken and planned to correct the violations and prevent recurrence is already adequately addressed in our records and in your correspondence dated July 8, 2016. Therefore, you are not required to respond to this letter unless the description of your corrective actions in this letter and your July 8, 2016, 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 Web site 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 Robin Elliott at 610-337-5076 if you have any questions regarding this matter.

Sincerely,

/RA/

James M. Trapp, Director
Division of Nuclear Materials Safety

Enclosure:
Notice of Violation

cc:
Xiaoqian Wen, Radiation Safety Officer
State of Delaware

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Sincerely,

/RA/

James M. Trapp, Director
Division of Nuclear Materials Safety

Enclosure:
Notice of Violation

cc:
Xiaoqian Wen, Radiation Safety Officer
State of Delaware

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DATE	07/28/16							

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NOTICE OF VIOLATION

Christiana Care Health Services, Inc.
Newark, DE
EA-16-142

Docket No. 030-01303
License No. 07-12153-02

During an NRC inspection conducted on June 23-29, 2016, three violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. 10 CFR Part 35.633(b)(5) requires, in part, that full calibration measurements must include, as applicable, a determination of timer accuracy and linearity over the typical range of use.

Contrary to the above, on March 29, 2016, the licensee did not conduct a full calibration that included a determination of timer linearity over the typical range of use. Specifically, the timer linearity was conducted out to 360 seconds instead of out to 12 minutes, as required. The treatments performed with the unit typically run as long as 12 minutes before the source is exchanged.

This is a Severity Level IV violation (NRC Enforcement Policy Section 6.3).

B. Condition 16 of NRC License No. 07-12153-02 requires, in part, that the licensee shall conduct its program in accordance with statements, representations, and procedures contained in the letter dated February 5, 2014, (ADAMS Accession No.: ML14087A049).

The letter dated February 5, 2014, requires in part, that the licensee include, in its daily spot check procedures, a determination of source positioning accuracy to within $\pm$ 1 mm.

Contrary to the above, on June 13, 15, and 17, 2016, the licensee did not conduct its program in accordance with the procedures contained in the letter dated February 5, 2014. The licensee submitted a form for conducting their spot check procedures as an attachment to their February 5, 2014, letter which required a determination of source positioning accuracy to within $\pm$ 1 mm each day prior to patient treatment. However, the licensee conducted daily spot procedures without performing a determination of source positioning accuracy to within $\pm$ 1mm.

This is a Severity Level IV violation (NRC Enforcement Policy Section 6.3).

C. 10 CFR Part 35.60(b) requires, in part, that a licensee shall calibrate the instrumentation used to measure the activity of byproduct material before it is administered to each patient in accordance with nationally recognized standards or the manufacturer's recommendations.

Nationally recognized standards and manufacturer's recommendations indicate that linearity tests should be conducted on a quarterly basis.

Contrary to the above, as of June 24, 2016, the licensee did not calibrate instrumentation used to measure the activity of byproduct material before it is administered to each patient in accordance with nationally recognized standards or the

manufacturer's recommendations. Specifically, the licensee performed the linearity test on the dose calibrator on March 1, 2016, and had not conducted another linearity test at the time of the inspection on June 24, 2016.

This is a Severity Level IV violation (NRC Enforcement Policy Section 6.3).

The NRC has concluded that information regarding the reason for the violations, 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 28th day of July 2016