

August 24, 2010

EA-10-141

Gary Ferguson
Chief Operating Officer
Christiana Care Health Services
Room 1127 – MAP 2
4755 Ogletown-Stanton Road
Newark, DE 19718

SUBJECT: NOTICE OF VIOLATION - NRC INSPECTION REPORT NO. 03001303/2010001

Dear Mr. Ferguson:

This refers to the reactive inspection conducted on March 1 and 3, and April 1, 2010, at Christiana Care Health Services (Christiana) in Newark, Delaware. The purpose of the inspection was to review the circumstances surrounding a medical event involving a patient for whom the radiation dose was delivered to a different location than had been prescribed during a high dose rate remote afterloader (HDR) treatment. The event was reported to the NRC Operations Center on February 24, 2010. In addition to the on-site review, the inspection also involved consideration of: (1) additional information regarding the circumstances and cause of the event, as well as Christiana's corrective actions, provided by Christiana in correspondence dated March 10, May 20, and July 1, 2010; and, (2) the findings of a medical consultant retained by the NRC to review this event, as documented in the consultant's report, dated May 20, 2010. You additionally provided a summary of the event and your corrective actions in a letter dated August 3, 2010. The NRC presented the results of the inspection to Dr. Patrick Grusenmeyer, Christiana's Senior Vice President, and other members of your organization during a telephonic exit meeting on July 12, 2010. Subsequently, in a letter dated July 13, 2010, the NRC transmitted the results of the inspection in NRC inspection Report No. 03001303/2010001.

In a telephone conversation on August 3, 2010, Mr. Marc Ferdas of my staff informed Dr. Grusenmeyer that the NRC was considering escalated enforcement for an apparent violation identified during the inspection, and that the NRC had sufficient information regarding the apparent violation and Christiana's corrective actions to make an enforcement decision without the need for a predecisional enforcement conference (PEC) or a written response from Christiana. Dr. Grusenmeyer indicated that a PEC would not be necessary, and that Christiana did not plan to submit a written response.

Based on the information developed during the inspection, the NRC has concluded that a violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in Inspection Report No. 03001303/2010001. The violation involves the failure to develop, implement, and maintain written procedures to provide high confidence that each administration was in accordance with the written directive, as required by 10 CFR 35.41(a)(2). Specifically, Christiana's written procedures for HDR treatments: a) did not require a quality assurance process to test and evaluate proper functioning of all measurement tools used to determine

treatment parameters, including the source positioning simulator (SPS) tool; and, b) did not specify how Christiana personnel should respond when unknown and questionable treatment distances were encountered during HDR simulation measurements. As a result of these procedural inadequacies, on January 18, 2010, Christiana did not identify that the SPS tool was damaged and was functioning improperly. The damaged SPS tool was used during a simulation to develop the treatment plan for a patient receiving an HDR treatment. Due to the damage, the catheter, through which the radioactive source used for treatment is inserted into the patient, was prevented from extending the full distance. This led to an incorrect measurement of the distance used during the actual treatment, which resulted in the patient receiving dose to unintended tissue, and not receiving the prescribed dose to the intended tissue (i.e., a medical event).

Since the violation involved a programmatic, rather than an isolated, weakness in the implementation procedures for administrations requiring a written directive, and a medical event occurred as a result, the NRC has categorized this violation in accordance with the NRC Enforcement Policy at Severity Level (SL) III.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$3,500 is considered for a SL III violation. Because your facility has not been the subject of escalated enforcement action within the last two years or the last two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section VI.C.2 of the Enforcement Policy. The NRC has concluded that credit is warranted for Christiana's corrective actions taken to address the violation, which include: (1) immediately removing the SPS tool from use and acquiring a replacement tool that has been confirmed to be functioning properly; (2) developing and posting a reference table of source to catheter tip distances at the HDR control console for all staff involved in HDR treatments to use; (3) revising the Christiana Quality Management procedure for HDR brachytherapy to require a double-check of all patient measurements, a daily and monthly quality assurance requirement to confirm that the SPS tool is functioning properly, and a process to ensure that all members of the treatment team agree on the specifics of the treatment; (4) conducting training of all personnel involved in the HDR program on the use of the reference table and procedure revision (the training will be provided to all new staff and will be repeated annually for all staff); and, (5) implementing a "New Product" committee that will review all new product plans for implementation, training, and vendor support.

Therefore, to encourage prompt and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this SL III violation constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken to correct the violation and prevent recurrence, and the date when full compliance was achieved is already adequately addressed on the docket in this letter, in Inspection Report No. 03001303/2010001, and in Christiana's letters dated March 10, May 20, July 1, and August 3, 2010. 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 and its Enclosure 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, if you choose to provide one, should not include any personal privacy, proprietary, or safeguards 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, 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 withholding of such information, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (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). The NRC also includes significant enforcement actions on its Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/current.html>.

Sincerely,

/RA/ Original Signed by David C. Lew for

Marc L. Dapas
Acting Regional Administrator

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

Enclosure: Notice of Violation

cc: State of Delaware

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NOTICE OF VIOLATION

Christiana Care Health Services
Newark, DE

Docket No. 03001303
License No. 07-12153-02
EA-10-141

During an NRC inspection conducted on March 1 and 3, 2010 and April 1, 2010, as well as an in-office review of information provided by the licensee on March 10, May 20, and July 1, 2010, for which a telephonic exit meeting was held on July 12, 2010, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 35.41(a)(2) states, in part, that for any administration requiring a written directive, licensees shall develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.

10 CFR 35.40(a), in part, requires a written directive for each administration of a therapeutic dose of radiation from byproduct material, which includes high dose rate remote afterloaders (HDRs)

Contrary to the above, as of January 18, 2010, Christiana Care Health Services did not develop, implement, and maintain written procedures to provide high confidence that each administration was in accordance with the written directive. Specifically, the written procedures for HDR treatments: (i) did not include a quality assurance process to test and evaluate proper functioning of all measurement tools used to determine treatment parameters; and, (ii) did not specify how personnel should respond when unknown and questionable treatment distances were encountered during HDR simulation measurements. As a result of these procedural inadequacies, there was not high confidence that each administration would be in accordance with the written directive. As a consequence, a medical event occurred during an HDR treatment conducted between January 18 and January 22, 2010.

This is a Severity Level III violation (Supplement VI).

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 NRC Inspection Report No. 03001303/2010001, in letters from Christiana dated March 10, May 20, July 1, and August 3, 2010, and in the letter transmitting this Notice of Violation (Notice). However, Christiana is 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, EA-10-141," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region I, 475 Allendale Rd., King of Prussia, PA 19406, within 30 days of the date of the letter transmitting this Notice.

If you choose to respond, your response 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>. Therefore, to

the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

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

Dated this 24th day of August 2010