



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

July 13, 2010

Docket No. 03001303

License No. 07-12153-02

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

SUBJECT: NRC INSPECTION REPORT NO. 03001303/2010001, CHRISTIANA CARE HEALTH SERVICES, NEWARK, DELAWARE SITE

Dear Mr. Ferguson:

On March 1 and 3, and April 1, 2010, Penny Lanzisera and Lester Tripp of this office conducted a special inspection at Christiana Care Health Services' (Christiana) high dose rate remote afterloader facility in Newark, Delaware. The inspection reviewed the circumstances surrounding a medical event reported by your staff to the NRC Operations Center on February 24, 2010. As discussed with your staff during the inspection, a medical consultant was retained by the NRC to review this event. The results of that review were completed on May 19, 2010. Additional information provided by Christiana in correspondence dated March 10, May 20, and July 1, 2010, was also examined as part of the inspection. The results of the inspection and the medical consultant's review were discussed with Dr. Patrick Grusenmeyer, Senior Vice President, and other members of your organization at the conclusion of the inspection on July 12, 2010, and are described in the enclosed report.

Based on the results of this inspection, one apparent violation was identified. The apparent 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 did not: (i) require a quality assurance process to test and evaluate proper functioning of all measurement tools used to determine treatment parameters (e.g., the source positioning simulator tool); and (ii) did not specify how hospital personnel should respond when unknown and questionable treatment distances were encountered during high dose rate remote afterloader simulation measurements. These procedural inadequacies resulted in a medical event, because Christiana did not identify that the measurement tool was functioning improperly and did not identify that an incorrect measurement distance was accepted for a patient treatment conducted between January 18 and January 22, 2010.

Because the NRC has not made a final determination in this matter with respect to the apparent violation, a Notice of Violation is not being issued at this time. You will be advised by separate correspondence of the results of our deliberations.

Christiana Care Health Services

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 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 are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material**; then **Regulations, Guidance, and Communications Page**. The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **About NRC; How We Regulate; Enforcement**; then **Enforcement Policy**. 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 7:00 a.m. to 6:30 p.m. EST, Monday through Friday (except Federal holidays).

No reply to this letter is required. Please contact Lester Tripp at (610) 337-5358 if you have any questions regarding this matter.

Sincerely,

Original signed by Marc Ferdas

Marc Ferdas, Chief
Medical Branch
Division of Nuclear Materials Safety

Enclosure:
Inspection Report No. 03001303/2010001

cc:
Joseph Solge, Radiation Safety Officer
State of Delaware

Christiana Care Health Services

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Marc Ferdas, Chief
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Enclosure:
 Inspection Report No. 03001303/2010001

cc:
 Joseph Solge, Radiation Safety Officer
 State of Delaware

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