



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

January 17, 2012

Docket No. 03001303
NMED No. 110412

License No. 07-12153-02

Patrick Grusenmeyer, ScD
Senior Vice President
Cancer and Imaging Services
Christiana Care Health Services
Room 1127 - MAP 2
4755 Ogletown-Stanton Road
Newark, DE 19718

SUBJECT: NRC INSPECTION REPORT NO. 03001303/2011001, CHRISTIANA CARE HEALTH SERVICES AND NOTICE OF VIOLATION

Dear Dr. Grusenmeyer:

On August 19, 2011, Janice Nguyen of this office conducted a special inspection at Christiana Hospital in Newark, Delaware. The inspection reviewed the circumstances surrounding a possible medical event reported by your staff to the NRC Headquarters Operations Center on August 16, 2011. The inspection consisted of observations by the inspector, interviews with personnel, and an examination of records. An in-office review of information provided by Christiana Care Health Services (Christiana) during the on-site inspection and additional information provided in your correspondence dated August 26 and November 3, 2011, continued through December 14, 2011. The findings of the inspection were discussed with you and other members of your organization during the telephonic exit on January 6, 2012.

Based on the results of this inspection, and in accordance with the NRC Enforcement Policy, the NRC has identified one violation of NRC requirements. The violation involved Christiana's failure to develop, implement, and maintain written procedures that provide high confidence that any administration requiring a written directive is in accordance with the treatment plan as required by 10 CFR 35.41(b)(2). Specifically, as of August 9, 2011, Christiana's procedures did not require the authorized user to fully review the treatment plan data that documented the dosage to be delivered prior to the dosage administration. A Notice of Violation (Notice) is enclosed that categorizes this violation as Severity Level IV. This violation is being cited in the Notice because it was identified by the NRC.

The NRC has concluded that information regarding the reason for the violation and 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 August 26 and November 3, 2011. Therefore, you are not required to respond to this letter unless the description of your corrective actions in this letter and your August 26 and November 3, 2011 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.

Notice of Violation
Christiana Care Health Services

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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 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 Janice Nguyen at 610-337-5006 if you have any questions regarding this matter.

Sincerely,

Original Signed by:

Joseph Nick, Chief
Medical Branch
Division of Nuclear Materials Safety

Enclosures:

1. Notice of Violation
2. Inspection Report 03001303/2011001

cc:

Joseph F. Solge, Radiation Safety Officer
State of Delaware

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cc:

Joseph F. Solge, Radiation Safety Officer
State of Delaware

Distribution:

D. J. Holody, RI

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OFFICE	DNMS/RI	N	DNMS/RI	N			
NAME	JNguyen/jn		JNick/jln				
DATE	01/17/12		01/17/12				

NOTICE OF VIOLATION

Christiana Care Health Services
Newark, DE

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

During an NRC inspection conducted on August 19, 2011, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

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

Contrary to the above, as of August 9, 2011, the licensee did not develop, implement, and maintain written procedures that provided high confidence that any administration requiring a written directive is in accordance with the treatment plan. Specifically, the licensee's procedures did not require the authorized user to fully review the treatment plan data that documented the fractionated dosage to be delivered prior to the dosage administration.

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 17th day of January 2012