

December 13, 2005

Docket No. 03013667
EA No. 05-201

License No. 45-15154-03

Mr. Will Iseman
Vice President of Operations
Danville Regional Medical Center
142 South Main Street
Danville, VA 24541

SUBJECT: NOTICE OF VIOLATION

Dear Mr. Iseman:

This letter refers to the NRC inspection conducted at your facility in Danville, Virginia, on July 12, 2005, as well as reviews of additional information you provided to the NRC through September 28, 2005. During the inspection, the NRC reviewed the circumstances associated with an apparent violation of NRC requirements involving the failure to maintain constant surveillance of licensed material contained in a high dose rate afterloader (HDR) unit. The results of the inspection, including the apparent violation, were discussed with you and members of your staff during an exit meeting at the conclusion of the inspection on September 28, 2005, and were described in a letter and inspection report sent to you on October 31, 2005.

On November 14, 2005, Ms. Pamela Henderson of my staff informed you that this apparent violation was being considered for escalated enforcement action, and the NRC did not need any additional information to make an enforcement decision. Nonetheless, Ms. Henderson provided you an opportunity to attend a predecisional enforcement conference or to provide a written response, prior to the NRC determining appropriate enforcement action. During that conversation, you declined the opportunity to attend a conference or to provide a written response.

Based on the information developed during the inspection, the NRC has determined 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 the subject inspection report. The violation involved the failure to secure from unauthorized removal and maintain constant surveillance of licensed material that was stored in a controlled area. Specifically, for an indeterminate period of time prior to July 12, 2005, an HDR unit, containing Iridium 192, was left unsecured and unattended in a treatment room at your facility during day shifts, contrary to the requirements of 10 CFR 20.1801 and 10 CFR 20.1802.

In this case, the failure of your staff to maintain constant surveillance and control of the HDR unit did not result in removal of the sources from their shielded position, nor did it result in any leakage from the sources. Furthermore, there is no evidence that unauthorized persons came into direct contact with the material during the time that it was unsecured and unattended. Nonetheless, this violation is of concern to the NRC because the failure to control radioactive material could result in the loss or theft of the material; and significant unintended radiation doses to members of the public could occur if this equipment was tampered with or if these sources were removed from their shielded position. Therefore, this violation is categorized at Severity Level III in accordance with the NRC Enforcement Policy.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$3,250 is considered for a Severity Level III violation involving the loss of control of radioactive material with this level of radioactivity. Because your facility has not been the subject of escalated enforcement action within the last two years or 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. Credit for corrective actions is warranted because your corrective actions were considered prompt and comprehensive. These corrective actions included: (1) removing the sources from the HDR unit and returning them to the vendor; and (2) deactivating the HDR unit as stated in your letter, dated September 21, 2005.

Therefore, to encourage prompt and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action at your facility, I have been authorized, after consultation with the Director, Office of Enforcement, to issue the enclosed Notice of Violation without a civil penalty for this Severity Level III violation. However, you should be aware that significant violations in the future could result in a civil penalty. In addition, issuance of this Severity Level III violation constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that since the HDR unit has been deactivated, and because information regarding the reasons for the violation and the date when full compliance was achieved is already adequately addressed in this letter, in your letter dated September 21, 2005, and in the inspection report issued on October 31, 2005, you are not required to respond to this violation unless the description herein 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. However, if you plan in the future to reinstate HDR licensed activities at the hospital, corrective actions to ensure appropriate security and control of the HDR unit must be addressed in detail prior to initiating licensed activities.

Mr. W. Iseman

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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 Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room). 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. The NRC also includes significant enforcement actions on its web site at <http://www.nrc.gov>; select **What We Do, Enforcement**, then **Significant Enforcement Actions**.

Sincerely,

/RA/ Original signed by Marc Dapas for

Samuel J. Collins
Regional Administrator

Enclosure: Notice of Violation

cc:
Peter J. Leider, M.D., Radiation Safety Officer
Commonwealth of Virginia

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 Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room). 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. The NRC also includes significant enforcement actions on its web site at <http://www.nrc.gov>; select **What We Do, Enforcement**, then **Significant Enforcement Actions**.

Sincerely,

/RA/ Original Signed by Marc Dapas for

Samuel J. Collins
Regional Administrator

Enclosure: Notice of Violation
cc:
Peter J. Leider, M.D., Radiation Safety Officer
Commonwealth of Virginia

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ENCLOSURE

NOTICE OF VIOLATION

Danville Regional Medical Center
Danville, Virginia

Docket No. 030-13667
License No. 45-15154-03
EA-05-201

Based on an NRC inspection conducted at the Danville Regional Medical Center in Danville, Virginia, on July 12, 2005, as well as reviews in the Region I office of additional information provided to the NRC until September 28, 2005, one violation of NRC requirements was identified. The violation was discussed during an exit meeting following the inspection on September 28, 2005. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas. 10 CFR 20.1802 requires that the licensee control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage. As defined in 10 CFR 20.1003, controlled area means an area, outside of a restricted area, but inside the site boundary, access to which can be limited by the licensee for any reason; and unrestricted area means an area, access to which is neither limited nor controlled by the licensee.

Contrary to the above, on July 12, 2005, and for an indeterminate period of time prior to that date, the licensee did not secure from unauthorized removal or limit access to a High Dose Rate Remote Afterloader (HDR) containing Iridium-192, located in a treatment room at the Danville Regional Medical Center, which is a controlled area, nor did the licensee control and maintain constant surveillance of this licensed material.

This is a Severity Level III violation, Supplement IV.

The NRC has concluded that information regarding the reasons 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 in this letter, in your request dated September 21, 2005, to amend your license, and in the inspection report issued on October 31, 2005. Therefore, no response to this Notice is required. 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, EA-05-201" and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 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 the violation, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555.

Because any response will be made available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS), to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room). If personal privacy or proprietary information is necessary to provide an acceptable response, then 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 material, 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).

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

Dated this 13th day of December 2005