

October 28, 2005

EA-05-164

Joseph J. Saunders
Vice President of Operations
Crozer-Chester Medical Center
One Medical Center Boulevard
Upland, PA 19103-3995

SUBJECT: NOTICE OF VIOLATION

Dear Mr. Saunders:

This letter refers to the NRC inspection conducted at your facilities in Upland and Ridley Park, Pennsylvania, on June 22-24, 2005, as well as reviews of additional information you provided to the NRC through July 28, 2005. During the inspection, the NRC reviewed the circumstances associated with an apparent violation of NRC requirements, identified by your staff in November 2004, 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 on July 28, 2005, and were described in a letter and inspection report sent to you on September 1, 2005.

On August 12, 2005, Mr. Randolph Ragland of my staff, contacted Ms. Diana Stockdale, your Radiation Safety Officer (RSO), and informed her that the NRC was considering escalated enforcement action for the apparent violation in accordance with its enforcement policy. During that call, Mr. Ragland informed your RSO that we were aware that you identified the violation and took appropriate corrective actions, and therefore, the NRC did not need any additional information to make an enforcement decision. However, Mr. Ragland provided you the opportunity to attend a predecisional enforcement conference (PEC) or submit a written response. Ms. Stockdale indicated that you wished to attend a PEC.

On September 20, 2005, the PEC was conducted with you and your staff to discuss the apparent violation, its cause, and your corrective actions. At this conference, you (1) acknowledged the facts surrounding the event as presented in the inspection report, (2) stated that the staff at Crozer-Chester Medical Center takes the security of licensed material very seriously, and (3) described your corrective actions to preclude recurrence of the violation.

Based on the information developed during the inspection, and the information you provided during the conference, 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 or access and/or maintain constant surveillance of licensed material that was stored in a controlled or unrestricted area. Specifically, on November 19, 2004, an HDR unit containing Iridium-192 was left unsecured and unattended in a treatment room at your facility for approximately 15 minutes, contrary to 10 CFR 20.1801 and 10 CFR 20.1802.

In this case, the failure 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, which you described during the PEC held on September 20, 2005, included, but were not limited to: (1) immediately providing a temporary guard for the room to prevent unauthorized removal of the sources; (2) counseling and re-training the Authorized Medical Physicist regarding responsibilities for maintaining access control to the HDR unit; (3) briefing all staff members on this event; (4) conducting a detailed investigation of the event for the Radiation Safety Committee; (5) installing a key card reader at the entrance to the treatment suite; and (6) ordering key card readers for your other licensed facilities to strengthen security of licensed materials.

Therefore, to encourage prompt and comprehensive identification and 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, not to propose a civil penalty in this case. 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 information regarding the reasons 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 this letter and in the inspection report issued on September 1, 2005. Therefore, you are not required to respond to this letter unless the description herein, as well as in the inspection report, 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 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/

Samuel J. Collins
Regional Administrator

Enclosure: Notice of Violation

cc:
Diana Stockdale, Radiation Safety Officer
Commonwealth of Pennsylvania

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ENCLOSURE

NOTICE OF VIOLATION

NOTICE OF VIOLATION

Crozer-Chester Medical Center
Upland, Pennsylvania

Docket No. 030-03159
License No. 37-12240-01
EA-05-164

Based on an NRC inspection conducted at the Crozer-Chester Medical Center in Upland, Pennsylvania, on June 22-24, 2005, as well as reviews in the Region I office until July 28, 2005, the date on which an exit meeting was held, one violation of NRC requirements was identified. 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 November 19, 2004, 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 Crozer-Chester facility, 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 on the docket in this letter and in the inspection report issued on September 1, 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-05-164" 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 28th day of October 2005