

September 2, 2005

EA-05-127
NMED No. 050340

Michael Shirk, President
Boone Hospital Center
1600 East Broadway
Columbia, MO 65201

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY -
\$3,250 (NRC SPECIAL INSPECTION REPORT NO. 030-02305/2005-01(DNMS))

Dear Mr. Shirk:

This refers to the special inspection conducted on May 25, 2005, at Boone Hospital Center, Columbia, Missouri. The purpose of the special inspection was to review the circumstances, root and contributing causes, and proposed corrective actions related to a loss of prostate implant seeds, containing iodine-125, that were inadvertently washed down a sink during cleaning activities. Your staff notified the NRC of the loss of the prostate implant seeds on May 18 and provided an initial report regarding the event on May 20, 2005. The inspection resulted in the identification of an apparent violation of the NRC requirements concerning security and control of NRC-licensed material.

In the letter transmitting the inspection report, dated June 23, 2005, we provided you the opportunity to address the apparent violation identified in the report by either attending a predecisional enforcement conference, or by providing a written response before we made our final enforcement decision. On June 27, 2005, you paid the proposed civil penalty of \$3,250 and declined the opportunity to meet with the NRC staff in a predecisional enforcement conference. On July 30, 2005, you provided a written response to the apparent violation.

Based on the information developed during the inspection and that you provided in your May 20 and July 30, 2005, letters, 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. In summary, on May 18, 2005, a medical physicist inappropriately transferred a new, unused brachytherapy cartridge, containing iodine-125 seeds, to an unauthorized and untrained employee. The cartridge was subsequently transferred to a second unauthorized and untrained employee who opened the cartridge as a part of a routine cleaning process for used cartridges. As a result of this cleaning effort, iodine-125 seeds were inadvertently washed into the sanitary drain system.

The failure to control or maintain constant surveillance of the quantity of iodine-125 contained in the new, unused brachytherapy cartridge and the loss of a significant portion of this NRC-licensed material into the sanitary drain system, is a significant regulatory concern and the violation has been categorized in accordance with the NRC Enforcement Policy at Severity Level III.

In accordance with the Enforcement Policy, a base civil penalty in the amount of \$3,250 is considered for a Severity Level III violation. Because your facility has not been the subject of escalated enforcement actions within 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. Credit was warranted for your corrective actions that included: (1) labeling cartridges for sterilization only in surgery; (2) instructing the medical physicist to verify that cartridges containing seeds are only sent to surgery for sterilization; (3) providing familiarization training to central supply personnel on prostrate seed implant applicators and cartridges; and (4) training surgical personnel on protocols for handling and sterilizing implant cartridges. Therefore, application of the normal civil penalty assessment process would not have resulted in a civil penalty in this case.

However, the revised Enforcement Policy published December 18, 2000 (effective February 16, 2001), provides that, notwithstanding the normal civil penalty assessment process, a civil penalty of at least the base amount should normally be proposed in this type of case to reflect the significance of the violation and to emphasize the importance of maintaining control of licensed material. Therefore, to emphasize the importance of maintaining the security and control of NRC-licensed material, I have been authorized, after consultation with the Deputy Executive Director for Materials, Research, State, and Compliance Programs, and the Director, Office of Enforcement, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty in the base amount of \$3,250 for the Severity Level III violation. In addition, issuance of this Notice 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 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 Inspection Report No. 03002304/2005-001(DNMS) and in your May 20 and July 30, 2005, letters. Additionally, you paid the proposed civil penalty on June 27, 2005. Therefore, you are not required to respond to the provisions of 10 CFR 2.201 or 10 CFR 2.205 unless the description in the inspection report or your letter 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, should you choose to provide one, 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>. The NRC will not make publicly available the information requested by HHS, as described above. The NRC also includes significant enforcement actions on its Web site at www.nrc.gov; select **What We Do, Enforcement**, then **Significant Enforcement Actions**.

M. Shirk

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Please contact John Madera, Chief, Materials Inspection Branch, at telephone number (630) 829-9834 with any questions you may have.

Sincerely,

/RA by Geoffrey E. Grant for/

James L. Caldwell
Regional Administrator

Docket No. 030-02304
License No. 24-01565-01

Enclosure: Notice of Violation and Proposed
Imposition of Civil Penalty

cc w/encl: Barbara Weaver, Chair
Board of Trustees

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DATE	08/29/05		08/24/05		09/02/05		09/02/05	

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¹Concurrence from HQ in 8/29/05 e-mail from S. Merchant, OE, to Ken O'Brien, RIII

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NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Boone Hospital Center
Columbia, Missouri

Docket No. 030-02304
License No. 24-01565-01
EA-05-127

During an NRC inspection conducted on May 25, 2005, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the NRC proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violation and associated civil penalty are set forth 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 materials that are in a controlled or unrestricted area and that are 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 May 18, 2005, the licensee failed to control and maintain constant surveillance of iodine-125 in a controlled area. Specifically, a cartridge containing iodine-125 seeds was transferred to an unauthorized and untrained licensee employee. Subsequently, the cartridge was transferred to a second unauthorized and untrained licensee employee who opened the cartridge and inadvertently lost iodine-125 seeds down a sanitary drain system.

This is a Severity Level III violation (Supplement IV).
Civil Penalty - \$3,250. (EA-05-127)

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 Inspection Report No. 03002304/2005-001(DNMS) and in the licensee's May 20 and July 30, 2005, letters. Therefore, you are not required to respond to the provisions of 10 CFR 2.201 unless the description in the inspection report or your letter does not accurately reflect your corrective actions or your position. 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-05-127," 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 and Enforcement Officer, U.S. Nuclear Regulatory Commission, Region III, 2443 Warrenville Road, Suite 210, Lisle, IL 60532-4352, within 30 days of the date of the letter transmitting this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). If you choose to respond, you may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. Under

Proposed Imposition of
Civil Penalty

the authority of Section 182 of the Act, 42 U.S.C. 2232, the response shall be submitted under oath or affirmation.

A reply pursuant to 10 CFR 2.205 is not necessary, unless you choose to reply, since you paid the civil penalty on June 27, 2005.

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.

Dated this 2nd day of September 2005