

September 4, 2008

EA-08-180  
NMED No. 080273

Mr. Bruce Backus  
Assistant Vice Chancellor  
Environmental Health & Safety  
Washington University in St. Louis  
Campus Box 1010  
350 North Skinker Boulevard  
St. Louis, MO 63130

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL  
PENALTY – \$3250, NRC REACTIVE INSPECTION REPORT NO.  
030-02271/2008-001(DNMS) – WASHINGTON UNIVERSITY IN ST. LOUIS

Dear Mr. Backus:

This refers to the inspection conducted on May 22, 2008, at Washington University in St. Louis, St. Louis, Missouri. The purpose of the inspection was to review the circumstances, root and contributing causes, and proposed corrective actions related to a loss of two prostate implant seeds that occurred following a prostate implant procedure performed on May 7, 2008. You reported the event to the NRC by telephone on May 8, 2008, and in a letter dated June 5, 2008. During the inspection apparent violations of 10 CFR 20.1802 and 35.404 (a) were identified. Details regarding the apparent violations were provided in NRC reactive Inspection Report No. 030-02271/2008-001(DNMS), dated June 20, 2008.

In the letter transmitting the inspection report, we provided you the opportunity to address the apparent violations identified in the report by either attending a pre-decisional enforcement conference or by providing a written response before we made our final enforcement decision. In a letter dated July 15, 2008, you provided a response to the apparent violations.

Based on the information developed during the inspection and the information that you provided in your response to the inspection report dated July 15, 2008, the NRC has determined that two violations of NRC requirements occurred. The violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report. On May 7, 2008, your staff administered a permanent iodine-125 prostate implant using an applicator with a cartridge containing 15 iodine-125 seeds. The prescribed dose to the prostate required 13 seeds. After completion of the procedure, the authorized user left the cartridge in the applicator and attended to the patient's additional medical needs. A radiation oncology nurse, assisting in the procedure, noted that the cartridge was still in the applicator. The nurse incorrectly removed the top portion of the cartridge from the applicator

leaving the bottom portion with the two remaining seeds in the applicator. The nurse transported the applicator to the decontamination room and placed it in a wash basin. The seeds were washed down the drain into the sanitary sewer when the apparatus was cleaned. The failure to control and maintain constant surveillance of the two iodine-125 seeds was a violation of 10 CFR 20.1802. Additionally, after completion of the procedure, the nurse did not immediately perform a survey to locate and account for all seeds that had not been implanted. This was a violation of 10 CFR 35.404(a). The root cause of the violations was the inadequate training of the nurse in the mechanics of the applicator and the lack of accounting and surveying of the sources.

The violations are of a concern because the radioactive material is in the public domain which could result in a potential radiation exposure to members of the public. Therefore, the violations have been categorized collectively in accordance with the NRC Enforcement Policy as a Severity Level III problem.

In accordance with Section VII.A.1(g) of the Enforcement Policy, the NRC is exercising discretion to propose imposition of a civil penalty of at least the base amount for violations involving the loss of sealed sources. The base civil penalty amount for the Severity Level III problem discussed above and included in the enclosed Notice is \$3250.

Therefore, to emphasize the importance of performing surveys, and controlling and maintaining constant surveillance of licensed material, I have been authorized, after consultation with the Director, Office of Enforcement, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the base amount of \$3250 for the Severity Level III problem. 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 violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance was achieved is already adequately addressed on the docket in NRC Reactive Inspection Report No. 030-02271/2008-001 (DNMS) and in your letters dated June 5 and July 15, 2008. Therefore, you are not required to respond to this letter unless the description therein 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 enclosures, and your response, if you choose to make 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>. 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. If personal privacy or proprietary information is necessary to provide an acceptable response, 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

information, 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). The NRC also includes significant enforcement actions on its Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/current.html>.

Please contact Patrick Loudon, Chief, Materials Inspection Branch, with any questions. Mr. Loudon can be reached at telephone number (630) 829-9627.

Sincerely,

***/RA by Mark A. Satorius Acting for/***

James L. Caldwell  
Regional Administrator

Docket No. 030-02271  
License No. 24-00167-11

Enclosures:

1. Notice of Violation and Proposed Imposition of Civil Penalty
2. NUREG/BR-0254 Payment Methods (Licensee only)

cc w/encl 1: Susan Langhorst, Ph.D., CHP, Radiation Safety Officer  
State of Missouri

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cc w/encl 1: Susan Langhorst, Ph.D., CHP, Radiation Safety Officer  
 State of Missouri

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DATE	9/02/08		9/02/08		9/04/08	9/04/08		8/28/08
OFFICE	OGC		FSME		RIII	RIII		
NAME	Marco <sup>2</sup>		MBurgess <sup>3</sup>		O'Brien	Satorius for Caldwell		
DATE	8/25/08 NLO		8/25/08		9/04/08	9/04/08		

**OFFICIAL RECORD COPY**

<sup>1, 2, 3</sup> OE, OGC, and FSME concurrence received via E-mail on September 2, 2008, from L. Sreenivas.

Letter to Bruce Backus from James Caldwell dated September 4, 2008

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL  
PENALTY – \$3250, NRC REACTIVE INSPECTION REPORT NO.  
030-02271/2008-001(DNMS) – WASHINGTON UNIVERSITY IN  
ST. LOUIS

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NOTICE OF VIOLATION  
AND  
PROPOSED IMPOSITION OF CIVIL PENALTY

Washington University in St. Louis  
St. Louis, Missouri

Docket No. 030-02271  
License No. 24-00167-11  
EA-08-180

During an NRC inspection conducted on May 22, 2008, violations of NRC requirements were 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 violations and associated civil penalty are set forth below:

- A. 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 May 7, 2008, the licensee failed to control and maintain constant surveillance of licensed material that was in a controlled area and not in storage. Specifically, the licensee transferred an applicator, containing two iodine-125 seeds from the operating room to the decontamination room. The nurse subsequently opened the loaded cartridge during the cleaning process and the two iodine-125 seeds were washed down the drain into the sanitary sewer.

- B. 10 CFR 35.404(a) requires that immediately after implanting sources in a patient, the licensee shall make a survey to locate and account for all sources that have not been implanted.

Contrary to the above, on May 7, 2008, the licensee failed to make a survey to locate and account for two iodine-125 sources that were not implanted.

This is a Severity Level III problem (Supplements IV and VI).

Civil Penalty - \$3250 (EA-08-180)

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance was achieved is already adequately addressed on the docket in NRC Inspection Report No. 030-02271/2008-001(DNMS) and in your letters dated June 5 and July 15, 2008.

However, if the description therein does not accurately reflect your position or your corrective actions, you are required to submit a written statement or explanation under 10 CFR 2.201. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, EA-08-180" and send it to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville, MD 20852-2738, with a copy to the Regional Administrator, U.S., Nuclear Regulatory Commission, Region III.

The Licensee may pay the civil penalty proposed above in accordance with NUREG/BR-0254 and by submitting to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, a statement indicating when and by what method payment was made, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within 30 days of the date of this Notice, the NRC will issue an order imposing the civil penalty. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice, in whole or in part; (2) demonstrate extenuating circumstances; (3) show error in this Notice; or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the response should address the factors addressed in Section VI.C.2, "Civil Penalty Assessment," of the Enforcement Policy. Any written answer addressing these factors pursuant to 10 CFR 2.205, should be set forth separately from the statement or explanation provided pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205 to be due, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The responses noted above, i.e., Reply to Notice of Violation, Statement as to payment of civil penalty, and Answer to a Notice of Violation, should be addressed to: Cynthia A. Carpenter, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, with a copy to the Regional Administrator and Enforcement Officer, U.S. Nuclear Regulatory Commission, Region III, 2443 Warrenville Road, Lisle, IL 60532.

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>. 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. If personal privacy

Notice of Violation and  
Proposed Imposition of Civil Penalty

-3-

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 that such material is withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (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). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

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

Dated this 4<sup>th</sup> day of September 2008