

May 22, 2009

EA-09-039

Van Coots, M.D.
Hospital Commander
Department of the Army
Walter Reed Army Medical Center
6900 Georgia Avenue, NW
Washington, D.C. 20307-5001

SUBJECT: NOTICE OF VIOLATION - NRC Inspection Report No. 03001317/2008001

Dear Dr. Coots:

This letter refers to the NRC inspection conducted at the Walter Reed Army Medical Center (WRAMC) in Washington, D.C. on December 19, 2008, as well as subsequent in-office review of additional information provided by Colonel Mark Melanson of your staff on February 8 and 11, and March 20, 2009. The purpose of the inspection was to review circumstances associated with the temporary loss of manual brachytherapy ribbons containing radioactive sources on November 14, 2008. WRAMC reported the missing sources to the NRC Operations Center on November 19, 2008. Ms. Penny Lanzisera and Ms. Janice Nguyen of my staff discussed the preliminary inspection findings with members of your staff at the conclusion of the on-site inspection on December 19, 2008.

A final inspection exit was conducted with you on March 20, 2009, by telephone. During the telephone call, Mr. James Noggle of my staff informed you that the NRC was considering escalated enforcement for three apparent violations including WRAMC's temporary loss of licensed radioactive material and the related failure to immediately notify the NRC. Mr. Noggle also informed you that the NRC had sufficient information regarding the apparent violations and your corrective actions to make an enforcement decision without the need for a predecisional enforcement conference (PEC) or a written response from you. However, Mr. Noggle offered your organization an opportunity to submit an additional written response or attend a PEC. You indicated that a PEC would not be necessary, and WRAMC did not plan to submit a written response. The inspection report related to this action was issued on April 17, 2009.

Based on the information developed during the inspection and provided in the subsequent telephone conversations, the NRC has determined that violations of NRC requirements occurred. These 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 November 14, 2008, WRAMC failed to control licensed material (three ribbons containing 29.2 millicuries of iridium-192 seeds), as required by 10 CFR 20.1802, resulting in the ribbons being improperly discarded in a trash container and subsequently removed from the controlled area. WRAMC had implanted eight ribbons containing a total of 77.8 millicuries of iridium-192 seeds in a patient for manual brachytherapy treatment on November 10, 2008. At approximately 9:00 a.m. on November 14, 2008, when the ribbons were scheduled to be

removed, WRAMC's medical staff identified that three of the ribbons were missing. WRAMC's medical staff also determined that a medical student had changed the bandage holding the ribbons in place sometime between 6:30 a.m. and 7:00 a.m. on November 14, 2008. The medical student had improperly discarded the bandage with the three iridium-192 ribbons attached to the tape in a trash receptacle within the patient's room. Subsequently, WRAMC's housekeeping staff entered the patient's room and removed the trash from the controlled area, eventually placing it into a compactor on the WRAMC loading dock at approximately 9:00 a.m. on November 14, 2008.

Afterwards, WRAMC radiation safety staff surveyed all hospital areas, and discovered the three ribbons in the trash compactor at 12:10 p.m. on November 14, 2008. WRAMC's radiation safety staff leak tested the sources and identified no detectable leakage. WRAMC's radiation safety staff also estimated that, as a result of this event, the housekeeping staff received a maximum radiation dose of 18 millirem and the medical student received 32 millirem. WRAMC's radiation safety staff further determined that no other exposure to a member of the general public occurred. The WRAMC Radiation Safety Officer (RSO) was unavailable at the time of the event, and a Senior Health Physicist improperly determined that immediate notification to the NRC was not required, because the sources had been found. Upon his return to WRAMC on November 19, 2008, the RSO made the NRC telephone notification as required by 10 CFR 20.2201(a)(i).

10 CFR 35.410 requires, in part, that licensees provide radiation safety instruction to personnel caring for brachytherapy patients. The instruction is to include the safe handling and shielding instructions of the brachytherapy sources. WRAMC did not provide this training to the medical student who had changed the brachytherapy patient's bandage and had inadvertently discarded the bandage with three brachytherapy sources attached. In addition, housekeeping staff, who are trained by the radiation safety staff to not enter the rooms of patients undergoing radiation therapy, entered this patient's room and removed the trash. This resulted in loss of control of the licensed material, in violation of 10 CFR 20.1802. In assessing the significance of the violations associated with WRAMC temporarily losing control of three brachytherapy ribbons containing sources, the NRC considered that, even though no overexposures occurred, and WRAMC retrieved the sources within three hours of discovering they were missing, unplanned exposures to WRAMC personnel did occur. Therefore, the NRC has categorized these two violations collectively in accordance with the NRC Enforcement Policy as a Severity Level (SL) III problem.

In addition, 10 CFR 20.2201(a)(i) requires, in part, that licensees make a telephone report to the NRC immediately after it becomes known that such material is lost, stolen, or missing. In this case, the amount of missing licensed material, 29.2 millicuries of iridium-192, was greater than 1,000 times the quantity specified in appendix C to 10 CFR Part 20, and WRAMC did not make the required report. In assessing the significance of this reporting violation, the NRC considered that, even though WRAMC quickly recovered the sources, the failure to immediately notify the NRC of the loss of specified quantities of licensed material is a potential impact to the regulatory process since the loss of licensed material increases the risk of radiation exposure to the public. Therefore, this violation is categorized in accordance with the NRC Enforcement Policy as a SL III violation.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$3,250 is considered for a SL III violation or problem involving the loss, abandonment, or improper transfer of sealed sources or devices with this level of radioactivity (Lost Source Policy), as well as the failure to report such violations. However, the NRC considered that,

within three hours of identifying its loss, WRAMC personnel located the material in a trash compactor located on WRAMC property in an area that, while unrestricted, is not accessed by the general public. In addition, because WRAMC has not been the subject of escalated enforcement actions within the last two years, or 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. The NRC has concluded that corrective action credit is warranted for both the SL III problem and violation. Corrective actions taken to address the violations include: (1) immediate retraining of WRAMC medical staff on entry requirements and safe handling and shielding requirements for brachytherapy patient rooms; (2) the institution of a new requirement for a member of the WRAMC radiation safety staff to survey bandages and all trash prior to removal from a brachytherapy patient's room; (3) updating of all brachytherapy room door signs to clearly state that housekeeping staff are prohibited from entry; (4) retraining of all WRAMC's housekeeping staff on the updated signs and entry prohibitions; and, (5) retraining of WRAMC's radiation safety staff on NRC reporting requirements.

Therefore, to encourage prompt identification of missing material, prompt reporting of such issues, as well as prompt and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of these SL III violations 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 dates when full compliance was achieved is already adequately addressed on the docket in this letter and in Inspection Report No. 03001317/2008001. 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 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 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/reading-rm/doc-collections/enforcement/actions/>).

Sincerely,

/RA/ Original Signed by Marc L. Dapas for

Samuel J. Collins,
Regional Administrator

Docket No. 03001317
License No. 08-01738-02

Enclosure:
Notice of Violation

cc:
District of Columbia

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 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/reading-rm/doc-collections/enforcement/actions/>).

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NOTICE OF VIOLATION

Walter Reed Army Medical Center
Washington, D.C.

Docket No. 03001317
License No. 08-01738-02
EA-09-039

During an NRC inspection conducted at the Walter Reed Army Medical Center (WRAMC) on December 19, 2008, and continued in the Region I office to assess additional information provided on February 8 and 11, and March 20, 2009, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed 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.

Contrary to the above, on November 14, 2008, WRAMC did not secure from unauthorized removal or limit access to brachytherapy sources consisting of three ribbons containing 29.2 millicuries of iridium-192 located in a brachytherapy patient's room, which is a controlled area. Specifically, the licensee lost control of the brachytherapy sources for approximately 5.5 hours when they were improperly transported to the trash compactor, an uncontrolled area, on the WRAMC loading dock.

- B. 10 CFR 35.410 requires, in part, that the licensee provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who are receiving brachytherapy and cannot be released under 10 CFR 35.75.

Contrary to the above, WRAMC did not provide adequate radiation safety instruction to a medical student who, on November 14, 2008, provided care to a brachytherapy patient. Specifically, the medical student had not been trained on the safe handling and shielding of brachytherapy sources and, as a result, inadvertently removed three ribbons containing 29.2 millicuries of iridium-192 from a patient when changing the patient's bandage and improperly disposed of the sources.

These two violations represent a Severity Level III problem (Supplements IV and VI).

- C. 10 CFR 20.2201(a)(1)(i) requires that each licensee report by telephone immediately after its occurrence becomes known to the licensee, any lost, stolen, or missing licensed material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix C to Part 20 under such circumstances that it appears to the licensee that an exposure could result to persons in unrestricted areas.

Contrary to the above, on November 14, 2008, WRAMC did not immediately report to the NRC the loss of licensed material in an aggregate quantity greater than 1,000 times the quantity specified in Appendix C to Part 20 that could have resulted in exposure to persons in unrestricted areas. Specifically, WRAMC lost control of 29.2 millicuries of iridium-192 for approximately 5.5 hours on November 14, 2008, and located the material in a trash compactor in an

unrestricted area. WRAMC did not notify the NRC that the material had been missing until November 19, 2008.

This is a Severity Level III violation (Supplement IV).

The NRC has concluded that information regarding the reasons 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 Inspection Report No. 03001317/2008001, and in the letter transmitting this Notice. Therefore, you are not required to respond to the letter transmitting this Notice unless the description therein does not accurately reflect WRAMC's corrective actions or position. In that case, or if you choose to respond, clearly mark the response as a "Reply to a Notice of Violation, EA-09-039," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 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 choose to respond, the 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.

If you contest this enforcement action, 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 20555-0001.

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

Dated this 22 day of May 2009