



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BLVD.
KING OF PRUSSIA, PA 19406-2713

July 19, 2016

EA-16-109

Gayle Thompson Smilie
Senior Director of Imaging and
Radiation Safety
MedStar Washington Hospital Center
110 Irving Street, NW
Washington, DC 20010-2975

SUBJECT: MEDSTAR WASHINGTON HOSPITAL CENTER, NOTICE OF VIOLATION -
NRC INSPECTION REPORT NO. 03001325/2015003

Dear Ms. Thompson Smilie:

This letter provides you the U.S. Nuclear Regulatory Commission's (NRC's) enforcement decision for an apparent violation identified during an announced reactive inspection conducted on June 17, 2015, at your facility, with continued in-office review through May 18, 2016. The inspection reviewed the circumstances surrounding an event that occurred on May 15, 2015, when waste contaminated with iodine-131 was transferred to a facility not licensed to receive the radioactive material. Shawn Seeley, Health Physicist, discussed the apparent violation during a telephonic exit with you and Dr. Shashadhar Mohapatra of your staff on May 18, 2016. The apparent violation was also described in the NRC inspection report sent to you with a letter dated June 17, 2016 (ML16169A302).¹

In the June 17, 2016, letter transmitting the inspection report, we provided you an opportunity to address the apparent violation by either attending a pre-decisional enforcement conference (PEC) or by providing a written response before we made our final enforcement decision. In the letter, we also informed you that we had sufficient information regarding the apparent violation and Medstar Washington Hospital Center's (MWHC's) corrective actions to make an enforcement decision without the need for a PEC. In a telephone call on June 20, 2016, Dr. Mohapatra informed Mr. James Dwyer, Chief, Medical Branch, that MWHC neither required a PEC nor intended to send a written response.

Based on the information developed during the inspection, the NRC has determined that one 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 Inspection Report No. 03001325/2015003, issued on June 17, 2016. Specifically, the violation involved

¹ Designation in parentheses refers to an Agency-wide Documents Access and Management System (ADAMS) accession number. Documents referenced in this letter are publicly-available using the accession number in ADAMS.

the transfer of contaminated waste to an unauthorized recipient. This transfer of licensed material to an unauthorized facility is of significant concern to the NRC because the transfer resulted in the contamination, closure, and decontamination of the facility. The potential also existed for contamination of other facilities and unnecessary exposure to workers. Therefore, this violation has been categorized, in accordance with the NRC Enforcement Policy, at Severity Level III (SL III).

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$3,500 is considered for a SL III violation. Because MWHC 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 2.3.4 of the Enforcement Policy. The NRC has concluded that credit is warranted for MWHC's corrective actions taken to address the violation. Specifically, MWHC implemented the following actions: (1) retrained staff in the proper procedure for waste handling, including patient waste containing radioactive material; (2) added security measures to restrict access to the waste area and waste receptacles; (3) reviewed policies and procedures for responding to and handling medical emergencies associated with patients involved with diagnostic or therapeutic nuclear medicine studies; (4) installed video monitoring capability in the waste area; and (5) installed cages around the monitoring detection equipment to prevent the units from becoming inoperable or unplugged.

Therefore, in recognition of the absence of previous escalated enforcement action, and to encourage prompt and comprehensive correction of violations, 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 this SL III violation constitutes an escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding: (1) the reason for the violation; (2) the corrective actions that have been taken and the result achieved; and (3) the date when full compliance was achieved is already adequately addressed on the docket in Inspection Report No. 03001325/2015003. 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 and in the NRC's Agency-wide Documents Access and Management 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 [\(http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/\)](http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/).

Sincerely,

/RA/

Daniel H. Dorman
Regional Administrator

Docket No. 03001325
License No. 08-03604-03

Enclosure: Notice of Violation

cc w/enclosure: Shashadhar M. Mohapatra, Ph.D,
Radiation Safety Officer
District of Columbia
State of Maryland

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 [\(http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/\)](http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/).

Sincerely,

/RA/

Daniel H. Dorman
Regional Administrator

Docket No. 03001325
License No. 08-03604-03

Enclosure: Notice of Violation

cc w/enclosure: Shashadhar M. Mohapatra, Ph.D,
Radiation Safety Officer
District of Columbia
State of Maryland

Distribution: see next page

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DATE	7/1/2016	7/5/16	7/6/16	7/7/16	7/12/16
OFFICE	RI/DNMS				RA
NAME	J Trapp/jmt*				D Dorman
DATE	07/18/16				07/18/16

*See previous concurrence** OE to perform a quick review OFFICIAL RECORD COPY

Letter to Gayle Thompson Smilie from Daniel H. Dorman dated July 19, 2016

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NOTICE OF VIOLATION

Medstar Washington Hospital Center
Washington, DC

Docket No. 03001325
License No. 08-03604-03
EA-16-109

During an NRC inspection conducted on June 17, 2015, with continued in-office review through May 18, 2016, for which an exit meeting was conducted on May 18, 2016, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 20.2001(a)(1) requires, in part, that a licensee shall dispose of licensed material only by transfer to an authorized recipient.

Contrary to the above, on May 15, 2015, Medstar Washington Hospital Center (MWHC) transferred licensed material to an unauthorized recipient. Specifically, MWHC transferred radioactive waste containing Iodine-131 to Stericycle, Inc. in Curtis Bay, Maryland, a waste processing company that was not authorized to receive the radioactive waste.

This is a Severity level III violation (NRC Enforcement Policy Section 6.7).

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 will be (was) achieved, is already adequately addressed on the docket in Inspection Report No. 03001325/2015003 and in this letter. 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-16-109)," 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, 2100 Renaissance Boulevard, Suite 100, King of Prussia, PA 19406, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's Agencywide Documents Access and Management 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 of receipt.

Dated this 19th day of July, 2016