UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

June 17, 2016

Docket No. 03001325 License No. 08-03604-03
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: NRC INSPECTION REPORT NO. 03001325/2015003 and NRC OFFICE OF INVESTIGATIONS (OI) REPORT NO. 1-2015-0019, MEDSTAR WASHINGTON HOSPITAL CENTER (MWHC), WASHINGTON, D.C. SITE

Dear Ms. Thompson Smilie:

On June 17, 2015, Mr. Shawn Seeley of this office began an announced reactive inspection at your facility to follow up on an event that occurred on May 15, 2015, when waste contaminated with iodine-131 was transferred to a facility in Baltimore, Maryland, and that facility was not licensed to receive radioactive material. Transfer of the waste resulted in the contamination and closure of the facility for nearly 48 hours while the facility was decontaminated. The inspection continued through May 18, 2016, when Mr. Seeley discussed the inspection findings with you and Dr. Shashadhar Mohapatra of your staff during a telephone exit meeting. The results of the inspection are discussed in detail in Inspection Report No. 03001325/2015003, included as an enclosure to this letter.

In addition to the inspection, the NRC OI initiated an investigation on June 5, 2015, to determine whether individuals at MWHC had either deliberately ignored a radiation alarm or unplugged another alarm and placed radioactive waste in a container that was subsequently taken offsite to an unauthorized recipient. Based on the testimonial and documentary evidence obtained during the OI investigation, the NRC did not conclude that the actions associated with the event were deliberate.

Based on the results of the inspection and the evidence developed during the investigation, the NRC identified one apparent violation of NRC requirements, which is being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web Site at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The apparent violation being considered for escalated enforcement is documented in the enclosed report and involves the transfer of licensed material to an unauthorized recipient. This is an apparent violation of 10 CFR 20.2001(a)(1).

The circumstances surrounding this apparent violation, the significance of the issues, and the need for lasting and effective corrective actions were discussed with you and Dr. Mohapatra on May 18, 2016. As a result, it may not be necessary to conduct a pre-decisional enforcement

conference (PEC) in order to enable the NRC to make an enforcement decision. In addition, since your facility has not been the subject of escalated enforcement actions within the last two inspections, and based on our understanding of your corrective action, a civil penalty may not be warranted in accordance with Section 2.3.4 of the Enforcement Policy. The final decision will be based on you confirming on the license docket that the corrective actions previously described to the NRC staff have been or are being taken.

We believe we have sufficient information to make an enforcement decision regarding the apparent violation. Therefore, you may accept the violation as characterized in this letter and notify us of that decision within **10** days. Alternatively, before the NRC makes its final enforcement decision, you may choose to provide your perspective on this matter, including the significance, cause, and corrective actions, as well as any other information that you believe the NRC should take into consideration by: (1) requesting a PEC to meet with the NRC and provide your views in person; (2) responding to the apparent violation in writing; or (3) accepting the violation as characterized in the letter and its enclosures (in which case the NRC will proceed with its enforcement decision). Please contact James Dwyer at (610) 337-5309 **within 10 days** of the date of this letter to notify NRC whether you are interested in attending a PEC, providing a written response, or accepting the violation.

If you choose to request a PEC, the meeting should be held in our office in King of Prussia, PA within 30 days of the date of this letter. The PEC will afford you the opportunity to provide your perspective on the apparent violation and any other information you believe the NRC should take into consideration before making an enforcement decision. The topics discussed during the conference may include the following: information to determine whether the violation has occurred, information to determine the significance of the violation, information related to the identification of the violation, and information related to any corrective actions taken or planned to be taken. The guidance in the excerpt from NRC Information Notice 96-28, “Suggested Guidance Relating to Development and Implementation of Corrective Action,” may be helpful. The guidance is included on NRC’s Web Site at http://www.nrc.gov/reading-rm/basic-ref/enf-man/app-d.html. If a PEC is held, it will be open for public observation and the NRC will issue a press release to announce the conference time and date.

If you choose, instead, to provide this information in a written response, it should be sent to the NRC within 30 days of the date of this letter. Your response may reference or include previously docketed correspondence. It should be clearly marked as a “Response to Apparent Violations in Inspection Report No. 03001325/2015003; EA-16-109,” and sent 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, King of Prussia, PA 19406.

In addition, please be advised that the number and characterization of apparent violation described in the enclosed inspection report may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

With respect to the NRC OI investigation, please note that final NRC investigation documents, such as the OI report, may be made available to the public under the Freedom of Information Act (FOIA) subject to redaction of information appropriate under FOIA. Requests under the FOIA should be made in accordance with 10 CFR 9.23, “Requests for Records,” which can be accessed at the NRC Web Site at http://www.nrc.gov/reading-rm/doc-collections/cfr/part009/part009-0023.html.

Current NRC regulations and guidance are included on the NRC's Web Site at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses**; then **Regulations, Guidance and Communications**; then **Enforcement Policy** (under **“Related Information”**). You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

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 provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC 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.

Sincerely,

/RA/

James M. Trapp, Director
Division of Nuclear Materials Safety

Enclosure:
Inspection Report No. 03001325/2015003

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

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Sincerely,

/RA/

James M. Trapp, Director
Division of Nuclear Materials Safety

Enclosure:
Inspection Report No. 03001325/2015003

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

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OFFICE	DNMS/RI	N	DNMS/RI		ORA		~~ORA~~	
NAME	Seeley/sws		Dwyer/jpd		Crisden/cjc w/comment		~~Bickett~~	
DATE	06/09/16*		06/09/16		06/14/16			
OFFICE	DNMS/RI	N						N
NAME	Trapp/jmt							
DATE	06/17/16							

*see prior concurrence

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	03001325/2015003
Docket No.	03001325
License No.	08-03604-03
EA No.	EA-16-109
Licensee:	MedStar Washington Hospital Center
Location:	110 Irving Street, NW Washington, D.C. 20010-2975
Inspection Dates:	June 17, 2015 – May 18, 2016

Inspector:

/RA/ _____ ***06/09/16*** _____

Shawn Seeley, Health Physicist — date
Medical Branch
Division of Nuclear Materials Safety

Approved By:

/RA/ _____ ***06/09/16*** _____

James P. Dwyer, Chief — date
Medical Branch
Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

Washington Hospital Center
NRC Inspection Report No. 03001325/2015003

An announced reactive inspection was conducted at MedStar Washington Hospital Center (MWHC) from June 17, 2015, through May 18, 2016, to follow up on an event that occurred on May 15, 2015, when patient waste contaminated with iodine-131 (I-131) was transferred to Stericycle in Baltimore, Maryland, a medical waste facility not licensed to receive radioactive material. As a result, the Stericycle facility was contaminated and the facility had to be closed for almost two days while RSO, Incorporated, a contractor licensed by the State of Maryland, decontaminated the facility.

Stericycle notified the State of Maryland and MWHC of the contamination event on May 15, 2015, and staff from the MWHC Radiation Safety Office responded immediately to the waste facility. MWHC staff performed surveys and confirmed that no one at the waste facility received more than minor external exposure from the contamination. RSO, Incorporated reported to the Stericycle facility on May 16, 2015, and estimated that the waste contained less than 700 microcuries of I-131. RSO, Incorporated completed decontamination of the waste facility and the facility was reopened on May 17, 2015. The State of Maryland notified the NRC's Headquarters Operations Center of the event on May 18, 2015 (Event No. 51076). The MWHC Radiation Safety Officer notified NRC Region I and the NRC Headquarters Operations Center of the event on May 18, 2015. The contaminated waste was returned to MWHC on May 20, 2015. MWHC staff determined that the waste contained 1.7 millicuries of I-131. MWHC's investigation revealed that radiation detectors placed in areas where medical waste was packaged for offsite transport were possibly disregarded by MWHC employees or Stericycle contractors who moved the waste past the detectors.

One apparent violation of 10 CFR 20.2001(a)(1) was identified for the transfer of radioactive material to a recipient not licensed to receive radioactive material.

MWHC's corrective and preventive actions included:

(1) ordering that no waste be sent to Stericycle until there was an understanding of how the I-131 was not detected in the waste;
(2) retraining of Stericycle waste contractors and MWHC environmental services, nursing, and Radiation Safety Office staff in the proper procedures for MWHC waste handling, including patient waste containing radioactive material;
(3) adding additional physical security measures to restrict access to the Stericycle area and waste containers/receptacles;
(4) reviewing policies and procedures for responding and handling medical emergencies associated with patients involved with diagnostic or therapeutic nuclear medicine studies;
(5) installing video monitoring capability in the waste area; and
(6) installing cages around the radiation detection equipment to prevent the units from being unplugged/rendered inoperable.

REPORT DETAILS

I. Event Response

a. Inspection Scope

The inspector reviewed the licensee's preliminary event report dated May 22, 2015, [ML16159A028], and 30-day report required by 10 CFR 30.50(c)(2) dated June 11, 2015, [ML16159A017]; interviewed management and staff from MWHC who were involved with the event response and Stericycle contractors who worked at the MWHC site; reviewed records; and toured MWHC facilities.

b. Observations and Findings

MWHC operates a broad scope medical program that utilizes unsealed radionuclides for diagnostic nuclear medicine studies and therapy treatments. The program includes the performance of a broad spectrum of diagnostic and therapeutic procedures including in-patient and out-patient I-131 therapies. The Nuclear Medicine Department performs approximately 200 I-131 therapies per year (with a maximum dosage of 475 millicuries) and approximately 350 hyperthyroid treatments/whole body scans using I-131. Patients administered greater than 33 millicuries of I-131 are held in the iodine dosing area for 4 hours before being released. Patients receiving greater than 200 millicuries and/or patients unable to meet the release criteria are hospitalized in dedicated shielded treatment rooms. The licensee uses the criteria in Appendix U of NUREG-1556, Volume 9, Revision 2, for patient release.

All radioactive waste is handled directly by the Nuclear Medicine Department staff or Radiation Safety Office staff. All radioactive waste is held for decay in a trailer adjacent to the loading dock and once decayed to background levels, it is surveyed by Radiation Safety Office staff prior to release as normal trash. All trash from the hospital is handled by Stericycle personnel. MWHC Environmental Service Department personnel collect the trash and leave it in a designated area for Stericycle employees to process prior to placement in a receptacle/dumpster. All trash is wheeled past radiation detectors at a slow pace prior to disposal. If an alarm sounds, the trash is re-monitored bag-by-bag and the "hot" bag segregated and set aside for Radiation Safety Office staff to pick up (daily). In addition, there is a second detector outside on the loading dock that waste will pass prior to reaching the biohazard waste container. The inspector observed Stericycle employees handling and processing trash past the radiation detectors in a proper manner.

On May 8, 2015, MWHC administered 94.6 millicuries of I-131 to a patient for treatment of thyroid carcinoma. The patient spent the night at the hospital and was not released from radiation precautions. The patient was scheduled to receive dialysis on May 9, 2015, and then be released. A Radiation Safety Office staff member checked the patient on the morning of May 9, 2015, and found the patient to be very ill and unresponsive. The Radiation Safety Office staff member notified the Nursing staff about the patient's condition and performed surveys of the patient and the patient's room while taking actions to control the spread of contamination. The Radiation Safety Office staff member notified the Medical staff that the patient was still under radiation precautions. The Medical staff elected to take the patient to the MWHC's Intensive Care Unit (ICU). The Radiation Safety Office staff member prepared a room in the ICU for the patient to

control contamination. When the patient arrived in ICU, the Medical staff intubated and performed dialysis on the patient. The inspector determined that the patient had liquid suctioned from his lungs and airway. The Radiation Safety Office staff member made daily visits to the patient's room to insure waste was properly stored and handled. The Medical staff extubated the patient on May 14, 2015, and the suction unit and canister were placed in a red bag and taken to a waste storage area. The patient remained in the ICU until May 15, 2015.

The inspector determined that sometime between the afternoon of May 14, 2015, and the morning of May 15, 2015, the red bag containing the suction unit and canister were transferred to the waste disposal area by MWHC Environmental Services personnel. Subsequently the waste was handled and monitored by Stericycle contract workers prior to being placed in the biohazard dumpster and transferred from the MWHC site to the Stericycle facility in Baltimore, Maryland. This red bag waste containing the suction unit and canister would have had to pass by two alarming radiation detectors.

On May 15, 2015, staff at the Stericycle facility identified areas of contamination in the facility. Stericycle notified the State of Maryland and the Radiation Safety Officer at MWHC. The MWHC Radiation Safety Officer and a staff member responded immediately to the Stericycle facility and performed surveys to assess the level of personnel and facility contamination. RSO, Incorporated was contacted to assess the level of contamination and decontaminate the facility. RSO, Incorporated closed the Stericycle facility at approximately 9:30pm on May 15, 2015. On May 16, 2015, the Radiation Safety Officer at MWHC ordered that no waste be transferred to Stericycle until he could determine why the radioactive material in the waste was not detected by the radiation detectors. A check of the radiation detectors by the MWHC Radiation Safety Officer on May 16, 2015, found all to be operational.

RSO, Incorporated did not reopen the Stericycle facility until decontamination was completed at approximately 6:00pm on May 17, 2015. RSO, Incorporated estimated the waste contained less than 700 microcuries of I-131. The MWHC Radiation Safety Officer later reported he did not believe the event was reportable within 24 hours because the I-131 loss was less than 1000 times the quantity in Appendix C of Part 20 (for I-131 the quantity in Appendix C of Part 20 is one microcurie). The inspector noted that the MWHC Radiation Safety Officer was focused on the reporting requirements of 10 CFR 20.2201 and not the requirements of 10 CFR 30.50(b) which requires a 24 hour report when there is an unplanned contamination event involving a quantity greater than 5 times the lowest Annual Limit of Intake (for I-131 the quantity is 30 microcuries) and where access to the contaminated area is restricted for more than 24 hours. The inspector noted that the MWHC Radiation Safety Officer was aware that Stericycle had immediately notified the State of Maryland, the regulatory authority with jurisdiction for the location where the contamination occurred, on May 15, 2015, so any violation of 10 CFR 30.50(b) would be a minor violation. The MWHC Radiation Safety Officer also reported that, until the waste was returned to MWHC and examined on May 20, 2015, he was unsure that the waste came from MWHC. On May 18, 2015, the MWHC notified NRC Region I and the NRC Headquarters Operations Center about the event via telephone.

On May 19, 2015, the MWHC Radiation Safety Officer contacted RSO, Incorporated and asked that the bag of waste be returned. At that time, RSO, Incorporated reported that the waste contained more than one millicurie of I-131. The bag of waste was returned to MWHC on May 20, 2015, and MWHC confirmed the waste originated from their facility.

The MWHC Radiation Safety Officer also noted that the radiation detectors alarmed when the waste was returned to MWHC. The MWHC Radiation Safety Officer confirmed that the waste contained 1.7 millicuries of I-131 and that the I-131 was in the form of liquid suctioned from the patient's lung. The MWHC 30-day report was dated June 11, 2015. The report indicated MWHC employees or Stericycle contractors possibly disregarded the alarms.

The inspector noted that the suction unit and canister were not noticed by the Radiation Safety Office staff member during radiation surveys because the suction unit and canister were placed behind the patient while the patient was still in the ICU room. The suction unit, the canister and its contents were what contaminated the Stericycle facility.

The inspector determined through discussions with the Radiation Safety Office staff that the radiation detectors and monitoring systems were discovered to be inoperable by the radiation safety technician on the morning of May 15, 2015. The technician promptly restored the system to operation and notified the Stericycle supervisor who worked at the MWHC facility and the MWHC Radiation Safety Officer. Based upon interviews with MWHC and Stericycle personnel, the inspector could not determine how or when the radiation detection system became inoperable.

10 CFR 20.2001(a)(1) requires, in part, that a licensee shall only transfer licensed material to an authorized recipient. The inspector concluded that MWHC's transfer of licensed radioactive material to an unauthorized recipient is an apparent violation of 10 CFR 20.2001(a)(1).

MWHC's corrective and preventive actions included:

(1) ordering that no waste be sent to Stericycle until there was an understanding of how the I-131 was not detected in the waste;
(2) retraining of Stericycle waste contractors and MWHC environmental services, nursing, and Radiation Safety Office staff in the proper procedures for MWHC waste handling, including patient waste containing radioactive material;
(3) adding additional physical security measures to restrict access to the Stericycle area and waste containers/receptacles;
(4) reviewing policies and procedures for responding and handling medical emergencies associated with patients involved with diagnostic or therapeutic nuclear medicine studies;
(5) installing video monitoring capability in the waste area; and
(6) installing cages around the monitoring detection equipment to prevent the units from being unplugged/rendered inoperable.

c. Conclusions

An apparent violation of NRC requirements was identified for the improper transfer of licensed material to an unauthorized recipient as required by 10 CFR Part 20.2001(a)(1).

II. Exit Meeting

The inspector met with MWHC management and the MWHC Radiation Safety Officer at the completion of the on-site inspection on June 23, 2015. Following periodic discussions with the Radiation Safety Officer and review of additional information provided by MWHC during the inspection period, the inspector conducted an exit meeting with MWHC management and staff by telephone on May 18, 2016.

PARTIAL LIST OF PERSONS CONTACTED

Licensee

+#*Shashadhar Mohapatra, Ph.D., Radiation Safety Officer
+ Gayle Thompson Smilie, Sr. Director of Imaging and Radiation Safety
Clive Hutchinson, Health Physics Technician
David Burch, Health Physics Technician
Curtis Downs, Health Physics Technician
Marie Davis, DES Staff
Marc Brown, DES Staff

Stericycle

Odis Glenn
Michael Mahoney
Jamal Craig
Alonzo Morgan

Individuals present at entrance meeting
* Individuals present at on-site preliminary exit meeting
+ Individuals present at telephonic exit meeting