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

September 20, 2016

Docket No. 03035409 License No. 08-30577-01

Michael C. Sachtleben
President
MedStar Georgetown Medical Center, Inc.
Hospital Administration, 1 Main Hospital
3800 Reservoir Road, N.W.
Washington, D.C. 20007

SUBJECT: NRC INSPECTION REPORT NO. 03035409/2016003, MEDSTAR GEORGETOWN MEDICAL CENTER, INC., WASHINGTON, D.C. AND NOTICE OF VIOLATION

Dear Mr. Sachtleben:

On July 13, 2016, Robert Gallaghar of this office conducted a special safety inspection at the above address to review the circumstances surrounding an event reported by your radiation safety officer (RSO), David A. Smith, Ph.D., to an NRC inspector via electronic mail on June 28, 2016. The event occurred during the administration of yttrium-90 microspheres to a patient on May 19, 2016. The RSO stated in his report that he did not believe the event constituted a medical event. NRC reviewed the event and concluded it was likely a medical event. On July 5, 2016, NRC recommended that the RSO contact the NRC's Operations Center and report the event as a medical event. The RSO made the report that same day. The preliminary findings of the inspection were discussed with Kifri Edwards, Director Environmental Health & Safety, at the conclusion of the on-site inspection on July 13, 2016. Additional clarifying information was provided to the inspector by the RSO during telephone discussions on August 18 and 30, 2016. The findings of the inspection were discussed with you on September 13, 2016. The inspection report is provided as Enclosure 2.

Based on the results of this inspection, the NRC determined that two Severity Level IV violations of NRC requirements were identified. The violations are evaluated 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 violations are cited in the Notice of Violation (Notice), provided as Enclosure 1 to this letter. The violations are cited because they were identified by the NRC.

The NRC has concluded that information regarding the reason for the violations and the corrective actions taken and planned to correct the violations and prevent recurrence is already adequately addressed in our inspection report. Therefore, you are not required to respond to this letter.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosures 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 website at http://www.nrc.gov/reading-rm/adams.html.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses;** then **Regulations, Guidance and Communications.** The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **About NRC, Organizations & Functions; Office of Enforcement; Enforcement documents;** 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).

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

Please contact Robert Gallaghar at 610-337-5182 if you have any questions regarding this matter.

Sincerely,

***/RA J. L. Nick for/***

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

Enclosures:
1. Notice of Violation
2. Inspection Report 03035409/2016003

cc w/Enclosures: David A. Smith, Ph.D., Radiation Safety Officer
District of Columbia

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses;** then **Regulations, Guidance and Communications.** The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **About NRC, Organizations & Functions; Office of Enforcement; Enforcement documents;** 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).

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Division of Nuclear Materials Safety

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1. Notice of Violation
2. Inspection Report 03035409/2016003

cc w/Enclosures: David A. Smith, Ph.D., Radiation Safety Officer
District of Columbia

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| OFFICE | DNMS/RI | N | DNMS/RI | | I | | | |
|---|---|---|---|---|---|---|---|---|
| NAME | RGallaghar/rlg | | JDwyer/jln f/ | | | | | |
| DATE | 09/19/16 | | 09/20/16 | | | | | |

OFFICIAL RECORD COPY

# NOTICE OF VIOLATION

MedStar Georgetown Medical Center, Inc.
Washington, D.C.

Docket No. 03035409
License No. 08-30577-01

During an NRC inspection conducted on July 13, 2016, at the Medstar Georgetown Medical Center facilities in Washington, D.C., and continued in-office review until September 13, 2016, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. 10 CFR 35.41(a)(2) states that for any administration requiring a written directive, the licensee shall develop, implement, and maintain procedures to provide high confidence that each administration is in accordance with the written directive.

   The MGMC's Department of Radiation Medicine written procedure "SIRSPHERE," dated September 16, 2013, states "to prevent wrong site, wrong procedure, wrong person surgery, a time out is conducted in the interventional radiology suite just before starting the procedure, and it: a) involves the entire team; and b) uses active communication."

   Contrary to the above, on May 19, 2016, the licensee failed to implement procedures to provide high confidence that each administration is in accordance with the written directive. Specifically, on May 19, 2016, the licensee failed to use active communication to verify that the administration was in accordance with the treatment plan and the written directive.

   This is a Severity Level IV problem (Enforcement Policy Section 6.3)

B. 10 CFR 35.3045(c) requires that the licensee notify, by telephone, the NRC Operations Center no later than the next calendar day after discovery of the medical event;

   Contrary to the above, on June 16, 2016, the licensee discovered, or should have discovered, a medical event that occurred on May 19, 2016, yet the licensee did not report the medical event to the NRC until June 28, 2016, and did not report the medical event to the NRC Operations Center, as specifically required by 10 CFR 35.3045(c), until July 5, 2016.

   This is a Severity Level IV problem (Enforcement Policy Sections 6.9).

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violation and prevent recurrence and the date when full compliance will be achieved is already adequately addressed on the docket. 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," 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, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

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

Dated this 20th day of September 2016

# U.S. NUCLEAR REGULATORY COMMISSION
# REGION I

## INSPECTION REPORT

| | |
|---|---|
| Inspection No. | 03035409/2016003 |
| Docket No. | 03035409 |
| License No. | 08-30577-01 |
| NMED Item No. | 160248 |
| Licensee: | MedStar Georgetown Medical Center, Inc. |
| Location: | Hospital Administration, 1 Main Hospital<br>3800 Reservoir Road, N.W.<br>Washington, D.C. 20007 |
| Inspection Dates: | July 13, August 18, and August 30, 2016 |

Inspector: ***/RA/*** _____ ***09/19/16*** _____

Robert L. Gallaghar, Health Physicist — date
Medical Branch
Division of Nuclear Materials Safety

Approved By: ***/RA/*** _____ ***09/06/16*** _____

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

## EXECUTIVE SUMMARY

MedStar Georgetown Medical Center, Inc.
NRC Inspection Report No. 03035409/2016003

An announced, special inspection was conducted on July 13, 2016, at MedStar Georgetown Medical Center (MGMC) in Washington, D.C., to review the circumstances surrounding an event reported by the licensee's radiation safety officer (RSO) to an NRC inspector via electronic mail on June 28, 2016. The licensee provided additional information to the inspector during a telephone discussion on August 18, and August 30, 2016. The event occurred during the administration of yttrium-90 microspheres to a patient on May 19, 2016, when the written directive specified treatment of the right lobe of the patient's liver and the patient's left lobe received the treatment. The RSO stated in his email report that the licensee did not believe the event constituted a medical event because the left lobe received a dose that was within 20 percent of the dose that would have been prescribed for the left lobe of the liver if the left lobe of the patient's liver was to be treated that day.

Following a review of the RSO's email report on June 30, 2016, the NRC identified the event as a likely medical event. This conclusion was communicated to the licensee's RSO on July 5, 2016, and NRC recommended that the licensee notify the NRC Operations Center. The RSO reported the event to the Operations Center later that day (EN 52063).

Based on the results of this inspection, two apparent violations of NRC requirements were identified. Specifically:

- 10 CFR 35.41(a)(2) states, in part, that for any administration requiring a written directive, the licensee shall implement procedures to provide high confidence that each administration is in accordance with the written directive.

  Contrary to the above, on May 19, 2016, the licensee failed to implement procedures to provide high confidence that each administration is in accordance with the written directive. Specifically, on May 19, 2016, the licensee failed to use active communication to verify that the administration was in accordance with the treatment plan and the written directive.

- 10 CFR 35.3045(c) requires that the licensee notify, by telephone, the NRC Operations Center no later than the next calendar day after discovery of the medical event;

  Contrary to the above, on June 16, 2016, the licensee discovered, or should have discovered, a medical event that occurred on May 19, 2016, yet the licensee did not report the medical event to the NRC until June 28, 2016, and did not report the medical event to the NRC OC, as specifically required by 10 CFR 35.3045(c), until July 5, 2016, a period in excess of the next calendar day.

## REPORT DETAILS

### I. Event and Notification Description

a. Inspection Scope

An announced, special inspection was conducted on July 13, 2016, at MedStar Georgetown Medical Center (MGMC) in Washington, D.C., to review the circumstances surrounding an event reported by the licensee's radiation safety officer (RSO) to an NRC inspector via electronic mail on June 28, 2016. The licensee provided additional information to the inspector during a telephone discussion on August 18 and August 30, 2016. The event occurred during the administration of yttrium-90 (Y-90) microspheres to a patient on May 19, 2016. The RSO stated in his email report that the licensee did not believe the event constituted a medical event. Following a review of the RSO's email report, the NRC identified the event as a likely medical event. This conclusion was communicated to the licensee's RSO on July 5, 2016, and NRC recommended that the licensee notify the NRC Operations Center. The RSO reported the event to the Operations Center later that day.

The inspection was conducted in accordance with Inspection Procedure 87103 and Management Directive 8.10. The inspector conducted interviews with licensee personnel, toured facilities, and reviewed records applicable to the event. The inspector also reviewed MGMC's procedures related to microsphere use.

b. Observations and Findings

License No. 08-30577-01 authorizes MGMC to perform microsphere procedures using the SIR-Sphere delivery system at its facility in Washington, D.C. The licensee began its microsphere program in 2007 and currently has one authorized user (AU), a radiation oncologist, approved to perform these procedures. The microsphere procedure also involves an interventional radiologist (IR) who performs a series of diagnostic imaging studies to determine the extent of the disease and who then administers the microspheres, and an authorized medical physicist (AMP) who works with the AU to develop a treatment plan. MGMC performs approximately 60 microsphere procedures each year.

On May 17, 2016, the IR communicated by electronic mail to the AU that he wanted to treat the right lobe of the patient's liver with a single dose of Y-90 SIR-Sphere. On that same day, the AU communicated by electronic mail to the AMP that he wanted to administer 32.13 Gray (Gy) to the right lobe of the patient's liver with a single administered dose of Y-90 SIR-Sphere. The AU included the dimensions of the patient's liver and the percent of shunting to the lung.

On May 18, 2016, the AMP drafted the written directive (WD) and notified the AU that the treatment plan and WD were ready for his review and signature. The WD prescribed that the right lobe of the patient's liver would receive a dose of 32.13 Gy from 29.1 millicuries of Y-90 SIR-Sphere.

On May 19, 2016, the AU reviewed the treatment plan and reviewed, signed and dated the WD while the IR catheterized the patient. The AU reviewed the written directive verbally with the IR stating that the patient's right lobe would be treated. The IR stated during the inspector's interview that, "when I saw the patient, I remembered that the left lobe of her liver contained more disease than the right lobe and it is my normal practice to first treat the lobe of the liver containing the most disease." The IR stated that while he heard the AU read the WD to treat the right lobe, he was focused on the left lobe and treated the left lobe of the liver. The treatment was not completed because of stasis.

During his review of the patient's records on June 16, 2016, and prior to the second treatment, the AU discovered that the treatment performed on May 19, 2016, was performed on the left lobe of the liver, not the right lobe as specified in the written directive. The AU notified the RSO and the IR. The AU and the AMP recalculated the May 19, 2016, treatment plan using the administered activity and the volume of the left lobe of the patient's liver and determined the administered activity was 119.4% of the amount prescribed in the WD. The AU concluded that no harm would come to the patient from this dose. The AU and the AMP developed a new treatment plan to treat the right lobe of the patient's liver. The WD specified that the right lobe of the patient's liver would receive a dose of 32.13 Gy. The delivered dose to the right lobe of the patient's liver on June 16, 2016, was 31.89 Gy or 99 percent of the intended dose.

Between June 16 and June 28, 2016, the RSO reviewed the circumstances of the May 19, 2016, event and concluded the dose that was administered to the left lobe of the patient's liver on that day was not a medical event because the dose administered to the left lobe of the patient's liver was only 119.4% of that dose that would have been prescribed for the left lobe of the patient's liver. The RSO concluded that the licensee may have violated 10 CFR 35.40(c) and/or 10 CFR 35.41(a)(2) and 35.41(b)(2) related to the licensee's use of the WD and it was for these reasons he submitted the June 28, 2016, email report to NRC.

On July 5, 2016, the inspector contacted MGMC to inform them of the NRC decision that the event did constitute a medical event and directed them to inform the NRC Operations Center and that a special inspection was to be performed to review the circumstances surrounding the event. MGMC also informed the patient of the event at that time.

10 CFR 35.3045(a)(3) requires a licensee to report any event, except for an event which results from patient intervention, in which the administration of byproduct material or radiation from byproduct material, results in a dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the WD.

The inspector noted that on May 19, 2016, the WD specified that the right lobe of the patient's liver was to receive a dose of 32.13 Gy (3213 rads) and, on that day, the right lobe of the patient's liver received essentially no dose and the left lobe of the patient's liver received a dose of 51.77 Gy (5177 rads). The inspector noted that the licensee did not identify patient intervention as a cause of the event and concluded that the May 19, 2016, administration constituted a medical event because it involved a dose to the skin or an organ tissue other than the treatment site.

10 CFR 35.3045(c) requires that the licensee notify, by telephone, the NRC Operations Center no later than the next calendar day after discovery of the medical event.

Contrary to the above, on June 16, 2016, the licensee discovered, or should have discovered, a medical event that occurred on May 19, 2016, yet the licensee did not report the medical event to the NRC until June 28, 2016, and did not report the medical event to the NRC OC, as specifically required by 10 CFR 35.3045(c), until July 5, 2016. This is an apparent violation of 10 CFR 35.3045(c).

10 CFR 35.41(a)(2) states, in part, that for any administration requiring a WD, the licensee shall implement procedures to provide high confidence that each administration is in accordance with the written directive.

The MGMC's Department of Radiation Medicine policy "SIRSPHERE," dated September 16, 2013, states "to prevent wrong site, wrong procedure, wrong person surgery, a time out is conducted in the interventional radiology suite just before starting the procedure, and it: a) involves the entire team; and b) uses active communication." On May 19, 2016, the AU reviewed the written directive verbally but the IR's attention was focused on the patient and not on the details of the written directive as it was read to him and therefore in this case the time out procedure did not involve the use of active communication.

Contrary to the above, on May 19, 2016, the licensee failed to follow MGMC's Department of Radiation Medicine policy "SIRSPHERE" procedures to provide high confidence that each administration is in accordance with the WD. Specifically, on May 19, 2016, the licensee failed to use active communication to verify that the administration was in accordance with the treatment plan and the WD.

c. Conclusions

The inspector concluded that the event that occurred on May 19, 2016, constituted a medical event because the WD specified treatment of the right lobe of the patient's liver and, on that day, the left lobe of the patient's liver was treated. Also, the inspector concluded that the intended treatment site – the right lobe of the patient's liver – received virtually no dose when it was supposed to receive 32.13 Gy and the left lobe of the patient's liver received 51.77 Gy when it was supposed to receive essentially no dose. The inspector concluded that the licensee should have determined this constituted a medical event on June 16, 2016, and should have reported it to the NRC Operations Center by the next calendar day as required by 10 CFR 35.3045(c).

The inspector concluded that the root cause of the medical event was the licensee's failure to follow procedures that provided high confidence that each administration was in accordance with the WD. Specifically, it was the failure, prior to administration of the dose, to verify that the administration was in accordance with the WD. This is an apparent violation of 10 CFR 35.41(a)(2).

## II. Corrective and Preventive Actions

a. Inspection Scope

The inspector questioned individuals directly involved with the licensee's microsphere therapy program and reviewed the licensee's corrective and preventive actions taken as a result of the medical event to determine if the actions proposed addressed the causes of the medical event.

b. Observations and Findings

The inspector determined that the licensee implemented the following corrective and preventive actions:

- The treatment plan, WD, and the patient's record were corrected to document the treatment provided. The patient was notified of the medical event.
- A time out will occur prior to the dose administration, when the AU, AMP and IR will review the specifics of the treatment plan and the WD. The time out will be documented via signatures from each of the aforementioned team members on the WD.
- After the diagnostic imaging studies the IR will clearly indicate the preferred treatment site(s) in his notes so the AU is clear as to the development of the treatment plan.
- These actions have been incorporated into the Radiation Medicine SIR-Sphere Policy and each member of the team has been instructed regarding the changes.

c. Conclusions

The inspector concluded that the above actions are reasonable to correct and prevent additional medical events.

## PARTIAL LIST OF PERSONS CONTACTED

Licensee

| | |
|---|---|
| # | Michael Sachtleben, Chief Executive Officer |
| # | Angela Jones, Assistant Vice President, Safety and Support Services |
| *+ | Kifri Edwards, Director, Environmental Health & Safety |
| *+# | David A. Smith, Ph.D., Director, Radiation Safety Office, Radiation Safety Officer |
| *+# | Dawn Claggett, MSNA, MHA, Deputy Director, Radiation Safety Office |
| *# | Keith Unger, M.D., Authorized User |
| * | Alexander Kim, M.D., Interventional Radiologist |
| * | Guowei Zhang, Ph.D., Medical Physicist |
| + | Donald J. Hixson, CNMT |
| +# | Giuseppe Esposito, M.D., Chief of Nuclear Medicine |

| | |
|---|---|
| * | Contacted during inspection |
| + | Present at preliminary exit meeting on July 13, 2016 |
| # | Present at formal exit meeting on September 13, 2016 |