



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

August 3, 2012

EA-12-085

Michael Sachtleben
Chief Operating Officer
MedStar Georgetown Medical Center
Hospital Administration, 1 Main Hospital
3800 Reservoir Road, N.W.
Washington, DC 20007

**SUBJECT: MEDSTAR GEORGETOWN MEDICAL CENTER - NOTICE OF VIOLATION -
NRC Inspection Report No. 03035409/2012001**

Dear Mr. Sachtleben:

This letter provides you with the U.S. Nuclear Regulatory Commission (NRC) enforcement decision for the apparent violations identified during an NRC inspection conducted on March 5 and 6, 2012, at MedStar Georgetown Medical Center (MGMC) in Washington, DC of MGMC's licensed activities as they relate to radiation safety and to compliance with NRC regulations. In addition to the onsite review, the inspection also involved in-office review of additional information provided by MGMC, in correspondence dated March 27, 2012 (ML12171A290)¹, regarding MGMC's corrective action for violations identified during the NRC inspection. The NRC discussed the findings of its inspection during a telephonic exit with you and other members of your staff on May 15, 2012. The findings were also described in the NRC inspection report (ML121670054)² sent to you with a letter dated June 15, 2012 (ML121670074).

In the letter dated June 15, 2012, the NRC indicated that three apparent violations were identified during the NRC inspection, and that one of these apparent violations was being considered for escalated enforcement. In the letter, we also provided you with the opportunity to address the apparent violations identified in the report by either attending a pre-decisional enforcement conference (PEC) or by providing a written response before we made our final enforcement decision. In letters dated July 10 and 16, 2012, MGMC provided a response that documented the reasons, corrective actions, and dates of full compliance for each of the apparent violations (ML12208A302). Therefore, based on the information developed during the inspection, and the additional information provided in MGMC's July 10 and 16, 2012, letters, the NRC has determined that three violations of NRC requirements occurred. The violations are

¹ Designation in parentheses refers to an Agency-wide Documents Access and Management System (ADAMS) accession number. This document is not publicly-available in ADAMS because the information contained therein is of a security-related nature.

² This document, and subsequent documents referenced in this letter, is publicly-available using the accession number in ADAMS.

cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report.

The most significant violation involved MGMC's failure to control and secure an iridium-192 radiation source (approximately 4 curies) that was neither in storage nor under constant surveillance, as required by Title 10 of the Code of Federal Regulations (CFR) Section 20.1802. Specifically, on December 13, 2011, following a scheduled radioactive source exchange for MGMC's high dose-rate remote afterloader (HDR), a vendor service engineer installed the new source in the HDR unit, placed the old source in a shielded container, and left the shielded container (with the iridium-192 source inside) in the unlocked room. Subsequently, two MGMC Authorized Medical Physicists (AMPs) entered the room, calibrated the HDR unit for the new source, and secured the HDR unit, but did not notice the shielded container with the old source inside. Additionally, a third MGMC AMP entered the room to conduct unrelated activities and also did not notice the unsecured source. The unsecured container containing the source was not identified until the following day when the MGMC assistant radiation safety officer entered the room, saw the container, and took immediate action to secure the source.

During its inspection, the NRC identified that MGMC had no formal procedure for conducting HDR source exchanges and that MGMC's radiation safety personnel did not oversee such activities. Further, the NRC identified that MGMC relied on the vendor service engineers to secure the old sources after completing source exchanges. However, after the December 13, 2011 source exchange, the vendor service engineer did not secure the old source.

The actual safety significance of this violation was low because the source, while unsecured, remained shielded within its container, and the AMP who had entered the room to conduct activities unrelated to the HDR source exchange received a maximum unplanned exposure of 0.0083 millirem. Nonetheless, the potential existed for additional unplanned and unauthorized radiation exposure, including the potential that other workers or members of the public could have entered the unlocked room and come in close contact with the shielded container holding the source, or that the source could have been removed from the room and exposed members of the public. Therefore, the violation has been categorized at Severity Level (SL) III in accordance with the Enforcement Policy.

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 MGMC has not been the subject of NRC 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 MGMC's corrective actions taken to address the violation. Specifically, MGMC: (1) developed a new policy and written procedure for the conduct of HDR source exchanges requiring involvement of MGMC radiation safety personnel during multiple steps of the evolution (such as, scheduling the exchange, controlling the new source, and collecting the old source); (2) reminded AMPs and vendor service engineers of the requirement that radioactive sources must be attended or secured at all times; and (3) included discussion of this event in its radiation safety training program.

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

The other two violations, also documented in the attached Notice, have been categorized at SL IV in accordance with the NRC Enforcement Policy. These violations are being cited because they were identified by the NRC. The circumstances surrounding these violations are documented in detail in the aforementioned inspection report.

The NRC has concluded that information regarding: (1) the reason for the violations; (2) the actions planned or already taken to correct the violations and prevent recurrence; and, (3) the date when full compliance was achieved, is already adequately addressed on the docket in this letter; in NRC Inspection Report No. 03035409/2012001; and in the letters from MGMC dated March 27, 2012, July 10, 2012, and July 16, 2012. Therefore, you are not required to respond to this letter unless the descriptions in the aforementioned correspondence do not accurately reflect 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 and its enclosure as well as your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room and from 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>. The NRC also includes significant enforcement actions on its Web site at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>.

To the extent possible, your response, if you choose to provide one, 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 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).

Sincerely,

/RA Original Signed by David C. Lew for/

William M. Dean
Regional Administrator

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

Enclosure: Notice of Violation

cc: w/enclosure
Maxwell Amurao, Ph.D., Radiation Safety Officer
District of Columbia

To the extent possible, your response, if you choose to provide one, 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 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).

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Regional Administrator

Docket No. 03035409

License No. 08-30577-01

Enclosure: Notice of Violation

cc: w/enclosure
Maxwell Amurao, Ph.D., Radiation Safety Officer
District of Columbia

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NOTICE OF VIOLATION

MedStar Georgetown Medical Center
Washington, DC

Docket No. 03035409
License No. 08-30577-01
EA-12-085

During an NRC inspection conducted between March 5, and May 15, 2012 (which included an on-site inspection as well as an in-office review of information provided by MedStar Georgetown Medical Center (MGMC) in correspondence dated March 7, and March 27, 2012), for which an exit meeting was conducted on May 15, 2012, 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 licensees 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, between December 13 and 14, 2011, MGMC did not control and maintain constant surveillance of licensed material that was in a controlled area and that was not in storage. Specifically, a 4.006 curie iridium-192 source, in a lead shielded container, was unsecured and not under constant surveillance in the high dose-rate remote afterloader (HDR) Procedure Room for approximately 24-30 hours. The HDR Procedure Room was unlocked during this period, and located is within MGMC's Radiation Oncology suite, which is a controlled area.

This is a Severity Level III violation (Section 6.7).

- B. 10 CFR 35.51 requires, in part, that a licensee shall require an authorized medical physicist (AMP) to be an individual who:

- a. is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State; and,
- b. has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c) and (a)(1) and (a)(2), or (b)(1) and (c) of this section, and has achieved a level of competency sufficient to function independently as an AMP for each type of therapeutic medical unit for which the individual is requesting AMP status. The written attestation must be signed by a preceptor AMP who meets the requirements in 10 CFR §§ 35.51, 35.57, or equivalent Agreement State requirements for an AMP for each type of therapeutic medical unit for which the individual is requesting AMP status.

Contrary to the above, for periods between April 8, 2011, and March 6, 2012, two MGMC AMPs did not meet the training criteria established in 10 CFR Part 35. Specifically: 1) neither individual had obtained written attestation that the individuals had satisfactorily completed the necessary requirements set forth in paragraphs (c) and (a)(1) and (a)(2), or (b)(1) and (c) of 10 CFR 35, and had achieved a level of competency sufficient to function independently as an AMP for each type of therapeutic medical unit for which the individuals requested AMP status; and, 2) one individual also was not certified by a specialty board whose certification process had been recognized by the Commission or an Agreement State.

This is a Severity Level IV violation (Section 6.3).

- C. Condition 24 of NRC License No. 08-30577-01, Amendment 10 (and Condition 26 of Amendments 11-16) requires, in part, that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the MGMC license application dated August 21, 1995.

Section III.B of Appendix H of the MGMC license application dated August 21, 1995, states that the Radiation Safety Committee will approve users for the device (HDR Remote Afterloader) who are physicists, in accordance with 10 CFR 35.2, and who meet requirements specified in 10 CFR 35.961.

Contrary to the above, between July 1, 2009, and April 8, 2011, an MGMC physicist had been using the HDR Remote Afterloader without receiving approval from the Radiation Safety Committee.

This is a Severity Level IV violation (Section 6.3).

The NRC has concluded that information regarding: (1) the reason for the violations; (2) the actions planned or already taken to correct the violations and prevent recurrence; and, (3) the date when full compliance was achieved, is already adequately addressed on the docket in this letter; in NRC Inspection Report No. 03035409/2012001; and in the letters from MGMC dated March 27, 2012, July 10, 2012, and July 16, 2012. Therefore, you are not required to respond to this Notice. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the descriptions in the aforementioned correspondence do not accurately reflect MGMC's corrective actions or its position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation – EA-12-085," and send it to the 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.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room and from 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>. 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 3rd day August, 2012