U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	03035409/2012001
Docket No.	03035409
License No.	08-30577-01
Licensee:	MedStar Georgetown Medical Center, Inc.
Address:	Hospital Administration, 1 Main Hospital 3800 Reservoir Road, N.W. Washington, D.C. 20007
Other Locations Inspected:	3750 Reservoir Road, N.W. Washington, D.C.
Inspection Dates:	March 5 - 6, 2012 and May 15, 2012 (Exit Meeting)
Dates Follow-up Information Received:	March 7 and 27, 2012

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EXECUTIVE SUMMARY

MedStar Georgetown Medical Center, Inc.
NRC Inspection Report No. 03035409/2012001

A routine, unannounced inspection was conducted at MedStar Georgetown Medical Center, Inc. (MGMC) located in Washington, D.C. on March 5 and 6, 2012. Additional information, contained in correspondence dated March 7 and 27, 2012, was also reviewed as part of this inspection. The inspection was performed in accordance with NRC Inspection Procedures 87134 and 87122 and reviewed activities associated with the use of licensed materials within MGMC's nuclear medicine, radiation medicine, and research departments. The inspectors conducted interviews with MGMC's personnel, observed day-to-day operations, toured MGMC's facilities, and reviewed documents and procedures.

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

- MGMC did not control access to 4.006 curies of iridium-192, as required by 10 CFR 20.1802, and this resulted in the source being left unsecured in a controlled area for approximately 24 to 30 hours.

- MGMC did not obtain the appropriate supporting documentation of training and experience for two individuals designated in writing by the licensee's Radiation Safety Committee (RSC) to work as authorized medical physicists (AMPs).

- MGMC's RSC did not approve a physicist as a user for devices, as required by Condition 26 of License No. 08-30577-01, Amendment 14 and 10 CFR 33.13(c)(3)(iii). Specifically, a physicist was acting as an AMP for the high dose rate remote afterloader (HDR) without receiving authorization by the RSC for approximately 2 years.

REPORT DETAILS

I. NRC On-Site Inspection

a. Inspection Scope

A routine, unannounced inspection was conducted at MedStar Georgetown Medical Center, Inc. (MGMC) on March 5 and 6, 2012. Additional information, contained in correspondence dated March 7 and 27, 2012, was also reviewed as part of this inspection. The inspection was performed in accordance with NRC Inspection Procedures 87134 and 87122. The following focus areas were reviewed: (i) security and control of licensed material; (ii) shielding of licensed material; (iii) comprehensive safety measures; (iv) radiation dosimetry program; (v) radiation instrumentation and surveys; (vi) radiation safety training and practices; (vii) management oversight; and (viii) licensee review of licensed activities performed by contracted personnel.

The inspectors assessed MGMC's performance associated with the use of licensed materials within their nuclear medicine, radiation medicine, and research departments. The inspection also included a review of MGMC's management of the radiation safety program, including oversight of activities by the Radiation Safety Office, the Radiation Safety Committee (RSC), and senior management.

The inspectors conducted interviews with MGMC's personnel, observed day-to-day operations, tested the operation of the licensee's equipment, toured MGMC's facilities, and reviewed documents and procedures.

b. Observations and Findings

License No. 08-30577-01 authorizes clinical activities in nuclear medicine and radiation medicine as well as limited human-use medical research and clinical trials. The licensee possesses a self-shielded irradiator for the irradiation of blood and blood products that is scheduled to be replaced in April 2012. Licensed activities are performed across their two locations at 3750 and 3800 Reservoir Road, N.W. in Washington, DC.

The inspectors toured the licensee's facilities and interviewed the staff present. The inspectors observed, reviewed and discussed a range of activities, including: material control and security; posting/labeling; shielding; personnel dosimetry use; survey meter use and calibration; package receipt/return procedures and surveys; radioactive waste handling and disposal; training; and program audits and reviews. Each member of the staff appeared knowledgeable in radiation safety. The inspectors performed independent and confirmatory radiation measurements which indicated radiation levels within regulatory limits that were consistent with licensee survey records and postings. The inspectors reviewed a sampling of records including: dose calibrator quality control tests, area surveys, wipe tests, sealed source leak tests and inventories, waste disposal, personnel dosimetry, radiation safety program manual procedures, radiation safety program audits, and radiation safety committee meeting minutes. All were found to be acceptable.

(i) Management Oversight of the Program

The inspectors reviewed MGMC's oversight of the radiation safety program. The Radiation Safety Officer (RSO) and assistant RSO (ARSO) duties include: performing audits, waste pickup and packaging, and radioactive material inventory. The program is overseen by the RSC. The RSO reports to the Assistant Vice President for Operations and Administrative Planning. The RSC has representation from all areas utilizing licensed materials. The licensee was issued a renewed license on January 9, 2012, and has changed their RSO since the last inspection. Plans are being made by the licensee to fill a health physics technician position. There are two Nuclear Medicine authorized users (AUs), nine Radiation Medicine AUs, and four authorized medical physicists (AMPs). One AU and two AMPs have been approved by the RSC since the last inspection. The RSC meets quarterly to review all aspects of the radiation safety program, including new uses and users. Based on a review of the RSC meeting minutes and discussion with the RSO, the inspectors concluded that the RSC was actively involved in the radioactive material program.

A review of the new user permits indicated that the two AMPs approved by the RSC did not have the appropriate supporting documentation of training and experience. The inspector determined that the licensee did not understand the requirements for training for an AMP related to obtaining a written preceptor attestation. For the first medical physicist, an American Board of Radiology (ABR) certificate was provided as documentation of training and experience; however, the licensee failed to obtain a preceptor attestation statement and the RSC approved the physicist for HDR use on February 8, 2012. The second medical physicist, approved for HDR use on April 8, 2011, was ABR certified; however, the board certificate was not recognized by the NRC because it did not have the words "AMP Eligible" appearing above the ABR seal and a preceptor attestation was not obtained as well. During the inspection, the licensee confirmed that both physicists only used licensed material for which they had appropriate training. The inspectors noted that the licensee obtained the required preceptor forms and revised their permits to more accurately reflect each user's training.

A review of the RSC meeting minutes identified that the second medical physicist above had been acting as an AMP between July 1, 2009, and April 8, 2011, without receiving authorization by the RSC. This was identified by the newly appointed RSO who then provided the medical physicist's ABR certificate to the RSC for review and approval. In addition, the RSO reviewed the RSC permit approvals for the entire roster of AMPs and authorized users (AUs) and confirmed that the required documentation of training and experience was on file.

(ii) Research Department

The licensee is authorized for research in humans, as well as research and development as defined in 10 CFR 30.4, including animal studies; instrument calibration; student instruction; and in-vitro studies. However, all research activities, except for limited clinical trials, are performed under the Georgetown University license.

(iii) Nuclear Medicine (NM)

The NM department houses five imaging cameras, one PET/CT camera, one hot lab, and one treadmill. The department is staffed by four nuclear medicine technologists (NMTs), three PET technicians (one of whom rotates between NM and PET), and two AUs. There have been no new AUs approved in this department since the last inspection. Approximately 20 to 30 diagnostic studies are performed daily, primarily using technetium-99m. In addition, one to two iodine-131 (I-131) treatments for thyroid carcinoma and hyperthyroidisim are performed per month and on occasion strontium-89 therapy is performed (one in 2011). The majority of I-131 therapy procedures are performed on an outpatient basis, with a few in-patient cases. The inspectors confirmed that no patients were released to locations other than private residences and the licensee is aware of NRC's guidance on release of patients. The inspectors confirmed that the licensee performed the required patient-specific release calculations to ensure that patients were releasable in accordance with 10 CFR 35.75 and provided patients with instructions prior to release. Written directives, patient release criteria, and patient release instructions were reviewed and found to be acceptable.

(iv) Radiation Medicine

Radiation Medicine is staffed by nine AUs and four AMPs. One AU and two AMPs have been approved since the last inspection. All radioactive materials are received and processed in NM, delivered to Radiation Medicine as needed, and returned to NM for disposal. Less than five prostate cases are performed per year with palladium-103 seeds. Cesium-137 temporary implants are occasionally performed for gynecologic cancers. Treatment with yttrium-90 SIR-Spheres has increased with nine procedures performed in 2011 and eight procedures performed thus far in 2012. The licensee also possesses a strontium-90 eye applicator that is currently in storage and was last used in November 2010. The licensee's HDR program is fairly active and is used for mammosite, prostate, and gynecological treatments. The licensee treats on average two HDR patients per month. The inspectors observed the daily spot-check and discussed full calibrations, treatment planning and treatment procedures with the AMP. The inspectors verified that written directives were completed in accordance with 10 CFR 35.40(b)(5) and safety procedures/ precautions were in accordance with 10 CFR 35.610 and 35.615. The inspectors reviewed written directives, patient release instructions, and surveys, and found them to be acceptable.

During the observation of daily spot check procedures for the HDR unit, the inspectors noted that the audio communication system between the control booth and the HDR treatment room was not functional. The licensee indicated that they had noted this issue during their morning QA and that the communication system was under repair. On March 7, 2012, the licensee submitted a completed work-order report from their clinical engineering department that the 2-way communication system had been repaired.

During a review of the licensee's incident report files, the inspectors noted an incident involving failure to control and secure a radioactive material package containing 4.006 curies of iridium-192 (Ir-192). On Tuesday, December 13, 2011, a service engineer from Varian Medical Systems, Inc. (Varian) arrived at MGMC to perform a scheduled exchange of the Ir-192 HDR source. Typically, the MGMC Radiation Safety staff would be informed of any scheduled source exchange and would arrange for the disposal of the old source following completion of the exchange. Radiation Safety would not supervise the source exchange procedure and would not be specifically informed when the activity was complete. Rather, MGMC relied on the Varian service engineer to lock the old source and the HDR unit in HDR storage cabinet following the exchange.

On this occasion, the service engineer notified the two available MGMC AMPs (AMP1 and AMP2) that he was going to perform the source exchange, and was informed by them that they would calibrate the unit following completion of the exchange. Between 10:00 am and 1:00 pm, the service engineer installed the new source in the HDR unit, and placed the old source in a shielded container, which the service engineer left, along with the HDR unit, in the unlocked HDR procedure room upon completing his work. It is not clear why the service engineer failed to place the container, containing the old source, in the storage cabinet. Subsequently, AMP1 and AMP2 entered the room, calibrated the HDR unit, and secured the unit in the storage cabinet. AMP1 and AMP2 apparently did not identify that the old source was not secured, and, therefore, did not place it in the cabinet. At some point, another AMP (AMP3) also entered the room to conduct unrelated activities. AMP3 also did not notice that the source container was unsecured in the room.

At approximately 2:30 pm on Wednesday, December 14, 2011, MGMC's ARSO discovered the container with the iridium-192 source unsecured in the HDR procedure room. AMP2 and MGMC's chief dosimetrist were immediately contacted, and the container was locked in the HDR storage cabinet. MGMC's RSO was notified and an investigation was launched.

The licensee's investigation determined that AMP3 was the only individual who entered the HDR Procedure Room during the time the shielded container with the Ir-192 source was unsecured. AMP3, it was determined, was in the room for approximately 10 minutes at a distance of 2 meters from the source. The surface reading of the shielded container was 1.85 R/hr, and the licensee estimated that AMP3 received a maximum unplanned exposure of 0.0083 millirem. The dosimetry report for the AMP3 from October 1, 2011, through December 31, 2011, indicated that less than 1 millirem exposure for photons was received for the deep dose equivalent.

(v) Blood Bank

The licensee's Gammacell 1000 self-shielded irradiator was not in use and was scheduled for replacement. The licensee confirmed on April 1, 2012, that the new Gammacell 1000 irradiator was installed and the old irradiator returned to the manufacturer.

c. Conclusions

The inspectors identified three apparent violations of NRC requirements. Specifically:

1. 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, between December 13 and 14, 2011, MedStar Georgetown Medical Center, Inc. did not control and maintain constant surveillance of licensed material that was in a controlled or unrestricted 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 HDR Procedure Room for approximately 24 to 30 hours. The HDR Procedure Room is within the Radiation Oncology suite, a controlled area.

2. 10 CFR 35.51(a) requires, in part, that a licensee shall require the authorized medical physicist to be an individual who is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State, has training for the types of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system, and has obtained written attestation signed by a preceptor AMP that the individual has satisfactorily completed the required training and has achieved a level of competency sufficient to function independently as an AMP.

   Contrary to the above, between April 8, 2011 and March 6, 2012, and again between February 2012 and March 6, 2012, two individuals were designated in writing by the licensee's RSC to work as authorized AMPs yet they had not obtained written attestation signed by a preceptor AMP that the individuals had satisfactorily completed the required training and had achieved a level of competency sufficient to function independently as an AMP. Specifically, documentation collected by the RSO and used to approve both individuals was incomplete in that neither individual had a preceptor attestation and one of the individuals was not certified through a process recognized by the Commission because the board certificate did not have the words "AMP Eligible" appearing above the American Board of Radiology (ABR) seal.

3. Condition 26 of License No. 08-30577-01, Amendment 14, states that the Radiation Safety Committee will approve users for the device who are physicists, in accordance with 10 CFR 35.2, and who meet the requirements specified in 10 CFR 35.961.

   10 CFR 33.13(c)(3)(iii) requires, in part, that an applicant for a Type A specific license of broad scope will be approved if the applicant has established administrative controls and provisions relating to organization and management procedures, record keeping, material control, and accounting and management review that are necessary to assure safe operations, including: the establishment of appropriate administrative procedures to assure review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with 10 CFR 33.13(c)(3)(ii) prior to use of the byproduct material.

Contrary to the above, between July 1, 2009 and April 8, 2011, a medical physicist had been acting as an AMP for HDR use without receiving authorization by the RSC. This apparent violation was identified by the licensee's new RSO and immediately corrected by the RSC with the approval of the physicist. The licensee updated the AMP roster and a discussion was noted in the RSC meeting minutes.

Licensee Corrective and Preventive Actions

The inspectors reviewed the corrective actions provided by MGMC during the inspection on March 5 and 6, 2012, and in documentation provided on March 27, 2012, and found their actions to be prompt and comprehensive. MGMC took the following corrective actions:

Violation 1: MGMC (1) promptly secured the licensed material in the storage cabinet; (2) thoroughly investigated the circumstances that lead to the unsecured radioactive material; (3) developed a policy for the conduct of HDR source exchanges, to include the service engineer notifying the RSO when the source exchange is complete; (4) discussed the issue in their radiation medicine training session on February 21, 2012; and (5) reminded the Radiation Medicine personnel and the Varian service engineer that the source must be attended or secured at all times, including during source exchanges.

Violation 2 and 3: During the inspection, the licensee confirmed that both physicists used only licensed material for which they had the appropriate training and experience. In addition, MGMC obtained the required preceptor forms and revised the AMPs permits.

II. Exit Meeting

At the conclusion of the on-site inspection on March 6, 2012, the preliminary inspection findings were discussed with MGMC's Radiation Safety Staff. MGMC acknowledged the inspectors' findings and immediately initiated corrected actions. A telephonic exit meeting was held on May 15, 2012, to discuss the results of the inspection with MGMC's senior management.

PARTIAL LIST OF PERSONS CONTACTED

Licensee

#*+Dr. Maxwell Amurao, RSO
#*Candi McDowell, Assistant RSO
+Michael Sachtleben, Chief Operating Officer
#Donald Hixson, Operations Director – Radiation
#*+Angela Jones, Assistant Vice President of Environmental and Clinical Health and Safety
Various researchers, radiation safety and nuclear medicine staff

#present at entrance meeting conducted on March 5, 2012
*present at preliminary exit meeting conducted on March 6, 2012
+present at final exit meeting conducted on May 15, 2012