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July 16, 2012

Raymond K. Lorson, Director
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region 1
2100 Renaissance Boulevard
King of Prussia, PA 19406

Reference: Response to NRC Inspection Report No. 03035409/2012001

Dear Mr. Lorson,

This correspondence is written to correct an error in the response letter dated 10-July-2012 from MedStar Georgetown Medical Center, Inc. (MGMC) to your office in relation to USNRC inspection report no. 03035409/2012001. The letter is attached for your reference.

On page 3 of the response letter, under the section "Apparent Violation 3, Reason for Apparent Violation", the fourth sentence indicates that Maxwell Amurao, PhD was named as Radiation Safety Officer for MGMC in November 2011. This is erroneous, as Dr. Amurao was in fact approved as RSO for MGMC in November 2010.

Please accept this amendment to reflect the corrected date (November 2010) wherein Dr. Amurao was named as RSO for MGMC in the response letter dated 10-July-2012.

Thank you for your continued guidance and oversight of our programs and initiatives promoting the safe use of radiation at MedStar Georgetown Medical Center, Inc. Please feel free to contact me for additional information regarding this matter.

Sincerely,

A handwritten signature in cursive script that reads "mla".

Maxwell Amurao, PhD
Radiation Safety Officer
MedStar Georgetown Medical Center, Inc.



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July 10, 2012

Raymond K. Lorson, Director
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region 1
2100 Renaissance Boulevard
King of Prussia, PA 19406

Reference: Response to NRC Inspection Report No. 03035409/2012001

Dear Mr. Lorson,

This correspondence is written in response to NRC inspection report no. 03035409/2012001 for MedStar Georgetown Medical Center, Inc. (MGMC), radioactive material license #08-30577-01. Three apparent violations were identified during the inspection conducted on March 5 and 6, 2012. The reasons, corrective actions, results, and dates of full compliance in relation to each of the apparent violations are included in the succeeding (3) pages attached.

Thank you for your continued guidance and oversight of our programs and initiatives promoting the safe use of radiation at MedStar Georgetown Medical Center, Inc. Please feel free to contact me or the MGMC Radiation Safety Officer – Maxwell Amurao, PhD – for additional information regarding this matter.

Sincerely,

A handwritten signature in black ink, appearing to read "M. Sachtleben".

Michael Sachtleben
Chief Operating Officer
MedStar Georgetown Medical Center, Inc.

Apparent Violation 1. 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.

- **Reason for apparent violation:** The root-cause of this apparent violation is the absence of a direct hand-off of the high-activity Ir-192 source between the vendor service engineer (VSE) and a member of the MGMC Radiation Safety department. In page 4 of the report details, it was described that:

“ 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. ”

Investigation by the RSO after discovery of this lapse resulted in an email from the VSE describing that a verbal transfer of possession of the container containing the old source took place between him and two Authorized Medical Physicists present in the HDR procedure room. Neither of the two AMP's placed the container in secure storage, nor did they communicate the transfer of possession with the RSO.

- **Corrective steps that have been taken and the results achieved:** Upon discovery of the unsecured source by a member of the Radiation Safety department, the said source was immediately placed in the secure cabinet assigned for HDR storage. An investigation was immediately launched and documented by the Radiation Safety Officer. An estimate of the radiation dose to potentially exposed individuals was obtained, and exposures were found to be below regulatory limits. An updated policy and procedure for HDR source exchanges was developed and was disseminated during the annual radiation safety in-service with the Radiation Medicine department personnel who use the HDR system. In the in-service, the critical importance of securing licensed material was re-emphasized.
- **Corrective steps that will be taken to avoid further violations:** In response to the root-cause analysis findings, a member of the Radiation Safety department will be involved in the direct hand-over of sources to/from the VSE. On the day of a source exchange, the VSE will page the RSO and a member of the Radiation Safety department will take the new Ir-192 source from secure storage and directly transfer the new source to the VSE. Upon completion of the source exchange, the VSE will page the RSO, then a member of the Radiation Safety department will collect the replaced Ir-192 HDR source from the VSE, and will place the source in secure storage.
- **Date when full compliance will be achieved:** Full compliance was achieved immediately upon completion of the RSO investigation. Two source exchanges have taken place since this event (7-March-2012 and 6-June-2012), and direct transfer of HDR sources between the VSE and the Radiation Safety department did occur as described in the new policy and procedure above.

Apparent Violation 2. 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).

- **Reason for apparent violation:** This apparent violation resulted from a misinterpretation of 10 CFR 35.51 (Training for an Authorized Medical Physicist), wherein a recognized specialty board certification was thought to be a sufficient condition for approval as an AMP. As was clarified by the inspection team during the site visit, a written attestation following the standard format provided in NRC Form 313A is also a requirement prior to approval as an AMP by the RSC.
- **Corrective steps that have been taken and the results achieved:** For one of the AMP's – Guowei Zhang, PhD – the required preceptor forms were generated and presented to the inspection team during the site visit. The other AMP – Yu Xia, PhD – was not able to produce a preceptor form, and his AMP status was immediately suspended pending completion of all required documentation. However, Dr. Xia resigned from MGMC before the incomplete documents were fulfilled as required. As such, Dr. Xia was removed as an AMP in the roster updated on 11-June-2012. The final results were that Dr. Zhang has completed an NRC Form 313A on record, and that Dr. Xia was removed as an AMP on the MGMC roster.
- **Corrective steps that will be taken to avoid further violations:** For approval of new AMP's in the future, a written attestation following NRC Form 313A will be completed in addition to the other requirements as described in 10 CFR 35.31.
- **Date when full compliance will be achieved:** Full compliance was achieved immediately upon completion of the NRC inspection on 6-March-2012. Since the addition of a new AMP occurs infrequently, verification of full compliance will be undertaken when a new AMP joins MGMC.

Apparent Violation 3. The MGMC Radiation Safety Committee (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.

- **Reason for apparent violation:** This violation involved Guowei Zhang, PhD, a therapeutic medical physicist, who was hired in June 2009 when Ms. Auroba Al-Samaraee was the MGMC interim RSO. Mr. Dennis Clum then joined MGMC as the RSO in October 2009 replacing Ms. Al-Samaraee. Unfortunately, Dr. Zhang was never approved by the RSC as an AMP, and this situation was never rectified during Ms. Al-Samaraee's nor Mr. Clum's tenure. In November 2011, Maxwell Amurao, PhD was named as RSO for MGMC. As soon as the violation in question was identified, Dr. Amurao promptly convened the RSC to review Dr. Zhang's qualifications whose approval as an AMP was obtained. The document

reflecting Dr. Zhang's approval as an AMP was signed by the MGMC Chief Operating Officer in April 2011.

- **Corrective steps that have been taken and the results achieved:** As soon as the violation was identified, Dr. Amurao convened the RSC seeking approval of Dr. Zhang as an AMP, and was ultimately carried by a majority vote.
- **Corrective steps that will be taken to avoid further violations:** The Medical Director as well as the Chief Physicist in the Radiation Medicine department were both counseled by Dr. Amurao that the qualifications of any medical physicist in MGMC must be evaluated and approved by the RSC prior to them acting as an AMP. In the future, the Radiation Safety Officer will conduct a review of the roster for both authorized physician users and authorized medical physicists in the Radiation Medicine department during each quarterly audit.
- **Date when full compliance will be achieved:** Full compliance was achieved in April 2011, when the roster of approved Authorized Medical Physicists and Authorized Users in the Radiation Medicine department was approved by the MGMC Chief Operating Officer.