Shashadhar M. Mohapatra, PhD,
DABR, DABSNM
Director, RSO

Washington
Hospital Center

MedStar Health

Radiation Safety

REPLY TO A NOTICE OF VIOLATION

Via Facsimile and First Class Mail

April 19, 2006

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555

SUBJECT: Reply to Notice of Violation Described in EA 05-212, Inspections 03001325/2005001 and 03035985/2005001, Washington Hospital Center, License Nos. 08-03604-03, 08-03604-05

The purpose of this letter is to provide Washington Hospital Center's ("WHC") Reply to the Notice of Violation Described in Enforcement Action No. 05-212, dated March 22, 2006.

On March 21-23, 2005, the NRC Division of Nuclear Materials Safety conducted a safety inspection at WHC of activities authorized by the above listed-licenses. The NRC discussed the results of the investigation with WHC on March 23, 2005. WHC provided additional information to the NRC in several subsequent correspondences dated March 31, June 20, August 4, September 23, 2005, and January 3, 2006. The NRC discussed additional inspection results with WHC on September 8, 2005 and March 3, 2006.

The resulting Inspection Report, dated March 21, 2006, identified three apparent violations of the requirements of 10 C.F.R. Part 35. On March 22, 2006, the NRC provided WHC with a notice of violation ("NOV") describing the three violations identified during the March 21-23, 2005 inspection. Each of the violations has been assessed with a Level IV significance according to the NRC's Enforcement Policy.[1] The NOV requires WHC to submit a written "Reply to a Notice of Violation" for the three violations. The NOV requested that the reply include (1) the reason for each violation; (2) the corrective steps that have been taken and the results achieved;

[1] General Statement of Policy and Procedure for NRC Enforcement Actions, *available at* (last visited Mar. 21, 2006) (Enforcement Policy).

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100 Irving Street, NW, Room 5106, Washington, DC 20010-2975
phone: 202 877 2906 • *fax:* 202 877 2902 • *e mail:* shashadhar.m.mohapatra@medstar.net

(3) the corrective steps that will be taken to avoid further violations; and (4) the date when full compliance will be achieved. The following sections provide the requested information.

WHC acknowledges that the three identified Level IV violations of 10 C.F.R. Part 35 occurred. However, WHC believes that the violations were of very low significance, meet the criteria for a non-cited violation ("NCV") and should be disposed of as such. Thus, WHC requests that the Notice of Violation be rescinded. Section IV of this letter provides a discussion of the NRC Enforcement Policy in this regard.

I. IMPROPERLY AUTHORIZED GAMMA KNIFE PROCEDURE BY A MEDICAL PHYSICIST

A. The reason for the apparent violation

WHC possesses a broad scope NRC license that authorizes WHC to perform numerous medical procedures involving byproduct materials. The WHC Radiation Safety Committee ("RSC") and Radiation Safety Officer ("RSO") oversee the broad scope license. Under the broad scope license, WHC has the authority to permit an individual to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license without amending its broad scope license.[2]

WHC also possesses a limited scope license for its authorization to perform procedures using a "Gamma Knife," or gamma stereotactic radiosurgery. The same RSC and RSO also oversee the limited Gamma Knife license.

In September 2003, WHC sought to have an individual (the "Medical Physicist") approved as an authorized medical physicist on the Gamma Knife. The Medical Physicist had exceeded the training and experience requirements for Gamma Knife operation. His educational background included a master's degree in Physics from Peking University in China and a Ph.D. in Mechanical Engineering from Worcester Polytechnic Institute in Massachusetts. Prior to joining WHC in June 2003, he had three years of medical physics work experience at the Longwood Radiation Oncology Center at the Harvard Medical School. In addition, he had previous work experience as a service engineer. Further, he had completed in depth manufacturer's training on the Gamma Knife at a class offered by the University of Pittsburgh, "Principles and Practice of Gamma Knife Radiosurgery," from September 8-12, 2003.

Following his completion of the Gamma Knife manufacturer's training, the WHC RSC considered the Medical Physicist for authorization to use the Gamma Knife under the supervision of Chief Medical Physicist. The WHC RSC provided that authorization on September 25, 2003. Subsequently, the WHC RSO communicated with a Senior NRC Health Physicist regarding the Medical Physicist's Gamma Knife authorization.[3]

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[2] 10 C.F.R. § 35.13(b)(4)(ii).

[3] See E-mail from James Dwyer, Senior Health Physicist, NRC, to Shashadhar Mohapatra, RSO, WHC (Nov. 12, 2003, 01:43 PM EST) (attached to this letter at Attachment 1).

The RSO explained to the NRC Health Physicist his belief that the RSC and RSO should have the authority to permit the Medical Physicist to use the Gamma Knife pursuant to the WHC broad scope license. Thus, an amendment of the Gamma Knife license was not required. As the attached e-mail from the NRC Health Physicist indicates, the Senior NRC Health Physicist agreed that a license amendment was not required as long as the Medical Physicist was board certified pursuant to 10 C.F.R. § 35.961(a) or (b).[4]

Recognizing that the Medical Physicist was not board certified, the WHC RSO continued his discussions with the Senior NRC Health Physicist concerning whether a license amendment was required if the Medical Physicist met the education, training, and work experience requirements of 10 C.F.R. § 35.961(c). To the best of the RSO's recollection, the NRC Health Physicist had agreed that no Gamma Knife license amendment was necessary if the Medical Physicist met the requirements of 10 C.F.R. § 35.961(c).[5] Thus, the RSC and RSO did not seek to amend the Gamma Knife license to add the Medical Physicist as an authorized user because he met the requirements of 10 C.F.R. § 35.961(c).

During the March 21-23, 2005 NRC inspection, the NRC inspectors concluded that the authority vested in the RSC and RSO by the WHC broad scope license did not include the authority to permit qualified individuals to use Gamma Knife because the Gamma Knife was covered by a separate limited scope license. Thus, according to the NRC inspectors, the WHC did not have the authority, pursuant to 10 C.F.R. § 35.13(b)(4)(ii), to permit an individual to use the Gamma Knife without amending the limited scope Gamma Knife license.

B. The corrective steps that have been taken and the results achieved

The NRC inspectors' findings were addressed at the next RSC meeting, held on March 25, 2005. The RSC unanimously agreed to address the inspectors' conclusion by filing an application to amend the limited scope Gamma Knife license to permit the Medical Physicist to use the Gamma Knife. WHC submitted the license amendment on March 31, 2005, and the NRC approved the license amendment on May 13, 2005.

C. The corrective steps that will be taken to avoid further violations

No further corrective steps are planned. WHC assures the NRC that future limited scope Gamma Knife license authorizations will be made according to the 10 C.F.R. § 35.13(b) requirement to obtain a license amendment or added to the existing broadscope license during the renewal process.

D. The date when full compliance will be achieved

WHC is presently in full compliance with its License Conditions and NRC Regulations.

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[4] Id.

[5] The RSO does not possess any documents, such as the previously discussed e-mail, supra note 4, that reflect these continued discussions with the Senior NRC Health Physicist.

II. INSUFFICIENT DOCUMENTATION FOR AUTHORIZED MEDICAL PHYSICIST

A. The reason for the apparent violation

Although WHC acknowledges that a violation of NRC's documentation requirements for approving an authorized medical physicist occurred, as an initial matter, the NOV and underlying Inspection Report incorrectly describe the basis for which that authorization was sought. The NOV states that, contrary to NRC regulations, "in June 2003, an individual was designated to work as an authorized medical physicist for the high dose-rate remote afterloader...."[6] The inspection report provides "[i]n June 2003, the licensee's RSC had authorized a new AMP to perform high dose-rate remote afterloader activities and in September 2003 the licensee's RSC had authorized the same AMP to perform GSR activities."[7] These descriptions are incorrect. WHC did not seek authorization for the Medical Physicist to perform high dose-rate afterloader activities in June of 2003, nor has WHC sought such authorization since then. Thus, the NOV and Inspection Report incorrectly describe the circumstances surrounding this violation.

In September 2003, WHC's RSC authorized the Medical Physicist to use the Gamma Knife. The authorization decision was based on the Medical Physicist's training and experience. To become an authorized medical physicist, an individual must have sufficient training and experience, including (1) a master's or doctor's degree in physics, biophysics, radiological physics, medical physics, or health physics; (2) one year of full time training in therapeutic radiological physics; and (3) training that includes hands-on use of the device for which authorization is sought, whether by completing a training program provided by the device vendor or under the supervision of an authorized user of the device.[8]

Here, the Medical Physicist exceeded the 10 C.F.R. Part 35 criteria for training, experience, and recentness of training, which must be met before an individual can be authorized as a Medical Physicist. Prior to joining WHC in June 2003, the Medical Physicist underwent both a rigorous interview process by the Oncology Department and a stringent background check conducted by the Human Resources Department. WHC selected the Medical Physicist from among 20 candidates for this position. His resume stood out from among the rest of the candidates. He has a master's degree in Physics from Peking University in China and a Ph.D. in Mechanical Engineering from Worcester Polytechnic Institute in Massachusetts. He had three years of medical physics work experience at the Longwood Radiation Oncology Center at the Harvard Medical School, and he had previous work experience as a service engineer. Further, he had completed in depth training on the Gamma Knife at a class offered by the University of Pittsburgh, "Principles and Practice of Gamma Knife Radiosurgery," from September 8-12, 2003. With such a background, WHC knew the Medical Physicist would be an asset to WHC's Gamma Knife program.

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[6] NOV at 1.

[7] Inspection Report at 2.

[8] 10 C.F.R. § 35.51(b)-(c).

There is no question that the Medical Physicist fully met the training, experience, and recentness of training criteria in Part 35. However, WHC failed to maintain sufficient documentation used to approve the Medical Physicist in his personnel file. Specifically, WHC did not collect and maintain NRC Form 313A, the "Training and Experience and Preceptor Statement" in the Medical Physicist's personnel file. This document provides the certification statement that the authorized medical physicist candidate has completed the one year of training and one year of work experience required to become an authorized medical physicist. The RSO intended to obtain the documentation and recalls speaking with the Chief Medical Physicist and the Medical Physicist about the need for the certificate on more than one occasion. However, the RSO inadvertently overlooked the need to follow up on obtaining the documentation.

B. The corrective steps that have been taken and the results achieved

The RSO has obtained all of the required documentation and it is maintained in the Medical Physicist's personnel file.

C. The corrective steps that will be taken to avoid further violations

No further corrective steps are planned. WHC assures the NRC that the necessary documentation used to approve an individual to a Medical Physicist or other position will be properly collected and maintained in the appropriate files prior to authorization.

D. The date when full compliance will be achieved

WHC is presently in full compliance with its License Conditions and NRC Regulations.

III. INSUFFICIENT TIMER LINEARITY CALIBRATION

A. The reason for the apparent violation

NRC regulations require, in part, that the Gamma Knife be fully calibrated over the range of use, including the timer accuracy and linearity.[9] The Chief Medical Physicist, an authorized medical physicist on the Gamma Knife, had been testing for timer linearity up to 4 minutes. In most procedures, treatment with the Gamma Knife consisted of multiple shots, and the treatment time for a single shot was typically two minutes or less. On a rare occasion when a particular procedure was performed (Trigeminal nerve treatment), the treatment time extended up to 20 minutes in a single shot only (because of the physical decay of the radioactive sources, that treatment time extended up to 40 minutes). The NRC inspectors pointed out to the Chief Medical Physicist that she was not testing the Gamma Knife's linearity for 40 minutes. Such testing was necessary to test the timer linearity for those rare treatments where a shot would last 40 minutes.

No adverse consequences resulted from the Chief Medical Physicist's failure to properly calibrate the timer linearity.

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[9] 10 C.F.R. §35.635(b)(4)

B. The corrective steps that have been taken and the results achieved

The Chief Medical Physicist immediately revised her protocol to extend the timer linearity check for Gamma Knife procedures up to the maximum treatment time. She has been continuing this linearity test for up to the maximum treatment time (currently 40 minutes) since the March 2005 inspection. All linearity tests since the March 2005 inspection have passed the tests up to the maximum treatment time.

C. The corrective steps that will be taken to avoid further violations

1. Training

WHC's annual training program reinforces the licensing and regulatory requirements to which WHC must adhere and which will assist in preventing future calibration violations. The Radiation Safety Department will continue to provide annual training to Medical Physicists and all relevant Nuclear Medicine Department personnel to emphasize the importance of complying with WHC's policies and NRC's regulations, particularly 10 C.F.R. Part 35, Subpart H, which provides regulations for, *inter alia*, gamma stereotactic radiosurgery units (*e.g.*, the Gamma Knife).

The WHC training program for relevant Nuclear Medicine Department personnel covers the following areas:

- NRC and DC Regulatory Affairs Regulations
- WHC's NRC License Requirements
- 10 C.F.R. Part 19
- 10 C.F.R. Part 20
- 10 C.F.R. Part 30
- 10 C.F.R. Part 35
- Dose Limits and Exposure History
- Survey and Monitoring Requirements
- Storage and Control of Licensed Material
- Precaution Procedures
- Worker Expectations including Deliberate Misconduct
- Notifications and Reports
- QMP
- Medical Events and Reporting of such events

D. The date when full compliance will be achieved

WHC is presently in full compliance with its License Conditions and NRC Regulations.

IV. THE THREE LEVEL IV VIOLATIONS SHOULD BE DISPOSED OF AS NON-CITED VIOLATIONS

WHC believes that the three Level IV apparent violations discussed above should be disposed of as NCVs because they were of very low safety significance and do not meet the criteria for being disposed of with an NOV. The Enforcement Policy provides that a Level IV violation will be considered for an NOV disposition if: (1) the licensee failed to identify the violation; (2) the licensee did not correct or commit to correct the violation; (3) the violation is repetitive as a result of inadequate corrective action; or (4) the violation was willful.[10] WHC does not believe that the above discussed violations meet these NOV criteria and, consequently, requests that the NOV be rescinded.

A. Improperly authorized Gamma Knife Procedure by a Medical Physicist

The Level IV violation for the procedure performed by the Medical Physicist without first amending the limited scope Gamma Knife license should be disposed of as an NCV because it does not meet the criteria for an NOV. First, WHC appropriately believed it had NRC concurrence to authorize the Medical Physicist to use the Gamma Knife pursuant to WHC's broad scope license as a result of the communications the RSO had with the NRC Senior Health Physicist. Thus, WHC could not have identified the improper Medical Physicist authorization to use the Gamma Knife. Second, WHC corrected the violation by immediately filing and subsequently obtaining a license amendment to add the Medical Physicist as an authorized user under the limited Gamma Knife license based on the recommendation of the NRC inspectors. Third, the violation was not repetitive as a result of inadequate corrective action because obtaining the license amendment fully addressed the violation, and no subsequent violations have occurred. Fourth, the violation was not willful because WHC believed it (1) was in compliance with NRC's regulations; and (2) had NRC approval to authorize the Medical Physicist as a Gamma Knife user.

B. Improper Documentation for Authorized Medical Physicist

The failure to maintain the proper documentation used to support the authorization of an individual to become a Medical Physicist was of such low safety significance that the NRC should exercise its discretion and dispose of this violation as an NCV, even though it meets one of the criteria for being disposed of with as an NOV. The Enforcement Policy specifically contemplates the exercise of such discretion.[11]

First, WHC did not identify the improper documentation violation. Nevertheless, the failure to have obtained the necessary documentation at the time the authorization occurred in no way undermined the authorization of this individual to become an authorized medical physicist. Citing WHC for what is, in essence, an administrative oversight would not serve the purpose of the requirement to maintain proper authorization documentation for medical physicists, which is to ensure that an authorization decision is based on sound training and experience credentials. In

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[10] Enforcement Policy at 18-19.

[11] Enforcement Policy at 30-39.

the instant case, the RSC's and RSO's decision to authorize this particular individual to become a Medical Physicist was based on his superior experience at Harvard Medical School's Radiation Oncology department, his background as an engineer, and the results of the background check conducted by the WHC Human Resources department. Indeed, at the time in question, the individual exceeded the NRC's training and experience requirements.

Second, WHC has corrected the violation by obtaining all of the necessary documentation. Third, this violation has not been repeated as a result of lacking or insufficient corrective action. Fourth, the violation was not willful. Indeed, the RSO intended to obtain the necessary documentation and spoke to the Chief Medical Physicist and the Medical Physicist on more than one occasion in this regard, but inadvertently overlooked the need to follow up on obtaining the documentation.

C. Insufficient Timer Linearity Calibration

The failure to properly calibrate the Gamma Knife timer linearity was of such low safety significance that the NRC should exercise its discretion and dispose of this violation as an NCV, even though it meets one of the criteria for being disposed of as an NOV. The Enforcement Policy specifically contemplates the exercise of such discretion.[12]

First, WHC did not identify the violation. However, the Chief Medical Physicist regularly calibrated the timer linearity for the Gamma Knife up to 4 minutes. In most procedures, the treatment shot took two minutes. It was only the rare occasion that timer linearity longer than 4 minutes would be required. In addition, no adverse consequences resulted from the failure to properly calibrate the timer linearity.

Second, upon notification of the violation, the Chief Medical Physicist immediately corrected her protocol to extend the timer linearity check for the Gamma Knife up to the maximum treatment time. Third, the Chief Medical Physicist has followed the revised protocol ever since March 2005, and the violation has not been repeated as a result of lacking or insufficient corrective action. All linearity tests up to the maximum treatment time have passed the tests since March 2005 and never failed. Linearity tests usually fail at the lower end. Fourth, the violation was not willful, but rather was an inadvertent oversight for the rare occasion that a Gamma Knife procedure exceeded 4 minutes.

V. CONCLUSION

WHC acknowledges that the three identified Level IV violations of 10 C.F.R. Part 35 occurred. WHC promptly undertook corrective actions in response to each incident, and the incidents have not been repeated. WHC believes that the Level IV violations were of very low significance and meet the criteria for an NCV and should be disposed of as such. Thus, WHC requests that the NRC rescind the NOV.

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[12] Id.

Sincerely,

Shashadhar Mohapata

Shashadhar M. Mohapatra, Ph.D.
Radiation Safety Officer
Washington Hospital Center

cc: Samuel J. Collins, Regional Administrator, Region I
Attachment

"James Dwyer"
<JPD1@nrc.gov>
11/12/03 01:43 PM

To: <Shashadhar.M.Mohapatra@Medstar.net>
cc:
Subject: Re: Shashi

Shashi:

(1). I now have your request for license amendment to add the new HDR source. I will issue the amendment later today and fax a copy to your office.

(2). With regards to the new gammaknife medical physicist. If the individual meets the specific certification requirements listed in:

10 CFR 35.961(a) - ABR in Therapeutic radiological physics, Roentgen ray and gamma ray physics, x-ray and radium physics or Radiological Physics; or

10 CFR 35.961(b) - ABMP in radiation oncology physics

Your RSC can consider approving of the individual as an authorized medical physicist without amending the license.

(3) You RSC can approve relocation of the waste trailer on the Washington Hospital Center site without amending the license.

jim

>>> <Shashadhar.M.Mohapatra@Medstar.net> 11/12/03 12:50PM >>>
James:

I forgot to ask you another question. I apologize for that. Our Radiation Safety Department has a waste trailer (shielded) near the rotoclave area where we store low level rad waste for short time before disposal . The Facility Management Department wants us to move that trailer to about 100 yards from the current location. It will still be located in the Washington Hospital Center's property. The question is: Do we need a license amendment for this ? Please send me a reply.

Thanks in advance for your help.

Regards,

Shashadhar Mohapatra, Ph.D., (Shashi)
RSO/ Washington Hospital Center