

February 15, 2005

EA-04-157

Mr. Kevin J. Harlen
Vice President of Professional Services
Washington Hospital Center
110 Irving Street, NW
Washington, DC 20010-2975

SUBJECT: NOTICE OF VIOLATION (OFFICE OF INVESTIGATIONS REPORT
NOS. 1-2003-046 AND 1-2003-046S)

Dear Mr. Harlen:

This refers to NRC investigations 1-2003-046 and 1-2003-046S conducted at Washington Hospital Center by the NRC's Office of Investigations (OI) and completed on August 12, 2004. The purpose of these investigations was to determine if two Nuclear Medicine Technologists (NMTs) used licensed radioactive material without the knowledge or approval of a physician or authorized user, in deliberate violation of NRC requirements.

Based on the OI investigation, the NRC concluded that a deliberate violation occurred. On October 29, 2004, we sent you a letter which contained a factual summary of the OI investigation. Our letter also informed you that the NRC had identified an apparent violation involving the deliberate use of licensed radioactive material in or on humans by two individual NMTs who were not authorized users and who were not under the supervision of an authorized user, contrary to your License Condition 11 and 10 CFR 35.27. Our letter also informed you that the NRC was considering escalated enforcement action in accordance with its enforcement policy and you were provided an opportunity to either respond in writing to this apparent violation or request a predecisional enforcement conference.

In a telephone conversation on November 9, 2004, your attorney, Mr. Daryl Shapiro, informed Mr. Joseph Nick of my staff, that you did not believe that a predecisional enforcement conference was required, but that you would provide a written response. In your response, dated November 23, 2004, you admitted that a violation of License Condition 11 and 10 CFR 35.27 occurred, but believed that the violation was of low safety significance and should be assessed as a Severity Level IV violation. Furthermore, you stated that the circumstances surrounding the violation meet the criteria for a non-cited violation (NCV) and should be disposed of as such. In addition, you stated that, should the NRC determine the violation to be a Severity Level III violation, WHC should receive credit for both self-identification and corrective actions and no civil penalty be assessed.

Based on our review of the apparent violation, including the information that we obtained during the investigation and the information that you provided in your written response dated November 23, 2004, we have determined that a deliberate violation of NRC requirements occurred. The violation occurred on July 20, 2003, when a NMT was injected with a diagnostic dosage of technetium-99m without the knowledge and approval of a physician or authorized user. The NMT admitted that he was injected and that he knew this was in violation of NRC

regulations. Deliberate violations are a very serious concern to the NRC because the NRC regulatory program relies, in part, on the honesty and integrity of NRC licensees and their employees. As such, deliberate violations cannot be tolerated. Given such egregious misuse of licensed radioactive material, and the deliberate nature of such misuse, this violation has been categorized at Severity Level III in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600.

Although our October 29, 2004, letter indicated that two NMTs deliberately used licensed radioactive material without the knowledge or approval of an authorized user, after further review, the NRC has concluded that while an unauthorized use occurred, there was insufficient evidence to allow us to determine that more than one NMT willfully violated NRC requirements.

In accordance with the Enforcement Policy, a base civil penalty in the amount of \$3,000 is considered for a Severity Level III violation for medical licensees. Because the violation was willful in nature, the NRC considered whether credit was warranted for *Identification and Corrective Action* in accordance with the civil penalty assessment process in Section VI.C.2 of the Enforcement Policy. Credit for identification is warranted because WHC identified that an NMT was injected with a diagnostic dosage of technetium-99m without the knowledge and approval of a physician authorized to administer this licensed material. WHC notified the NRC of this occurrence on August 25, 2003. Credit for corrective actions is also warranted because your actions subsequent to the investigation were considered comprehensive. These actions included, but were not limited to: (1) reviewing the incident with Nuclear Medicine Department employees and emphasizing strict adherence with NRC and WHC requirements; (2) conducting a radiation safety department inspection and radiation safety audit; (3) completing a review of procedures and processes for receiving, storing, administering and disposing of radiopharmaceuticals; and (4) initiating a fact finding investigation which resulted in disciplinary action.

Therefore, to encourage prompt identification and comprehensive correction of violations, I have been authorized, after consultation with the Director, Office of Enforcement, to issue the enclosed Notice of Violation for the Severity Level III violation with no civil penalty. However, you should be aware that significant violations in the future could result in a civil penalty. In addition, issuance of this Notice constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding the reasons for the violation, the corrective actions taken to correct the violation and prevent recurrence, and the date when full compliance was achieved is already adequately addressed on the docket in your November 23, 2004, letter, as well as herein. Therefore, you are not required to respond to this violation unless the description in your November 23, 2004, letter and herein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice. We appreciate your cooperation with us in this matter.

If you disagree with the enforcement sanction, you may request alternative dispute resolution (ADR) with the NRC. ADR is a general term encompassing various techniques for resolving conflict outside of court using a neutral third party. The NRC is currently utilizing ADR during a pilot program for any issues involving willful or deliberate violations. The technique that the NRC has decided to employ during the pilot program is mediation. In mediation, a neutral mediator with no decision-making authority helps parties clarify issues, explore settlement

options, and evaluate how best to advance their respective interests. The mediator's responsibility is to assist the parties in reaching an agreement. However, the mediator has no authority to impose a resolution upon the parties. Mediation is a confidential and voluntary process. If the parties to the ADR process (the NRC and the licensee) agree to use ADR, they select a mutually agreeable neutral mediator and share equally the cost of the mediator's services. Generally, the NRC is willing to discuss the resolution of three potential issues regarding any willful or deliberate violation: (1) whether a violation occurred; (2) the appropriate enforcement action; and (3) the appropriate corrective actions for the violation. Additional information concerning the NRC's pilot program can be obtained at <http://www.nrc.gov/what-we-do/regulatory/enforcement/adr.html>. The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as an intake neutral. Intake neutrals perform several functions, including: assisting parties in determining ADR potential for their case, advising parties regarding the ADR process, aiding the parties in selecting an appropriate mediator, explaining the extent of confidentiality, and providing other logistical assistance as necessary. Please contact ICR at (607)-255-1124 within 10 days of the date of this letter if you are interested in pursuing resolution of this issue through ADR. You may also contact Nick Hilton, Office of Enforcement, at (301) 415-3055 for additional information.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response (if you choose to provide one) will be made available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room). To the extent possible, your response should not include any personal privacy, proprietary or safeguards information so that it can be made available to the public without redaction. The NRC also includes significant enforcement actions on its web site at <http://www.nrc.gov>; select **What We Do, Enforcement**, then **Significant Enforcement Actions**.

Sincerely,

/RA/ JWiggins for

Samuel J. Collins
Regional Administrator

Docket No. 03001325
License Nos. 08-03604-03

Enclosure:
Notice of Violation

cc:
Shashadhar Mohapatra, Ph. D., Radiation Safety Officer
District of Columbia

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Enforcement Coordinators RII, RIII, RIV
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SISP Review Complete: FMC (1/21/05) (Reviewer's Initials)

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OFFICE	RI/ORA	RI/ORA	RI/DNMS	RI/DNMS	RI/OI
NAME	JWray	DHolody	PHenderson	GPangburn	EWilson KMonroe for w/dissent
DATE	1/13/05	1/20/05	1/13/05	1/17/05	1/20/05
OFFICE	RI/ORA	HQ/OE	HQ/NMSS	OGC	RI/RA
NAME	KFarrar	FCongel CNolan for (by phone)	*Linda Gersey for JStrosnider	*Daniel Fruchter for JMoore	SCollins JWiggins for
DATE	1/21/05	2/11/05	01/24/05	01/25/05	1/21/05

OFFICIAL RECORD COPY

*per Sally Merchant

ENCLOSURE

NOTICE OF VIOLATION

Washington Hospital Center
Washington, D.C.

Docket No. 030-01325
License No. 08-03604-03
EA 04-157

Based on an NRC investigation completed on August 12, 2004, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG-1600, the violation is listed below:

10 CFR 35.27 (a) requires, in part, that a licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user as allowed by 10 CFR 35.11 (b) (1), shall require the supervised individual to follow the instructions of the supervising authorized user for medical uses of byproduct material, written radiation protection procedures established by the licensee, written directive procedures, written regulations, and license conditions with respect to the medical use of byproduct material.

Contrary to the above, on July 20, 2003, a Nuclear Medicine Technologist (NMT), employed by the Washington Hospital Center, was injected with a diagnostic dosage of technetium-99m, without such an injection being authorized by, or being under the supervision of, the supervising authorized user.

This is a Severity Level III violation (Supplement IV).

The NRC has concluded that information regarding the reasons for the violation, the corrective actions taken to correct the violation and prevent recurrence, and the date when full compliance was achieved is already adequately addressed on the docket in your November 23, 2004, letter. 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, EA 04-157" and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 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 the violation, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555.

Because any response will be made available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS), to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room). If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed

NOTICE OF VIOLATION

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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 material, you must specifically identify the 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).

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

Dated this 15th day of February 2005