

October 14, 2005

IA-05-035

Shirley A. Knisely
HOME ADDRESS DELETED
UNDER 10 CFR 2.390

SUBJECT: NOTICE OF VIOLATION (NRC OFFICE OF INVESTIGATIONS REPORT NO.
1-2004-026)

Dear Ms. Knisely:

This refers to NRC investigation 1-2004-026 conducted at the Milton S. Hershey Medical Center (MSHMC) by the NRC's Office of Investigations (OI) and completed on October 28, 2004. The purpose of this investigation was to determine whether you, in your capacity as a nuclear medicine technologist (NMT) for MSHMC, deliberately had yourself injected with a diagnostic dosage of technetium-99m on April 29, 2004, for the purpose of a brain scan without the knowledge and approval of an authorized user, knowing this action was a violation of NRC regulations.

Based on the OI investigation, the NRC identified an apparent deliberate violation, as noted in a letter we sent you on May 19, 2005, which contained a factual summary of the OI investigation. The apparent violation involved your deliberate unauthorized use of licensed radioactive material. 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, attend a predecisional enforcement conference, or request alternate dispute resolution (ADR) with the NRC in an attempt to resolve this issue.

In a letter dated June 2, 2005, your attorney indicated that you desired to attend a predecisional enforcement conference to discuss the apparent violation. On July 18, 2005, a closed predecisional enforcement conference was conducted with you during which you admitted having yourself injected with licensed material without approval from an authorized user, but stated that you did not realize, at the time, that your actions were in violation of NRC requirements. You further stated that you did not do anything deliberately wrong and you believed that your actions were accepted practice at MSHMC.

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Based on the information that we obtained during the investigations, and our consideration of the information that you provided during the conference on July 18, 2005, the NRC has concluded that your deliberate actions placed MSHMC in violation of NRC requirements. As such, you were in violation of 10 CFR 30.10, "Deliberate Misconduct." This violation is cited in the enclosed Notice of Violation (Notice). 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. After considering the significance of the violation, and in particular, the deliberate nature of your actions, this violation has been categorized at Severity Level III in accordance with the NRC Enforcement Policy.

In determining the appropriate sanction to be issued to you in this case, the NRC considered all available enforcement options, including issuing an Order prohibiting your involvement in NRC-licensed activities. However, after consultation with the Director, Office of Enforcement, and after considering the circumstances of this case, I have decided that issuance of an Order is not warranted given that (1) the safety consequence of this case was low in that you did not receive excessive radiation exposure, (2) you were not functioning as a supervisor at the time of your actions, (3) disciplinary action was taken against you by MSHMC, and (4) you admitted that your actions resulted in a violation of NRC requirements. However, your actions were egregious since the misuse of radioactive material actually involved the injection of the radioactive material into a human (yourself) without authorization. Therefore, the NRC has determined that a Notice of Violation is warranted in this case. A Notice of Violation and Confirmatory Order was also issued to MSHMC on this date, based, in part, on your actions.

You should also be aware that any similar actions in the future involving NRC licensed activities at a licensed facility, whether identified by your employer, or by the NRC during an inspection or investigation, could result in the NRC taking significant enforcement action against you, and could also result in criminal prosecution.

The NRC has concluded that the information you provided on July 18, 2005, at the predecisional enforcement conference adequately addresses our concerns. Therefore, you are not required to respond to this violation unless the description herein does 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, or as an option, you may request alternative dispute resolution (ADR) with the NRC in an attempt to resolve this issue. ADR is a general term encompassing various techniques for resolving conflict outside of court using a neutral third party. The technique that the NRC has decided to employ during a pilot program which is now in effect is mediation. Additional information concerning the NRC's pilot program is described in the enclosed brochure (NUREG/BR-0317) and 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. Please contact ICR at 877-733-9415 within 10 days of the date of this letter if you are interested in pursuing resolution of this issue through ADR. If you have any questions regarding this letter, please contact Ms. Pamela Henderson of my staff at (610) 337-6952.

Ms. Shirley Knisely

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This letter will be maintained by the Office of Enforcement (OE) in an NRC Privacy Act system of records, NRC-3, "Enforcement Actions Against Individuals." The NRC-3 system notice, which provides detailed information about this system of records, can be accessed from our Web site at <http://www.nrc.gov/reading-rm/foia/privacy-systems.html>.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, any response to this letter, and our May 19, 2005 letter as well as your June 2, 2005 response to that letter 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/

Samuel J. Collins
Regional Administrator

Enclosures:

1. Notice of Violation
2. Letter to MSHMC with Notice of Violation and Confirmatory Order

cc w/encls:

L. K. Thompson, Administrator, MSHMC
Commonwealth of Pennsylvania

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NAME	KFarrar		GMorell		BJones/G. Longo for		MJohnson		SCollins	
DATE	09/13/05		09/20/05		09/16/05		9/30/05		09/23/05	

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ENCLOSURE 1

NOTICE OF VIOLATION

Ms. Shirley A. Knisely

IA-05-035

During the NRC investigation conducted at the Milton S. Hershey Medical Center by the NRC Office of Investigations completed on October 28, 2004, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 30.10(a) requires, in part, that any employee of a licensee may not engage in deliberate misconduct that causes a licensee to be in violation of any regulation of the Commission. Pursuant to 10 CFR 30.10(c), deliberate misconduct means an intentional act or omission that the person knows would cause a licensee to be in violation of any regulation of the Commission.

10 CFR 35.27(a) requires 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 April 29, 2004, you, as a Nuclear Medicine Technologist (NMT), engaged in deliberate misconduct that caused an NRC licensee to be in violation of a Commission regulation. Specifically, on April 29, 2004, you, as an NMT employed at Milton S. Hershey Medical Center, were injected with a diagnostic dosage of technetium-99m, for the purpose of performing a brain scan, without the knowledge and approval of a physician or authorized user, knowing that this action was a violation of NRC requirements.

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

The NRC has concluded that the information you provided on July 18, 2005, at the predecisional enforcement conference, regarding the reasons for the violation adequately address this issue. Therefore, you are not required to respond to this violation. However, if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, IA-05-035" and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region I within 30 days of the date of the letter transmitting this Notice.

If you contest this enforcement action, 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, D.C. 20555-0001.

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 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).

Dated this 14th day of October 2005