



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

May 18, 2005

Docket No. 03003203
EA-04-215

License No. 37-13831-01

L. K. Thompson
Administrator
The Milton S. Hershey Medical Center
The Pennsylvania State University
P.O. Box 850
Hershey, PA 17033

SUBJECT: OFFICE OF INVESTIGATIONS REPORT NOS. 1-2004-026, 1-2004-037,
1-2004-038, 1-2004-039

Dear Mr. Thompson:

This refers to four investigations conducted by the NRC Office of Investigations (OI), Region I (RI), between May 11, 2004 and March 16, 2005, to determine whether licensed byproduct material was improperly used by employees of the Milton S. Hershey Medical Center (MSHMC). As a result of three investigations, OI concluded that (1) in the 1996-1997 time frame, an authorized user deliberately administered byproduct material to an individual, with no medical reason, for the sole purpose of comparing images from two cameras, (2) in 2002, a former MSHMC employee deliberately used byproduct material to perform an unauthorized bone scan on himself, and (3) in 2004, a MSHMC employee deliberately used byproduct material to perform an unauthorized brain scan on herself. With respect to a fourth investigation, OI was unable to substantiate that an unauthorized nuclear medicine scan of a worker's lower extremities occurred in the early 1990s. A Factual Summary of the OI investigations is enclosed. Regarding Investigation No. 1-2004-038, the NRC staff has concluded that, based on all the evidence, the authorized user's administration of byproduct material to perform a comparison of images from two cameras violated NRC requirements but that deliberateness was not substantiated.

As a result of these OI investigations, two apparent violations were identified and are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at www.nrc.gov; select **What We Do, Enforcement**, then **Enforcement Policy**. The first apparent violation occurred in the 1996-1997 time frame and involved an authorized user administering byproduct material to an individual, with no medical reason, for the sole purpose of comparing images between two cameras. This is an apparent violation of 10 CFR 35.11. The second apparent violation involved the deliberate use of byproduct material to perform unauthorized nuclear medicine tests on two separate occasions. Specifically, (1) in October 2002, a Nuclear Medicine Technologist (NMT) used byproduct material without the consent of an authorized user when he

had a second NMT inject him with byproduct material for the purpose of performing an unauthorized bone scan, and (2) on April 29, 2004, another NMT used byproduct material without the approval of an authorized user when she instructed a student NMT to inject the NMT with byproduct material for the purpose of performing an unauthorized brain scan. These two incidents constitute an apparent violation of 10 CFR 35.27(a).

Before an enforcement decision can be made, the NRC would like to discuss these apparent violations with you at a Predecisional Enforcement Conference (PEC). This conference would be closed and transcribed. The decision to hold a PEC does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference would be held to obtain information to assist the NRC in making an enforcement decision. This may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned. The conference would provide you an opportunity to present your perspective on these matters and any other information that you believe the NRC should take into consideration in making an enforcement decision. In presenting your corrective action, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. The guidance in the enclosed excerpt from NRC Information Notice 96-28, "SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION," may be helpful.

Instead of a PEC, 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.

Please contact Ms. Pamela Henderson at (610) 337-6952 within 10 days of the date of this letter to notify the NRC of your decision to either participate in a PEC or pursue ADR.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,

/RA/

George Pangburn, Director
Division of Nuclear Materials Safety

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Enclosures:

1. Excerpt from NRC Information Notice 96-28
2. Factual Summary of OI Investigation Report Nos. 1-2004-026, 1-2004-037, 1-2004-038, and 1-2004-039
3. Brochure NUREG/BR-0317

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*J Luehman for F Congel based on e-mail from A Hayes to J Wray dtd 5/17/05 includes OGC concurrence

Enclosure 2

FACTUAL SUMMARY OF OI INVESTIGATION REPORT NOS. 1-2004-026; 1-2004-037; 1-2004-038; AND 1-2004-039

Between May 11, 2004, and March 16, 2005, the U. S. Nuclear Regulatory Commission's (NRC) Office of Investigations (OI), Region I (RI) Field Office, conducted four investigations to determine whether (1) a physician authorized user (AU) deliberately administered licensed radioactive material to a Nuclear Medicine Technologist (NMT) for the sole purpose of comparing the images from a new camera with the images from an old camera, contrary to the NRC requirement that there exist a medical reason for the administration of radioactive materials; (2) an NMT, formerly employed at the Milton S. Hershey Medical Center (MSHMC), deliberately had himself injected with licensed radioactive material by another NMT for the purposes of conducting a bone scan without the authorization of an AU; (3) an NMT directed a student technologist to inject her with licensed radioactive material for the purpose of conducting a brain scan without the knowledge, approval, or consent of an AU, in deliberate violation of NRC requirements; and (4) an NMT used byproduct material to perform an unauthorized nuclear medicine scan of her lower extremities.

CASE 1 OI Report 1-2004-038

This investigation was initiated on August 26, 2004, to determine if an AU administered licensed radioactive material to an NMT for no medical reason, contrary to NRC requirements. Based on the evidence developed during this investigation, OI concluded that in the 1996-1997 time frame the AU directed an NMT to inject another NMT with technetium-99m in order to compare images between a new and old camera, in deliberate violation of NRC requirements.

The evidence supporting the conclusion included the admission to OI from the NMT that in late 1997, she volunteered to be injected by radioactive material, with no medical symptoms or conditions, for the sole purpose of comparing images from two different cameras. The NMT stated that the Chief of Nuclear Medicine at MSHMC, an AU, asked for a volunteer after he was unable to locate a patient that was willing to participate and that she had a second NMT inject her. The second NMT confirmed that she injected the first NMT knowing that the sole purpose was to compare the imaging results of the new and old cameras. The AU stated that he had no recollection of administering a radioactive isotope for the sole purpose of comparing camera images.

CASE 2 OI Report 1-2004-037

This investigation was initiated on August 26, 2004, to determine if an NMT, formerly employed at MSHMC, had himself injected with technetium-99m by another NMT without the authorization of an AU for the purposes of conducting a bone scan. Based on the evidence developed during the investigation, OI concluded that the NMT used licensed radioactive material without the knowledge, approval, or consent of an AU, in deliberate violation of NRC requirements.

The evidence supporting this conclusion included the admission to OI from the NMT that in October 2002, he conducted an unauthorized bone scan on his right ankle. The NMT stated that he had another NMT inject him with technetium-99m and had a third NMT assist in the test. The two other NMTs admitted their involvement in the unauthorized bone scan.

CASE 3 OI Report 1-2004-026

An investigation was initiated on April 29, 2004, to determine if an NMT directed a student technologist to inject her with licensed radioactive material without the knowledge or approval of an AU, contrary to NRC requirements. Based on the evidence developed during this investigation, OI concluded that an NMT used licensed radioactive material without the knowledge, approval, or consent of an AU, in deliberate violation of NRC requirements. Specifically, the NMT directed a student technologist to inject the NMT with radioactive materials for the purpose of conducting a brain scan. This injection was performed without the authorization or supervision of an AU.

The evidence supporting this conclusion included the admission to OI from the NMT that she was injected by the student technician and that the injection had not been authorized by an AU. The student technologist stated that the NMT told her that the injection would be part of her (the student's) competency testing. However, the student technologist stated that she did not get approval from an AU prior to the injection. Evidence gathered indicates that the NMT knew this injection was in violation of NRC requirements and she stated that she would take any heat from this event.

CASE 4 OI Report 1-2004-039

An investigation was initiated on August 26, 2004, to determine if an NMT used licensed radioactive material, without the knowledge or approval of an AU, to perform a nuclear medicine scan of her lower extremities, in deliberate violation of NRC requirements. Based on the information developed during the investigation, OI concluded that there was insufficient evidence to substantiate that an NMT used licensed byproduct material to performed the unauthorized nuclear medicine scan.