

September 21, 2005

EA 05-158

Lydia Tarta
Director of Oncology
Mountainside Hospital
Bay and Highland Avenues
Montclair, New Jersey 07042

SUBJECT: NOTICE OF VIOLATION

Dear Ms. Tarta:

This refers to an in-office NRC inspection conducted on July 25-26, 2005, to review the circumstances involving the loss of control of NRC licensed radioactive material in the form of sealed sources contained in a nuclear imaging camera (Siemens Model ECAM) which was removed from your facility on June 30, 2005. You reported this event to the NRC Operations Center on July 1, 2005. At the time of your report, the camera was in transit to the MedX facility in Arlington Heights, Illinois. On July 2, 2005, the camera was returned to your facility in Montclair, New Jersey, and the sources, located in their protective housings at all times, were removed and placed in safe storage. As described in the NRC inspection report sent to you on September 15, 2005, two apparent violations of NRC requirements were identified during the inspection.

Based on the findings from the inspection, the NRC has determined that two violations of NRC requirements occurred. These violations are cited in the enclosed Notice of Violation (Notice). The first violation involves the failure to secure, control or maintain constant surveillance of the imaging camera containing NRC licensed material while in transit, contrary to the requirements of 10 CFR 20.1801 and 10 CFR 20.1802. In a telephone conversation on August 10, 2005, Ms. Pamela Henderson of my staff informed you that this violation was being considered for escalated enforcement action, and the NRC did not need any additional information to make an enforcement decision. However, Ms. Henderson provided you an opportunity to attend a predecisional enforcement conference or to provide a written response, prior to the NRC determining appropriate enforcement action. During this conversation, you declined the opportunity to attend a conference or to provide a written response.

In this case, the failure to maintain constant surveillance and control of the camera did not result in removal of the sources from their shielded position, nor did it result in any leakage from the sources. Furthermore, there is no evidence that unauthorized persons came into direct

contact with the material during the time that it was in transit. Nonetheless, this violation is of concern to the NRC because (1) the failure to control radioactive material could result in the loss or theft of the material; and (2) unintended radiation doses to members of the public could occur if the sources were removed from their shielded position. Therefore, this violation is categorized at Severity Level III in accordance with the NRC Enforcement Policy.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$3,250 is considered for a Severity Level III violation involving the loss of control of radioactive material with this level of radioactivity. Because your facility has not been the subject of escalated enforcement action within the last two years or two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section VI.C.2 of the Enforcement Policy. Credit for corrective actions is warranted because your corrective actions were considered prompt and comprehensive. These corrective actions, which you described during the inspection, included, but were not limited to: (1) immediately contacting the carrier in transit and returning the camera to your facility; (2) verifying that the sources had remained in their protective housings during transit, thereby not exposing any member of the public; (3) removing the sources from the camera, once back in your facility, and placing them into safe storage; (4) taking disciplinary action against the responsible staff member; (5) re-instructing appropriate staff members in the proper procedures for shipping licensed material; and (6) instituting a policy that no nuclear medicine imaging equipment or ancillary device containing radioactive material will be shipped for disposal without obtaining the consent of the Radiation Safety Officer or his designee.

Therefore, to encourage prompt and comprehensive correction of violations and in recognition of the absence of previous escalated enforcement action, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, you should be aware that significant violations in the future could result in a civil penalty. In addition, issuance of this Severity Level III violation constitutes escalated enforcement action that may subject you to increased inspection effort.

The second violation involved the failure to provide packaging for transportation according to the requirements of 10 CFR 71.5(a), 49 CFR 173.421(a), and 49 CFR 173.410. Although the violation was neither repetitive nor willful, and it was corrected in a timely manner, issuance of a citation for this violation is consistent with Section VI.A.8 of the NRC Enforcement Policy, because it was identified as a result of an event and not because of any special self-monitoring effort by your management or staff. In accordance with Supplement V.D.4 of the NRC Enforcement Policy, this violation has been classified at Severity Level IV.

The NRC has concluded that information regarding the reasons for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance was achieved is already adequately addressed on the docket in this letter and in the inspection report issued on September 15, 2005. Therefore, you are not required to respond to this letter unless the description therein 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.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, 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).

We appreciate your cooperation with us in this matter.

Sincerely,

/RA/ Marc L. Dapas Acting For

Samuel J. Collins
Regional Administrator

Docket No. 030-02470
License No. 29-03297-02

Enclosure: Notice of Violation

cc w/encl:
State of New Jersey

Distribution w/encls:

ADAMS (PARS)
 SECY
 CA
 OEMAIL
 OEWEB
 LReyes, EDO
 MVirgilio, DEDMRS
 MJohnson, OE
 SFiguroa, OE
 LChandler, OGC
 BJones, OGC
 MEIwood, OGC
 KRemsberg, OGC
 JStrosnider, NMSS
 CMiller, NMSS
 WOutlaw, OCM
 CMiller, OEDO
 GMorell, NMSS
 Enforcement Coordinators RII, RIII, RIV
 SGagner, OPA
 HBell, OIG
 PLohaus, STP
 GCaputo, OI
 LTremper, OC
 DScrenzi/NSheehan, RI
 GPangburn, RI
 FCostello, RI
 DWhite/SMinnick, RI SAO
 JKinneman, RI
 KFarrar, RI
 DHolody, RI
 JWray, RI
 DCorlew, RI
 Region I OE Files (with concurrences)

SISP Review Complete: Slg2 (Reviewer's Initials)

DOCUMENT NAME: E:\Filenet\ML052650359.wpd

After declaring this document "An Official Agency Record" it **will** be released to the Public.

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	RI/ORA	RI/DNMS	RI/DNMS RI/	RI/ORA	RI/ORA	RI/ORA
NAME	JWray	PHenderson	GPangburn	DHolody	RUrban	KFarrar
DATE	08/18/05	08/19/05	08/23/05	09/14/05	08/24/05	08/29/05
OFFICE	HQ/NMSS	HQ/OE	RI/RA			
NAME	GMorell *	CNolan *	SCollins (MLD for)			
	09/13/05	09/13/05	09/21/05			

OFFICIAL RECORD COPY

* Concurrence via e-mail from S. Merchant to J. Wray

NOTICE OF VIOLATION

Mountainside Hospital
Montclair, NJ

Docket No. 03002470
License No. 29-03297-02
EA 05-158

During an in-office NRC inspection conducted on July 25-26, 2005, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access, licensed materials that are stored in controlled or unrestricted areas. 10 CFR 20.1802 requires that the licensee control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and is not in storage. As defined in 10 CFR 20.1003, *controlled area* means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason; and *unrestricted area* means an area, access to which is neither limited or controlled by the licensee.

Contrary to the above, the licensee did not secure from unauthorized removal or access, licensed materials that were stored in controlled or unrestricted areas, nor did the licensee control and maintain constant surveillance of licensed material that was in a controlled or unrestricted area and was not in storage. Specifically, on June 30, 2005, a nuclear medicine imaging camera was removed from the licensee's premises and placed in a truck for transport to the MedX facility in Arlington Heights, Illinois. At that time, the camera contained NRC licensed radioactive material in the form of 28 sealed sources that were not removed and secured by the licensee prior to the camera being shipped from the licensee's facility.

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

- B. 10 CFR 71.5(a) requires that a licensee who transports licensed material outside of the site of usage, as specified in the NRC license, or where transport is on public highways, or who delivers licensed material for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 170 through 189.

49 CFR 173.3(a) requires the packaging of hazardous materials for transportation by air, highway, rail, or water to be as specified in 49 CFR Part 173.

49 CFR 173.421(a) permits the shipment of certain packages containing limited quantities of radioactive materials, excepted from the specification packaging, labeling, and marking requirements, provided, among other things, that each package meets the general design requirements in 49 CFR 173.410.

Contrary to the above, the licensee delivered an excepted package of Class 7 (radioactive) material for transport and the packaging was not as specified in 49 CFR Part 173 and the package did not meet the general design requirements in 49 CFR 173.410. Specifically, on June 30, 2005, a nuclear medicine imaging camera containing NRC licensed radioactive material in the form of 28 sealed sources was delivered for transport to the MedX facility in Arlington Heights, Illinois, and the licensee did not provide the required packaging.

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

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in the NRC letter transmitting this Notice, and in NRC Inspection Report No. 030-02470/2005-001 issued on September 15, 2005. Therefore, no response to this Notice is required. 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 05-158" 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 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, DC 20555.

If you choose to respond, your response will be placed in the NRC Public Document Room (PDR). Therefore, to the extent possible, the response should not include any personal privacy or proprietary information so that it can be placed in the PDR without redaction. ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/NRC/ADAMS/index.html> (the Public Electronic Reading Room).

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

Dated this 21st day of September 2005