

March 2, 2006

Docket No. 03002941
EA No. 05-237

License No. 37-00148-06

Mr. Bart T. Murtaugh
Vice President, Ancillary and Support Services
TJUH, Inc.
Thomas Jefferson University Hospital
Suite 2210 Gibbon Building
111 South 11th Street
Philadelphia, PA 19107-5096

SUBJECT: NOTICE OF VIOLATION

Dear Mr. Murtaugh:

This letter refers to the NRC inspection conducted at your facility in Philadelphia, Pennsylvania, on August 16, 2005, in response to an event you reported to the NRC Operations Center on August 12, 2005, with continuing in-office review until November 29, 2005. The in-office review consisted of an evaluation of additional information you provided to the NRC on September 8, 2005, October 10, 2005 and November 29, 2005. During the inspection, two apparent violations of NRC requirements were identified. The apparent violations involve an exposure in excess of limits to the skin of a thumb of one of your nuclear medicine technologists (NMTs), and the failure to conduct adequate surveys. The results of the inspection, including the apparent violations, were discussed with you and John Keklak of your staff by telephone during an exit meeting on December 29, 2005, and were described in a letter and inspection report sent to you on January 17, 2006.

In that letter of January 17, 2006, the NRC informed you that these apparent violations were being considered for escalated enforcement action, and the NRC did not need any additional information to make an enforcement decision. Nonetheless, the NRC 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 another telephone conversation between Sandra Gabriel of my staff and John Keklak of your staff on February 1, 2006, Mr. Keklak stated that Thomas Jefferson University Hospital declined the opportunity to attend a conference or to provide a written response.

Based on the information developed during the inspection, the NRC has determined that two violations of NRC requirements occurred. The violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report. The violations involved the failure to control the annual occupational shallow dose equivalent to 50 rem, and the failure to conduct adequate surveys. The failure to promptly identify the skin contamination, and assess the dose to the skin was directly related to your failure to ensure adequate surveys were conducted subsequent to the administration of a therapeutic iodine-131 treatment.

The contamination event occurred on August 11, 2005, and the NMT received a calculated shallow dose equivalent of 144.25 rem to the skin of the right thumb. The 144.25 rem dose resulted from thumb contamination that most likely occurred during preparation and administration of a therapeutic dose of iodine 131. It appears that the protective glove worn by the NMT was compromised at the tip of the thumb. The contamination was not initially detected because of an inadequate survey performed by the NMT following the patient administration. Specifically, the NMT quickly passed her hands over the survey instrument probe at a distance of approximately three to five inches and failed to place her thumb directly over the detector's window. Based on the failure to conduct an adequate survey, the contamination was not detected for a period of approximately 26 hours.

Violations involving an annual occupational shallow dose equivalent that exceeded 100 rem would normally be classified at Severity Level II. In this case, the shallow-dose equivalent to the skin of the thumb was estimated to be 144.25 rem; however, the contamination occurred in an area where the outer layer of the skin is 30 to 40 milligrams per square centimeter thick, rather than the 7 milligrams per square centimeter thickness used to determine skin exposure (shallow-dose equivalent) for regulatory purposes. In addition, a portion of the contamination was on the individual's thumbnail rather than on the skin of the thumb. Once the nail was trimmed, the measured contamination level was significantly reduced. As a result, while the shallow dose equivalent to the skin and nail of the thumb was in excess of the annual limit, the actual dose to the basal skin layer was estimated to be less than 100 rem. Therefore, these two violations are categorized as a Severity Level III problem 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 or problem involving the failure to control the occupational skin dose below regulatory limits. 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 included: (1) removal of the affected individual from duties involving handling of licensed material for the remainder of the 2005 calendar year; (2) issuance of a notice to nuclear medicine staff on August 15, 2005, that made mandatory a double gloving technique for all sodium iodide I-131 handling, and contained a reminder and instructions about performing careful and thorough hand surveys; and (3) performance of a competency evaluation of all NMTs' survey techniques which was completed on August 25, 2005.

Therefore, to encourage prompt and comprehensive correction of violations, and in recognition of the absence of any escalated enforcement action at your facility within the last two years or two inspections, I have been authorized, after consultation with the Director, Office of Enforcement, to issue the enclosed Notice of Violation without a civil penalty for these Severity Level III violations. However, you should be aware that significant violations in the future could result in a civil penalty. In addition, issuance of these Severity Level III violations constitute escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding the reasons for the violations, the corrective actions taken to correct the violations and prevent recurrence, and the date when full

Mr. Bart T. Murtaugh

3

compliance was achieved, is already adequately addressed in this letter; in additional information you provided on September 8, 2005, October 10, 2005, and November 29, 2005; and in the inspection report issued on January 6, 2006. Therefore, you are not required to respond to these violations unless the description 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.

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/

Samuel J. Collins
Regional Administrator

Enclosure: Notice of Violation

cc:
John Keklak, Radiation Safety Officer
Commonwealth of Pennsylvania

DISTRIBUTION w/encl:

ADAMS (PARS)
 SECY
 CA
 OEMAIL
 OEWEB
 L Reyes, EDO
 M Virgilio, DEDMRS
 M Johnson, OE
 B Jones, OGC
 L Chandler, OGC
 FCameron, OGC
 J Strosnider, NMSS
 C Miller, NMSS
 G Morell, NMSS
 Enforcement Coordinators
 RII, RIII, RIV
 S Figueroa, OE
 M Elwood, OGC

S Gagner, OPA
 H Bell, OIG
 J Schlueter, STP
 G Caputo, OI
 L Tremper, OCFO
 D Screnci, PAO-RI
 N Sheehan, PAO-RI
 G Pangburn, RI
 F Costello, RI
 P Henderson
 K Farrar, RI
 D Holody, RI
 J Wray, RI
 RSummers, RI
 C O'Daniell, RI
 S Villar, RI
 R1DNMS_Mail
 Region I OE Files (with concurrences)

DOCUMENT NAME: E:\Filenet\ML060610699.wpd

SISP Review Complete: _____ pan _____

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 w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	ORA/RI		DNMS/RI		DNMS/RI		ORA/RI	
NAME	JNicholson		PLanzisera		GPangburn		DHolody	
DATE	02/13/2006		02/13/06		02/13/06		02/14/06	
OFFICE	RC/RI		NMSS		OE		RA	
NAME	KFarrar						SCollins/MLD for	
DATE	02/14/06						03/02/06	

OFFICIAL RECORD COPY

ENCLOSURE

NOTICE OF VIOLATION

Thomas Jefferson University Hospital
Philadelphia, Pennsylvania

Docket No. 030-02941
License No. 37-00148-06
EA-05-237

Based on an NRC inspection conducted at the Thomas Jefferson University Hospital in Philadelphia, Pennsylvania on August 16, 2005, as well as reviews in the Region I office of additional information provided to the NRC in correspondence dated September 8, 2005, October 10, 2005, and November 29, 2005, two violations of NRC requirements were identified. The violations were discussed at an exit meeting on December 29, 2005. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 20.1201(a)(2)(ii) requires, with exceptions not applicable here, that the licensee control the occupational dose to the skin or to any extremity of individual adults to an annual dose limit of 50 rem shallow-dose equivalent.

Contrary to the above, on August 11, 2005, the licensee did not limit the dose to the skin of the right thumb of an adult nuclear medicine technologist (NMT) to an amount less than the annual limit of 50 rem shallow-dose equivalent. Specifically, the NMT received an exposure of 144.25 rem shallow-dose equivalent to the skin of the right thumb when it became contaminated with sodium iodide (iodine 131), during a post-thyroidectomy treatment of a thyroid cancer patient.

- B. 10 CFR 20.1501(a) requires that each licensee make or cause to be made surveys that may be necessary for the licensee to comply with the regulations in Part 20 and that are reasonable under the circumstances to evaluate the extent of radiation levels, concentrations, or quantities of radioactive materials, and the potential radiological hazards that could be present.

Pursuant to 10 CFR 20.1003, survey means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation.

Contrary to the above, on August 11, 2005, the licensee did not make adequate surveys to assure compliance with 10 CFR 20.1201(a)(2)(ii), which limits radiation exposure to the extremities. Specifically, an NMT did not perform adequate surveys necessary for the timely identification of skin contamination and assessment of dose to the skin of her right thumb. The survey was inadequate in that the contamination on the thumb was not detected initially after the dose preparation and administration. The NMT moved her hands too quickly and at a distance of 3 to 5 inches from the surface of the probe which was too far away. As a result, the NMT's skin was contaminated for 26 hours before being detected and the NMT received a shallow-dose equivalent of 144.25 rem to the right thumb.

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

The NRC has concluded that information regarding the reasons for the violations, the corrective actions taken to correct the violations and prevent recurrence, and the date when full compliance was achieved is already adequately addressed in this letter, in your letters dated September 8, 2005, October 10, 2005, and November 29, 2005, and in the inspection report issued on January 6, 2006. 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-05-237" 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 violations, 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 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 2nd day of March 2006