



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

March 27, 2008

Docket Nos. 03002941
03035567

License Nos. 37-00148-06
37-00148-08

Kimberly Evans
Vice President, Clinical & Support Services
Thomas Jefferson University Hospitals, Inc.
Nevil Building
919 Walnut Street, Suite 820
Philadelphia, PA 19107

SUBJECT: INSPECTIONS 03002941/2008001 AND 03035567/2008001, THOMAS JEFFERSON UNIVERSITY CAMPUS, THOMAS JEFFERSON UNIVERSITY HOSPITAL, JEFFERSON HOSPITAL FOR NEUROSCIENCE, 9501 ROOSEVELT BOULEVARD, AND NOTICE OF VIOLATION

Dear Ms. Evans:

On February 5-7, 2008, Penny Lanzisera and Michelle Simmons of this office conducted a safety inspection at the above noted locations in Philadelphia, Pennsylvania of activities authorized by the above listed NRC licenses. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selected examination of representative records. Additional information provided in your correspondence dated March 13, 2008 was also examined as part of the inspection. The findings of the inspection were discussed with you and other members of your organization at the conclusion of the inspection. This letter documents one violation of NRC requirements and three of the four concerns brought to your attention at the exit meeting. The fourth concern regarding the inventory of sealed sources, is still under review by NRC and will be documented under separate cover.

Based on the results of this inspection, it appears that your activities were not conducted in full compliance with NRC requirements. A Notice of Violation is enclosed that categorizes the violation by severity level. You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In addition, the following three concerns were discussed with you and your staff at the conclusion of the inspection: (i) research waste records were incomplete and did not accurately reflect the radioactive material contained within several waste drums; (ii) radiation safety audits did not identify a dose calibrator linearity record that documented test results outside of

K. Evans

2

Thomas Jefferson University Hospitals, Inc.

acceptable range and research audits often document repetitive concerns indicating that audit findings are not seriously addressed by the radiation safety office until an issue is repetitive; and (iii) a revised certification of financial assurance and an amended standby trust agreement should be submitted as soon as possible to correct the financial assurance amount and state an effective date. A written response to these concerns is not necessary, however, we appreciate your commitments during the exit meeting to address these concerns in a timely fashion.

Finally, additional information was provided to the NRC by your Radiation Safety Office on February 6, 2008, and by your Radiation Oncology Department on March 13, 2008, that documented the appropriate transfer of the gadolinium-153 sources listed in Item 6.CC. of your license and the depleted uranium listed in Item 6.DD. of your license. These records will be added to your file to support removal of these items during a future amendment to your license.

Current NRC regulations are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material**; then **Regulations, Guidance, and Communications Page**. The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **About NRC; Organization and Functions; Office of Enforcement; About Enforcement**; then **Enforcement Policy**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 7:00 a.m. to 8:00 p.m. EST, Monday through Friday (except Federal holidays).

Please contact Penny Lanzisera at 610-337-5169 if you have any questions regarding this matter.

Sincerely,

Original signed by Pamela J. Henderson

Pamela J. Henderson, Chief
Medical Branch
Division of Nuclear Materials Safety

Enclosure:
Notice of Violation

cc:
John Keklak, Radiation Safety Officer
Commonwealth of Pennsylvania

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Sincerely,

Pamela J. Henderson, Chief
Medical Branch
Division of Nuclear Materials Safety

Enclosure:
Notice of Violation

cc:
John Keklak, Radiation Safety Officer
Commonwealth of Pennsylvania

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OFFICE	DNMS/RI	N	DNMS/RI	DNMS/RI		
NAME	PLanzisera/PL		Msimmons/PL for	PHenderson/PH		
DATE	03/27/08		03/27/08	03/27/08		

NOTICE OF VIOLATION

Thomas Jefferson University Hospitals, Inc.
Philadelphia, PA

Docket No. 03002941
License No. 37-00148-06

During an NRC inspection conducted on February 5-7, 2008, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 20.1904(a) requires the licensee to ensure that each container of licensed material bears a durable, clearly visible label bearing the words "CAUTION, RADIOACTIVE MATERIAL," or "DANGER, RADIOACTIVE MATERIAL." The label must also provide sufficient information (such as the radionuclides present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, etc.) to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

Contrary to the above, on February 7-8, several containers in the Nuclear Medicine and Research waste storage areas containing technetium-99m, iodine-125, sulfur-35, etc did not bear a label that identified the radionuclides or the quantity of radioactivity, nor did they otherwise bear sufficient information to permit individuals handling or using the container, or working in the vicinity of the container, to take precautions to avoid or minimize exposure.

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

Pursuant to the provisions of 10 CFR 2.201, Thomas Jefferson University Hospitals, Inc. is hereby required to submit a written statement or explanation 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 of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personal privacy, proprietary,

Notice of Violation

2

Thomas Jefferson University Hospitals, Inc.

or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

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

Dated This 27 day of March 2008