

UNITED STATES NUCLEAR REGULATORY COMMISSION **REGION 1** 475 ALLENDALE ROAD KING OF PRUSSIA, PENNSYLVANIA 19406-1416

JAN - 1 1995

Docket No. 030-14526

License No. 37-00062-07

Mr. Earl F. Falast, Director Department of Veterans Administration Medical Center University and Woodland Avenues Philadelphia, PA 19104

SUBJECT: SPECIAL INSPECTION NO. 030-14526/95-002

Dear Ars Falast Dear Mr. Falast: On November 17, 1995, David B. Everhart and John R. McFadden, Ph.D., of this office conducted a special safety inspection at University and Woodland Avenues of activities authorized by the above listed NRC license. 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.

This unannounced inspection was prompted by information obtained during a routine inquiry by Region I management initiated by the potential Federal Government budget crisis. This inquiry raised uncertainty about the health and safety status of the radiation safety program. Specifically, the inspection addressed the conditions surrounding the intermittent furlough and replacement of your Radiation Safety Officer, Ann M. Lovell, and designation of Martin Zloty, H.D., the Chairman of the Radiation Safety Committee, as the new Radiation Safety Officer. This also refers to the telephone conversation on November 16, 1995 between yourself and myself.

The inspection consisted of observations by the inspectors, interviews with personnel, and a selective examination of representative records. Personnel interviewed included yourself, Heg O'Shea, the Associate Director, Philip Hatsis, the Chief of Facility Engineering,, Mitchell Machtay, M.D., Martin Zloty, M.D., William David, Chief Nuclear Medicine Technician. and Ann Lovell. The interviews focused on the effect of the change in radiation safety officer on the licensed activities in nuclear medicine, radiation therapy, and research and development.

Based on the results of this inspection, it appears that your activities were not conducted in full compliance with NRC requirements. Specifically, 10 CFR 35.13 requires that a licensee apply for and receive a license amendment before it changes Radiation Safety Officers. It appears that an amendment request, without concurrence by the Health Physics Programs Office of the Department of Veterans Affairs, was filed with this office on the afternoon of November 16, 1995, and that the original Radiation Safety Officer was effectively replaced early on the morning of November 17, 1995.

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Mr. E.F. Falast -2-Department of Veterans Administration Medical Center

It was also noted that a meeting of your Radiation Safety Committee was conducted later in the morning of November 17, 1995, and that the Committee then approved the appointment of Martin Zloty, M.D., as the new Radiation Safety Officer at that meeting. Condition 23 of your license requires that your program be conducted in accordance with statements, representations, and procedures contained in your letter dated March 17, 1994. This letter stated that the Radiation Safety Committee consisted of a Chairman and eleven other members. 10 CFR 35.22(a)(3) requires that, to establish a quorum and to conduct business, at least one-half of the Committee's membership must be present, including the Radiation Safety Officer and the management's representative. The minutes of the Radiation Safety Committee meeting, conducted on-November 17, 1995, indicate that only five individuals were present and do not indicate the present of the Radiation Safety Officer; <u>AlMotice</u> of Yf01 ation is enclosed and categorizes each violation by severity

<u>level in accordance with the "General Statement of Policy and Procedure for</u> NRC Enforcement Actions," (Enforcement Policy), NUREG 1600, (60 FR 34381; June 30, 1995). 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.

Please use the enclosed self-addressed green envelope when you respond to this letter to assist us in the timely processing of your response. In accordance with Section 2.790 of NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and your reply will be placed in the Public Document Room (PDR). To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR 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. The responses directed by this letter and the accompanying Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

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Mr. E.F. Falast -3-Department of Veterans Administration Medical Center

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Your cooperation with us is appreciated.

Sincerely,

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Mohamed H. Shanbaky, Chief Nuclear Materials Safety Branch 2 ____Division_of Nuclear Materials Safety communications

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-Enclosures: 1. Notice of Violation 2. NRC Region I Inspection Report Number 030-14526/95-002

cc w/enclosures: Martin Zloty, M.D. Ann M. Lovell Commonwealth of Pennsylvania

Docket-No.-: 030-14526

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NOTICE OF VIOLATION

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Department of Veterans Affairs Medical Center University and Woodland Avenue Philadelphia, PA 19104 Docket No. 030-14526 License No. 37-00062-07

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During an NRC inspection conducted on November 17, 1995; violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG 1600, (60 FR 34381; June 30, 1995), the violations are listed below:

A. 10 CFR 35.13(c) requires in part that a licensee apply for and must receive a license amendment before it changes Radiation Safety Officers.

Contrary to the above, on November 17, 1995, the licensee changed its named Radiation Safety Officer, and, as of that date, the licensee had not received a license amendment authorizing the change.

This is a Severity Level <u>IV</u> violation (Supplement VI).

B. 10 CFR 35.21(a) requires that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are being performed in accordance with approved procedures. The licensee's designation of the membership of the Radiation Safety Committee are described in the letter dated March 17, 1994 and were approved by License Condition No. 23.

The letter dated Harch 17, 1994 states in response to Item No. 6 that the membership of the Radiation safety Committee consists of eleven members.

10 CFR 35.22(a)(3) requires that to establish a quorum and conduct business, at least one half of the Radiation Safety Committee's membership must be present, including the Radiation Safety Officer and the management's representative.

Contrary to the above, on November 17, 1995, the licensee's Radiation Safety Committee met and conducted business and the Radiation Safety Officer and half of the membership was not present.

This is a Severity Level <u>IV</u> violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Department of Veterans Affairs Medical Center, Philadelphia, Pennsylvania 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 vicition: (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

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Notice of Violation

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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.

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Because your response will be placed in the NRC Public Document Room (PDR), to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. 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 2.790(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.221.
