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

138 Action/Coordinate
W/Dr. Mendez,
Chairperson Radiation
Safety Cmte Action

September 11, 1997

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, Pennsylvania 19104

97 SEP 12 PM 2:45
VA MEDICAL CENTER
PHILADELPHIA, PA

SUBJECT: INSPECTION NO. 030-14526/96-002

Dear Mr. Falast:

On October 29, 31 and November 5, 6, 7, 13, 14, 19, and 20, 1996 and April 15, 16, 21, 22, and 29, and May 13, 1997, Messrs. Thomas K. Thompson and David Everhart of this office conducted a safety inspection at your facility in Philadelphia 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. The inspection consisted of observations by the inspector, interviews with personnel, and a selective examination of representative records. The findings of the inspection were discussed with you at the conclusion of the inspection.

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 and categorizes each violation by severity level in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG 1600. 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.

From our inspection of your facility we have concluded that your radiation safety organization could function better if communications and cooperation exists between management, the Radiation Safety Committee Chairman, radioactive material users and the Radiation Safety Officer. There is evidence that most of the violations identified during this inspection could have been avoided with better communication and cooperation at your facility. We continue to be concerned about the effectiveness of your management systems with regard to radiation safety matters. NRC is unable

to identify any appropriate attempts by VA management to address this problem even after the August 1996 Enforcement Conference in Region I and many visits to your facility in which these issues were identified and discussed with you. Although at this time the violations identified during this inspection were not of high safety significance we are concerned that further program degradation may occur if your organization does not take appropriate steps to improve communications, and cooperation between the management, RSC Chairman, radiological workers and the RSO. Consequently, in reply to this letter, you should address the root cause of these violations and the specific actions to be taken to correct each violation.

NRC will continue to closely monitor your program for compliance until we are confident that communications and cooperation have significantly improved.

Item E described in the enclosed Notice of Violation involves the storage and control of licensed material. The violation is classified at a Severity Level IV violation after careful consideration of the factors involved in this specific instance and in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) NUREG 1600. Specifically, this incident posed a minimal health and safety problem because it involved one laboratory with very small quantities of radioactive material and represents an isolated rather than a programmatic weakness in your radiation safety program. Similar violations of this type in the future may result in additional enforcement action.

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.

Your cooperation with us is appreciated.

Sincerely,

A. Randolph Blough, Director
Division of Nuclear Materials Safety

Docket No.: 030-14526
License No.: 37-00062-07

Enclosures:
1. Notice of Violation
2. Inspection Report No. 030-14526/96-002

cc w/enclosures:
Ann M. Lovell, RSO

Francis K. Herbig
Department of Veterans Affairs
Health Physics Programs (115HP)
915 North Grand Boulevard
St. Louis, MO 63106

Commonwealth of Pennsylvania

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NOTICE OF VIOLATION

Department of Veterans Administration
Medical Center
Philadelphia, Pennsylvania

Docket No. 030-14526

License No. 37-00062-07

During an NRC inspection conducted on October 29, 31 and November 5, 6, 7, 13, 14, 19, and 20, 1996 and April 15, 16, 21, 22, and 29, and May 13, 1997, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG 1600, the violations are listed below:

A. 10 CFR 19.11(a) and (b) require, in part, that the licensee post any notice of violation (NOV) involving radiological working conditions, or proposed imposition of civil penalty, and any response from the licensee.

10 CFR 19.11(e) requires, in part, that Commission documents posted pursuant to paragraph (a)(4) shall be posted within two working days after receipt of the documents from the Commission; the licensee's response, if any, shall be posted within two working days after dispatch by the licensee. Such documents shall remain posted for a minimum of five working days or until action correcting the violation has been completed, whichever is later.

Contrary to the above, the NOV dated January 4, 1996, the licensees' reply letters dated February 23, 1996, May 6, 1996, and the NOV and Proposed Imposition of Civil Penalty dated September 18, 1996, were not posted as of October 31, 1996 as required above.

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

B. 10 CFR 35.22(a)(5) requires that, the Radiation Safety Committee must promptly provide each member with a copy of the meeting minutes, and retain one copy for the duration of the license.

Contrary to the above, as of November 14, 1996, the licensee had not promptly provided each member of the Radiation Safety Committee with a copy of the meeting minutes for meetings that took place May 16, 1995, October 24, 1995, November 17, 1995, November 22, 1995 and December 19, 1995.

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

C. 10 CFR 35.50(d) requires, in part, that a licensee shall repair or replace the dose calibrator if the constancy error exceeds 10 percent.

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Contrary to the above, on July 9, 1996 and August 7, 1996, the licensee did not repair or replace the dose calibrator when the constancy test indicated an error exceeding 10 percent.

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

D. 10 CFR 35.92(b) requires that a licensee retain for three years a record of each disposal of byproduct material permitted under 10 CFR 35.92(a), and that the record include the date of the disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

Contrary to the above, on April 20, 30, May 6, June 28, July 17, 20 October 8, 10, and 17, 1996 the licensee's records of disposal of byproduct material permitted under 10 CFR 35.92(a) did not include the radionuclide disposed. On April 20, August 9, 22, September 27, October 1, 10, 17, and 21, 1996 the licensee's records of disposal of byproduct material permitted under 10 CFR 35.92(a) did not include the date of the disposal, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

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

E. 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 that 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 nor controlled by the licensee.

Contrary to the above, on or about November 7, 1996, the licensee did not secure from unauthorized removal or limit access to ten microcuries of Sulfur 35 located in a posted laboratory Room 314 which is a controlled area. The licensee did not control and maintain constant surveillance of this licensed material.

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

F. Condition 23 of License No. 37-00062-07 requires that licensed material be used in accordance with statements, representations and procedures contained in application dated January 22, 1991.

1. Item 10.1 of the application dated January 22, 1991, Medical Center Memorandum No. 00-134 as revised March 1994, page 2 requires that the

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licensee's RSC review on the basis of safety and approve or deny consistent with the limitations of the regulations all requests for use of radioactive materials.

Contrary to the above, as of May 13, 1997, the licensee did not have the RSC review on the basis of safety and approve or deny intramuscular administration of Xenon-133 which was being used.

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

2. Item 10.1 of the application dated January 22, 1991, Medical Center Memorandum No. 00-134 as revised March 1994, page 4, requires that the RSC meeting minutes upon approval and action of the Committee will be recorded, signed by the Chairperson and routed through appropriate channels for review and approval. The location where approved minutes will be maintained will be designated by the Director.

Contrary to the above, as of November 14, 1996, the licensee did not upon approval have the Chairperson sign and route through appropriate channels the RSC meeting minutes for 1995 and 1996. Additionally, as of November 7, 1996 the Director had not designated the location where approved minutes were maintained in 1995 and 1996.

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

3. Item 9.4 of the application dated January 22, 1991, Bioassay Program, page 3 requires that measurements of thyroid burden will be obtained for each individual who helped prepare or administer a therapeutic dosage of iodine 131 within three days after administering the dosage.

Contrary to the above, as of October 11, 1996, the licensee did not measure the thyroid burden of an individual who helped prepare and administer a therapeutic dosage of Iodine 131 on October 7, 1996. This exceeded the 3-day period.

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

4. Item 11.1 of the application dated January 22, 1991, page 1 of the application requires the licensee to follow Appendix R, of Regulatory Guide 10.8, Rev.1 for waste disposals by decay-in-storage.

Item 2, under the Model Procedure for Disposal by Decay-in-Storage requires the licensee to attach an identification tag to the waste that includes the date sealed, the longest-lived radioisotope in the container, and the initials of the person sealing the container.

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Contrary to the above, on February 7, and April 12, 1997, the licensee placed radioactive waste of Sr-89 (on February 7) and I-131 (on April 12) in storage for decay and did not attach an identification tag to the waste that includes the date sealed, the longest-lived radioisotope in the container, and the initials of the person sealing the container.

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

Pursuant to the provisions of 10 CFR 2.201, Department of Veterans Administration Medical Center 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.

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 73.21.

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