



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

June 9, 2008

Docket No. 03003297

License No. 45-00048-17

Brian Ohlinger, P.E.  
Associate Vice President for Facilities Management  
Virginia Commonwealth University (VCU)  
Office of Environmental Health & Safety  
P. O. Box 980112  
Richmond, VA 23298-0112

SUBJECT: INSPECTION 03003297/2008001, VIRGINIA COMMONWEALTH UNIVERSITY,  
RICHMOND, VIRGINIA SITE AND NOTICE OF VIOLATION

Dear Mr. Ohlinger:

On February 22 and April 8, 2008, Willie Lee of this office conducted a safety inspection of activities authorized by the above listed NRC license. The inspection was limited to a review of activities regarding the use of yttrium-90 microspheres. The inspection consisted of observations by the inspector, interviews with personnel, and a selected examination of representative records. The findings of the inspection were discussed with you and Dr. Dean Broga of your organization at the conclusion of the inspection on June 3, 2008.

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, including the revision of written procedures, 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.

Current NRC regulations are included on the NRC's website at [www.nrc.gov](http://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](http://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).

B. Ohlinger  
Virginia Commonwealth University

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Please contact Willie Lee at 610-337-5090 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:  
Dean W. Broga, Ph.D., Radiation Safety Officer  
Commonwealth of Virginia

B. Ohlinger  
Virginia Commonwealth University

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Please contact Willie Lee at 610-337-5090 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:  
Dean W. Broga, Ph.D., Radiation Safety Officer  
Commonwealth of Virginia

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D. J. Holody, RI

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DATE	06/09/08		06/12/08					

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## NOTICE OF VIOLATION

Virginia Commonwealth University  
Richmond, VA

Docket No. 03003297  
License No. 45-00048-17

During an NRC inspection conducted on February 22 and April 8, 2008, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 35.41(a)(2) requires that for any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.

Contrary to the above, the licensee failed to implement procedures for all written directives to provide high confidence that each procedure was in accordance with the written directive. Specifically, on February 20, 2008, the licensee did not implement written procedures that addressed precautions issued by the manufacturer of the yttrium-90 microspheres regarding mounting of the blue three-way stopcock in the proper direction relative to the dose vial, to ensure infusion of the microspheres into the patient. The blue three-way stopcock was mounted in a position opposite that which the manufacturer specifies in their written instructions, apparently causing crimping of the outlet line and the inability to deliver the prescribed dose documented in the written directive.

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

Pursuant to the provisions of 10 CFR 2.201, Virginia Commonwealth University 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  
Virginia Commonwealth University

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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 9 day of June 2008