



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

December 14, 2005

Docket No. 03003308  
EA-05-215-1

License No. 45-01589-01

M. Todd Way  
Vice President  
Valley Health System  
1840 Amherst Street  
Winchester, VA 22604

SUBJECT: INSPECTION 03003308/2005001, VALLEY HEALTH SYSTEM, WINCHESTER,  
VIRGINIA SITE AND NOTICE OF VIOLATION

Dear Mr. Way:

On August 4 through December 6, 2005, Willie Lee of this office conducted a safety inspection of activities authorized by the above listed NRC license. A site visit was conducted on August 4, 2005. The inspection was limited to a review of activities relative to the medical event involving the administration of Samarium-153, reported to the NRC Operations Center on July 26, 2005. Additional information provided by telephone conversation and facsimile during that time period by members of your staff was also examined as part of the inspection. The findings of the inspection were discussed with you, Teri Williams, Dana Hare, and Dan Cameron of your organization at the conclusion of the inspection on December 6, 2005.

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.

Current NRC regulations are included on the NRC's website at [www.nrc.gov](http://www.nrc.gov); select **Nuclear Materials; Medical, industrial, and academic uses of nuclear material; then toolkit index page**. The current Enforcement Policy is included on the NRC's website at [www.nrc.gov](http://www.nrc.gov); select **What We Do, Enforcement, then Enforcement Policy**. Or you may obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 9:00 p.m. EST, Monday through Friday (except Federal holidays).

M. Way  
Valley Health System

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Your cooperation with us is appreciated.

Sincerely,

***Original signed by Pamela J. Henderson***

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

Enclosure:  
Notice of Violation

cc:  
Dana Hare, M.S., Radiation Safety Officer  
Commonwealth of Virginia

M. Way  
Valley Health System

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**SISP Review Complete: WLee**

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## NOTICE OF VIOLATION

Valley Health System  
Winchester, VA

Docket No. 03003308  
License No. 45-01589-01

During an NRC inspection conducted on August 4 through December 6, 2005, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

- A. 10 CFR 35.41(a)(2) states, in part, 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, on July 22, 2005, the licensee did not implement and maintain written procedures to provide high confidence that each administration was in accordance with the written directive. Specifically, the licensee's written procedures for administration of Samarium-153 (Sm-153) did not contain the correct dose calibrator correction factor for assay of Sm-153. This resulted in an administration of Sm-153 to a patient that was not in accordance with the written directive,

This represents a Severity Level IV violation, Supplement VI.

Pursuant to the provisions of 10 CFR 2.201, Valley Health System 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, 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

Notice of Violation  
Valley Health System

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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 14 day of December 2005