



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

October 20, 2006

Docket No. 03003143

License No. 37-11562-01

Terry Biss  
Vice President  
Heritage Valley Health System  
1000 Dutch Ridge Road  
Beaver, PA 15009-9700

**SUBJECT:** INSPECTION 03003143/2006001, HERITAGE VALLEY HEALTH SYSTEM, BEAVER, PENNSYLVANIA SITE AND THE SEWICKLEY VALLEY HOSPITAL, SEWICKLEY, PENNSYLVANIA, AND NOTICE OF VIOLATION

Dear Mr. Biss:

On October 2, 3, and 4, 2006, Richard McKinley of this office conducted a safety inspection at the above address and the Sewickley Valley Hospital, 720 Blackburn Road, Sewickley, Pennsylvania 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 also examined the circumstances of two apparent medical events on September 1, 2006, and September 21, 2006. 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 others of your organization 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 that categorizes the violations by severity level. The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violation and prevent recurrence is already adequately addressed on the docket in the facsimile dated October 8, 2006. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

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 **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 8:00 p.m. EST, Monday through Friday (except Federal holidays).

T. Biss  
Heritage 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:  
Mark T. Perna, Radiation Safety Officer  
Commonwealth of Pennsylvania

T. Biss  
Heritage Valley Health System

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DATE	10/20/06		10/20/06				

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## NOTICE OF VIOLATION

Heritage Valley Health System  
Beaver, PA

Docket No. 03003143  
License No. 37-11562-01

During an NRC inspection conducted on October 2, 3, and 4, 2006, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 35.41(a)(2) states, 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 performed in accordance with the written directive.

Contrary to the above, the licensee did not develop, implement, nor maintain written procedures to provide high confidence that administrations requiring a written directive were performed in accordance with the written directive. For example, on September 1, 2006, a patient was prescribed 100 millicuries of iodine 131 but received 35.6 millicuries, an underdose of approximately 65%, which was not in accordance with the written directive. Additionally, on September 21, 2006, a patient was prescribed 25 millicuries of iodine 131 but received 5.3 millicuries, an underdose of approximately 80%, which was not in accordance with the written directive.

This a Severity Level IV violation (Supplement VI).

- B. 10 CFR 71.5(a) requires that a licensee who transports licensed material outside of the site of usage, as specified in the NRC license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 170 through 189.

49 CFR 173.421 states, in part, that a Class 7 (radioactive) material whose activity per package does not exceed the limits specified in 49 CFR 173.425 (limited quantity) and its packaging are exempted from the specification packaging, marking, labeling, and the shipping paper and certification requirements of this subchapter if they meet certain other requirements.

Contrary to the above, on September 2, 2006, and on September 22, 2006, the licensee shipped packages which exceeded the limits specified in 49 CFR 173.425 (limited quantity). The packages contained 70.4 millicuries and 20.7 millicuries, respectively, of iodine-131 in one capsule, activities each in excess of the normal form limited quantity of 19 millicuries for iodine-131.

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

Pursuant to the provisions of 10 CFR 2.201, Heritage 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 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 20 day of October, 2006