



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

December 22, 2005

Docket No. 03036131

License No. 37-30775-01

James Stuppino  
Director/Co-Owner  
Valley Advanced Gamma Knife, LLC  
2407 Butler Street  
Easton, PA 18042

SUBJECT: INSPECTION 03036131/2005001, VALLEY ADVANCED GAMMA KNIFE, LLC,  
EASTON, PENNSYLVANIA SITE AND NOTICE OF VIOLATION

Dear Mr. Stuppino:

On November 29, 2005, Penny Lanzisera, Shirley Xu and Michelle Simmons of this office conducted a safety inspection at the above address 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 selected examination of representative records. The findings of the inspection were discussed with Mr. Marc Miner and Drs. Cardiges and Chovanes 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 each 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).

J. Stuppino  
Valley Advanced Gamma Knife, LLC

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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:  
Marc Miner, Radiation Safety Officer  
Commonwealth of Pennsylvania

J. Stuppino  
Valley Advanced Gamma Knife, LLC

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DATE	12/14/05		12/14/05	12/16/05		

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## NOTICE OF VIOLATION

Valley Advanced Gamma Knife, LLC  
Easton, PA

Docket No. 03036131  
License No. 37-30775-01

During an NRC inspection conducted on November 29, 2005, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 35.635(b)(2) requires, that full calibration measurements on a gamma stereotactic radiosurgery unit include determination of the relative helmet factors.

Contrary to the above, as of November 29, 2005, the licensee's full calibration measurements of the gamma stereotactic radiosurgery unit did not include determination of the relative helmet factors.

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

- B. 10 CFR 35.645(d) requires, in part, that spot-checks on a gamma stereotactic radiosurgery unit include assuring proper operation of emergency off buttons before first use of the unit on a given day.

Contrary to the above, as of November 29, 2005, the licensee's daily spot-checks did not include the assurance of proper operation of emergency off buttons. Specifically, the licensee performed this check monthly instead of daily, as required.

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

Pursuant to the provisions of 10 CFR 2.201, Valley Advanced Gamma Knife, LLC 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.

Notice of Violation  
Valley Advanced Gamma Knife, LLC

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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 22 day of December 2005