



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

September 28, 2007

Docket No. 03002947

License No. 37-00358-04

William K. Wilkison  
Vice President, Ambulatory Care/Ancillary Services  
Pinnacle Health System Hospitals  
Department of Radiology  
111 South Front Street  
Harrisburg, PA 17105

**SUBJECT: INSPECTION 03002947/2006001, PINNACLE HEALTH SYSTEM HOSPITALS,  
HARRISBURG, PENNSYLVANIA SITE AND NOTICE OF VIOLATION**

Dear Mr. Wilkison:

On December 19-21, 2006, Tara Weidner of this office conducted a safety inspection at PinnacleHealth at Harrisburg Hospital, PinnacleHealth at Polyclinic Hospital, PinnacleHealth at Community General Osteopathic Hospital, PinnacleHealth Fredericksen Outpatient Center, and the George and Luella Bloom Diagnostic Outpatient Center, 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. Additional information provided in the telephone conversations on August 31, 2006 between Rebekah Tischbein, of your organization and this office and on September 4, 2007 between Adrian Oliver, Ph.D. of your organization and this office was also examined as part of the inspection. Preliminary findings of the inspection were discussed with yourself, Rebekah Tischbein, Radiation Safety Officer (RSO), and Joanne Hand, Radiology Director, of your organization on December 21, 2006. The final findings were discussed with Rebekah Tischbein, RSO 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, 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**

W. Wilkison  
Pinnacle Health System Hospitals

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**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).

Please contact Tara Weidner a 610-337-5272 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:  
Rebekah Tischbein, Radiation Safety Officer  
Commonwealth of Pennsylvania

W. Wilkison  
Pinnacle Health System Hospitals

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

Enclosure:  
Notice of Violation

cc:  
Rebekah Tischbein, Radiation Safety Officer  
Commonwealth of Pennsylvania

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**SUNSI Review Complete: TWeidner**

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## NOTICE OF VIOLATION

Pinnacle Health System Hospitals  
Harrisburg, PA

Docket No. 03002947  
License No. 37-00358-04

During an NRC inspection conducted on December 19-21, 2006, one violation of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 35.40 requires, in part, that a written directive for an administration of any therapeutic dose of radiation from byproduct material, (1) before implantation, be dated and signed by an authorized user and include the patient's name, treatment site, radionuclide and dose and (2) after implantation, but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).

Contrary to the above, on January 10, 2006 and March 2, 2006, written directives for the administration of therapeutic doses of radiation from byproduct material, before implantation, were not signed by an authorized user and did not include the treatment site and dose and after implantation, but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose). Specifically,

1. On January 10, 2006 a patient was implanted with 31 millicuries of Iodine-125 and the written directive did not include the treatment site and dose, prior to implantation.
2. On March 2, 2006, 29.5 millicuries of Iodine-125 was implanted in a patient and the written directive was not signed by the authorized user and the written directive did not contain the treatment site and dose prior to implantation.

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

Pursuant to the provisions of 10 CFR 2.201, Pinnacle Health System Hospitals 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 28th day of September 2007