



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

February 22, 2006

Docket No. 03003100
EA No. 06-033

License No. 37-07939-01

Lisa Dutterer
Associate Vice President
St. Luke's Hospital
801 Ostrum Street
Bethlehem, PA 18015

SUBJECT: INSPECTION 03003100/2005001, ST. LUKE'S HOSPITAL, BETHLEHEM,
PENNSYLVANIA SITE AND NOTICE OF VIOLATION

Dear Ms. Dutterer:

On August 9, 2005, Penny Lanzisera of this office conducted a safety inspection at the above address of activities authorized by the above listed NRC license. The inspection was limited to a review of your SIR-sphere program following a reported medical event involving SIR-spheres that occurred on July 26, 2005. Additional information provided in your correspondence dated November 7, 2005, and during telephone conversations conducted between September 2005 to January 2006 with Mr. Walter Robinson, your Radiation Safety Officer, and Ms. Margo Fisher, your nuclear medicine technologist, were also examined as part of the inspection. The findings of the on-site review were discussed with you on August 9, 2005, and with Mr. Walter Robinson at the conclusion of the inspection on February 3, 2006.

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. The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence is already adequately addressed on the docket in November 7, 2005. 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; 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; 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).

L. Dutterer
St. Luke's Hospital

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Your cooperation with us is appreciated.

Sincerely,

Original signed by Pamela Henderson

Pamela J. Henderson, Acting Deputy Director
Division of Nuclear Materials Safety

Enclosure:
Notice of Violation

cc:
Walter L. Robinson, Radiation Safety Officer
Commonwealth of Pennsylvania

L. Dutterer
St. Luke's Hospital

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OFFICE	DNMS/RI	N	DNMS/RI	ORA/RI		
NAME	Planzisera/PL		Phenderson/PDH	Dholody/JN f/		
DATE	02/21/06		02/21/06	02/21/06		

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NOTICE OF VIOLATION

St. Luke's Hospital
Bethlehem, PA

Docket No. 03003100
License No. 37-07939-01

During an NRC inspection conducted on August 9, 2005, and following review of additional information provided in a letter dated November 7, 2005, 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 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 July 26, 2005, a patient was prescribed 12.4 millicuries of yttrium-90 but, received 6.8 millicuries, an underdose of approximately 45%, which was not in accordance with the written directive.

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

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence and the date when full compliance will be achieved is already adequately addressed on the docket. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation," and send it 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).

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 22nd day of February 2006