



Sacred Heart Hospital

Affiliated with Sacred Heart HealthCare System

421 Chew Street, Allentown, PA 18102-3490
610-776-4500 • www.shh.org

March 6, 2006

U.S. Nuclear Regulatory Commission,
ATTN: Document Control Desk
Washington, DC 20555

Re: Reply to a Notice of Violation

License No: 37-00554-03
Docket No: 030-02961

To Whom It May Concern:

This is in response to your letter dated February 27, 2006 in regards to the "Notice of Violation". During an inspection here at Sacred Heart Hospital on January 31, 2006, a violation was identified. The violation occurred due to an increased demand on staff because of an equipment problem on the Nuclear Medicine camera and the need to continue to treat patients. Since the violation occurred, an automatic door closer was installed on the door on February 8, 2006. A punch lock was installed on the door to assure authorized individuals have access to the Hot Lab. All staff have been notified of the violation and have been reinstructed on radiation safety.

We hope you find this written response acceptable and we await your final inspection report.

Sincerely,

Belle A. Rodrigues
Director, Radiology and Nuclear Medicine

Enclosure: Copy of the Notice of Violation

BAR/dlc

Cc: Regional Administrator, Region I
Penny Lanzisera, Acting Chief Medical Branch NRC
Ralph Natale, Radiation Safety Officer, Sacre
Dennis Pfleiger, VP of Clinical Services, Sac



**Sacred Heart
HealthCare System**

Belle A. Rodrigues, R.T. (R)
Director, Radiology and Nuclear Medicine

421 Chew Street, Allentown, PA 18102
610-776-5309 • Pager: 610-606-3034
Fax: 610-776-4671 • brodrigu@shh.org • www.shh.org

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

February 27, 2006

Docket No. 03002961

License No. 37-00554-03

Belle A. Rodrigues
Director, Radiology and Nuclear Medicine
Sacred Heart Hospital
421 Chew Street
Allentown, PA 18102

SUBJECT: INSPECTION 03002961/2006001, SACRED HEART HOSPITAL, ALLENTOWN,
PENNSYLVANIA SITES AND NOTICE OF VIOLATION

Dear Ms. Rodrigues:

On January 31, 2006, Sandra Gabriel and Donna Janda of this office conducted a safety inspection at the above address and 325 North 5th Street, Allentown, 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 consisted of observations by the inspector, interviews with personnel, and a selected examination of representative records. Additional information provided in a telephone conversation on February 8, 2006 between Belle Rodrigues of your organization and this office was also examined as part of the inspection. The findings of the inspection were discussed with Dennis Pflieger, Vice President of Clinical Services, and other staff members 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 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; 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).

NOTICE OF VIOLATION

Sacred Heart Hospital
Allentown, PA

Docket No. 03002961
License No. 37-00554-03

During an NRC inspection conducted on January 31, 2006, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

- A. 10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas. 10 CFR 20.1802 requires that the licensee control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage. As defined in 10 CFR 20.1002, *controlled area* means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason; and *unrestricted area* means an area, access to which is neither limited nor controlled by the licensee.

Contrary to the above, on January 31, 2006, the licensee did not secure from unauthorized removal or limit access to technetium-99m and cesium-137 located in the Nuclear Medicine Department hot lab, which is an unrestricted area, nor did the licensee control and maintain constant surveillance of this licensed material. Specifically, the NRC inspectors observed the door to the Nuclear Medicine Department hot lab open and did not observe any licensee personnel in the vicinity of the hot lab.

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

Pursuant to the provisions of 10 CFR 2.201, Sacred Heart Hospital 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.

B. Rodrigues
Sacred Heart Hospital

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Your cooperation with us is appreciated.

Sincerely,

Original signed by Penny Lanzisera

Penny Lanzisera, Acting Chief
Medical Branch
Division of Nuclear Materials Safety

Enclosure:
Notice of Violation

cc:
Ralph Natale, Radiation Safety Officer
Commonwealth of Pennsylvania

Notice of Violation
Sacred Heart Hospital

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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 27th day of February 2006