



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

May 16, 2007

Docket Nos. 03002446  
03002465 (Terminated)

License Nos. 29-02114-03  
29-03047-01 (Terminated)

Patricia Peterson,  
President and Chief Executive Officer  
St. Mary's Hospital  
350 Boulevard  
Passaic, NJ 07055

**SUBJECT: INSPECTION 03002465/2007001, PBI REGIONAL MEDICAL CENTER,  
PASSAIC, NEW JERSEY SITE AND NOTICE OF VIOLATION**

Dear Ms. Peterson:

On January 30, 2007, Randolph Ragland and Michelle Simmons of this office conducted a safety inspection at the above address, with continued in-office review until May 16, 2007, of activities previously authorized by Passaic Beth Israel (PBI) Regional Medical Center, NRC License No. 29-03047-01. During the period of this inspection, St. Mary's Hospital, NRC License No. 29-02114-03, Amendment 52, acquired all assets and responsibilities for activities previously authorized under PBI's NRC license (29-03047-01). The inspection at PBI Regional Medical Center was an examination of 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 PBI Regional Medical Center's correspondence dated February 5, 2007, was also examined as part of the inspection. The findings of the inspection were discussed with Ms. Ann Marie Shears, Vice President PBI Regional Medical Center, Mr. Robert Lyons, PBI Regional Medical Center, Interim Chief Operating Officer, and Mr. Mark Belanich, PBI Regional Medical Center Radiation Safety Officer, at the conclusion of the onsite inspection on January 30, 2007, and with Ed Condit, St. Mary's Hospital, Vice President, Professional Services, and Mr. Mark Belanich of your staff at the conclusion of the inspection on May 16, 2007.

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.

**P. Peterson**  
St. Mary's Hospital

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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**. The current Enforcement Policy is included on the NRC's website at [www.nrc.gov](http://www.nrc.gov); select **About NRC, Organization & Functions, How We Regulate, Enforcement**, then **Enforcement Policy**. 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).

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:  
Charles Herbstman, Radiation Safety Officer  
Mark Belanich, PBI Regional Medical Center, Radiation Safety Officer  
State of New Jersey

**P. Peterson**  
St. Mary's Hospital

2

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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:  
Charles Herbstman, Radiation Safety Officer  
Mark Belanich, PBI Regional Medical Center, Radiation Safety Officer  
State of New Jersey

Distribution:  
D. J. Holody, RI

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**SUNSI Review Complete: RRagland**

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OFFICE	DNMS/RI	N	DNMS/RI		DNMS/RI	N		
NAME	MSimmons/ms		RRagland/rcr		Phenderson/pjh			
DATE	05/16/07		05/16/07		05/17/07			

OFFICIAL RECORD COPY

## NOTICE OF VIOLATION

St. Mary's Hospital  
Passaic, NJ

Docket Nos. 03002446 and 03002465 (terminated)  
License Nos. 29-02114-03 and 29-03047-01 (terminated)

During an NRC safety inspection conducted at Passaic Beth Israel Regional Medical Center, on January 30, 2007, with continued in-office review until May 16, 2007, three violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 30.34(h)(1) requires, in part, that each specific licensee notify the appropriate NRC Regional Administrator, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of Title 11 (Bankruptcy) of the United States Code by or against the licensee. The notification needs to include (1) the bankruptcy court in which the petition was filed, and (2) the date that the petition was filed.

Contrary to the above, PBI Regional Medical Center did not notify NRC immediately upon filing bankruptcy. Specifically, PBI Regional Medical Center filed chapter 11 bankruptcy on July 10, 2006, in the District Court of NJ, and did not notify the NRC Region I Regional Administrator, in writing, until the submittal of a letter dated February 5, 2007.

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

- B. 10 CFR 35.75(b) requires NRC licensees to provide individuals who have been administered unsealed byproduct material, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable (ALARA), if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem).

Contrary to the above, PBI Regional Medical Center did not provide individuals who had been administered unsealed byproduct materials, with written instructions on actions recommended to maintain doses to other individuals ALARA. Specifically, on May 20, 2005, and June 14, 2005, PBI Regional Medical Center administered patients with radioiodine in quantities in which it was likely that dose to other individuals would exceed 1 mSv (0.1 rem), and did not provide these individuals with specific written instructions on actions to maintain doses to others individuals ALARA.

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

- C. 10 CFR 35.75(c) requires licensees to maintain a record of the basis for authorizing the release of individuals who have been administered unsealed byproduct material in accordance with 10 CFR 35.2075(b).

Contrary to the above, PBI Regional Medical Center did not maintain a record of the basis for authorizing the release of the individuals who had been administered byproduct material as required by 10 CFR 35.2075. Specifically, on May 20, 2005, and June 14, 2005, PBI Regional Medical Center administered patients with radioiodine, in quantities exceeding 33 millicuries of radioiodine, and did not maintain a record of the basis for authorizing the release of the individuals in accordance with 10 CFR 35.2075.

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

Pursuant to the provisions of 10 CFR 2.201, St. Mary's 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.

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 16th day of May 2007