



**SHORE MEMORIAL  
HOSPITAL**

June 21, 2005

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

Reply to Notice of Violation  
License no. 29-116402-01

The required response to the violation cited in Docket No. 03002535 is as follows:

**Reason:**

- A. The nuclear medicine technologist did not follow our procedures for the proper execution of a written directive. The physician approved the dosage because it was within the dosage range that he normally prescribes.

**Corrective steps:**

- A. The technologist was re-educated on the proper procedures to follow for written directives.

**Corrective steps to avoid future occurrences:**

- A. We will continue to provide training for proper procedures for written directives during orientation and annual review. The physician has been instructed to carefully review the written directive prior to administration and to prescribe a dosage range when he feels that it is medically indicated.

**Date for full compliance:**

- A. Full compliance was achieved as of May 12, 2005.

Please contact Jonathan Law, RSO at (609) 652-3409 if there are any questions.

Sincerely,

Albert L. Gutierrez  
President/CEO  
Shore Memorial Hospital

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

June 16, 2005

Docket No. 03002535

License No. 29-11642-01

Albert L. Gutierrez  
President  
Shore Memorial Hospital  
1 East New York Avenue  
Somers Point,, NJ 08244

SUBJECT: INSPECTION 03002535/2005001, SHORE MEMORIAL HOSPITAL, SOMERS  
POINT, NEW JERSEY SITE AND NOTICE OF VIOLATION

Dear Mr. Gutierrez:

On May 20, 2005, Shirley Xu of this office conducted a special telephone inspection with several of your staff. The inspection was limited to review of a medical event reported by your staff to the NRC Operation Center on May 12, 2005. The specific event involved the administration of 14.8 mCi of iodine -131 to a patient scheduled to receive 12 mCi.

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 and the General Policy and Procedure for NRC Enforcement Actions are available at the NRC web site at <http://www.nrc.gov/materials/miau/mat-toolkits.html> and <http://www.nrc.gov/what-we-do/regulatory/enforcement> or 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).

Your cooperation with us is appreciated.

Sincerely,

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

A. Gutierrez  
Shore Memorial Hospital

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Enclosure:  
Notice of Violation

cc:  
Jonathan N. Law, Radiation Safety Officer  
State of New Jersey

## NOTICE OF VIOLATION

Shore Memorial Hospital  
Somers Point, NJ

Docket No. 03002535  
License No. 29-11642-01

During an NRC inspection conducted over the phone on May 20, 2005, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

- A. 10 CFR 35.41(a)(2) states that for any administration requiring a written directive, licensees are required to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.

Contrary to the above, the licensee did not implement written procedures to provide high confidence that each administration is in accordance with the written directive. Specifically, on May 11, 2005, a patient received a therapeutic dose of iodine-131 (I-131) that differed from the prescribed dose by 20% or more. The patient was scheduled to receive a dose of 12 millicuries (mCi) of I-131, but was administered 14.8 mCi which differs from the prescribed dose by 23%.

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

Pursuant to the provisions of 10 CFR 2.201, Shore Memorial 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.

Current NRC regulations and the General Policy and Procedure for NRC Enforcement Actions are available at the NRC web site at <http://www.nrc.gov/materials/miau/mat-toolkits.html> and

Notice of Violation  
Shore Memorial Hospital

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<http://www.nrc.gov/what-we-do/regulatory/enforcement>. Or 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). 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 16 day of June, 2005