



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

June 17, 2005

Docket No. 03002489

License No. 29-06750-01

Bruce Traub  
Vice President  
Princeton Healthcare System  
253 Witherspoon Street  
Princeton, NJ 08540

**SUBJECT: INSPECTION 03002489/2004001, PRINCETON HEALTHCARE SYSTEM,  
PRINCETON, NEW JERSEY SITE AND NOTICE OF VIOLATION**

Dear Mr. Traub:

On November 2, 2004, Sandy Gabriel and Shirley Xu of this office conducted a safety inspection at the above address 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. The findings of the inspection were discussed with members of your staff at the conclusion of the inspection. NRC continued a review of these findings through June 9, 2005.

During this inspection, it was noted that your staff performed an administration of I-131 sodium iodide requiring a written directive based on an electronic written directive generated in your hospital's electronic medical record system. This electronic order did not contain the authorized user's physical signature. Your staff believed that use of the electronic medical record system constituted use of an electronic written directive with an electronic signature. At the conclusion of the on-site inspection, your staff agreed to include a handwritten authorized user's signature in all future written directives.

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 reasons for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance was achieved is already adequately addressed on the docket. Therefore, you are not required to respond to this violation unless the description herein 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 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).

B. Traub  
Princeton Healthcare System

2

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:  
Robert B. Berger, M.D., Radiation Safety Officer  
Yale Bohn, General Counsel and VP of Medical Affairs  
State of New Jersey

B. Traub  
Princeton Healthcare System

3

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## NOTICE OF VIOLATION

Princeton Healthcare System  
Princeton, NJ

Docket No. 03002489  
License No. 29-06750-01

During an NRC inspection conducted on November 2, 2004, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 35.40(a) requires a written directive to be signed by an authorized user before the administration of I-131 sodium iodide greater than 30 microcuries.

Contrary to the above, a written directive was not signed by an authorized user before the administration of I-131 sodium iodide greater than 30 microcuries. Specifically, on October 18, 2004, licensee staff administered 103.6 millicuries of I-131 sodium iodide based on an electronic order that was not signed by an authorized user.

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

Pursuant to the provisions of 10 CFR 2.201, Princeton Healthcare System 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 <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

Notice of Violation  
Princeton Healthcare System

2

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 17th day of June 2005