



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

January 30, 2006

Docket No. 03002489  
EA 05-178

License No. 29-06750-01

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

SUBJECT: WITHDRAWAL OF NOTICE OF VIOLATION

Dear Mr. Traub:

This refers to the undated letter from your Radiation Safety Officer, Robert Berger, M.D., received August 12, 2005, in response to our letter and enclosed Notice of Violation (NOV) dated June 17, 2005. The NOV addressed administration of I-131 sodium iodide greater than 30 microcuries based on an electronic written directive that did not include the authorized user's physical signature.

Dr. Berger contested the NOV, stating that 10 CFR 35.5 allows for records to be stored electronically as long as there are electronic safeguards to prevent tampering and that NRC has no guidelines for electronic signatures. On September 8, 2005, we informed you that we were reviewing the issues raised in Dr. Berger's letter and would contact you with the results of our review. On October 11, 2005, Sandy Gabriel of this office visited your site and obtained further information about your use of the electronic medical record system to create written directives.

We have concluded that current NRC regulations are ambiguous on the issue of electronic signatures. The regulations do not preclude the use of electronic written directives, nor do they specifically require a handwritten signature on a written directive. Therefore, we are withdrawing the NOV attached to our letter dated June 17, 2005. Please note that we are reviewing the controls that constitute and define an adequate electronic signature and plan to inform the NRC medical licensees of these criteria in a future generic communication. In the interim, you should take any measures needed to assure that only an authorized user can sign a written directive.

Thank you for your cooperation.

Sincerely,

*/RA/*

George Pangburn, Director  
Division of Nuclear Materials Safety

B. Traub

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cc:

Robert Berger, M.D., Radiation Safety Officer  
State of New Jersey

B. Traub

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**SISP Review Complete: SGabriel**

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