



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

September 8, 2005

Docket No. 030-02489
EA 05-178

License No. 29-06750-01

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

SUBJECT: RESPONSE TO DISPUTED VIOLATION REGARDING THE USE OF AN
ELECTRONIC SIGNATURE ON A WRITTEN DIRECTIVE

Dear Mr. Traub:

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

In Dr. Berger's letter, he contested the NOV regarding Princeton HealthCare's electronic signature system, stating that 10 CFR 35.5 allows for records to be stored electronically as long as there are adequate safeguards to prevent tampering and that NRC has no guidelines for electronic signatures. We are reviewing the issues raised in Dr. Berger's letter and will contact you in the future with the results of our review.

In accordance with 10 CFR 2.309 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (The Public Electronic Reading Room).

Your cooperation with us is appreciated.

Sincerely,

Original signed by Francis Costello

George Pangburn, Director
Division of Nuclear Materials Safety

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

B. Traub

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