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REGION 1

2005 AUG 12 AM 11: 17

Redefining Care.

Regional Administrator
United State Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA 19406-1415

Docket No. 03002489 / 2004001

License No. 29-06750-01

Reply to Notice of Violation:

This is to inform you that we are contesting our Certificate of Violation. We contest on the grounds that the University Medical Center at Princeton has a well established electronic signature system in place with excellent safeguards in place that have functioned here for computerized Physician order entry and we believe it is a safe and effective method for the written directive.

Access to the electronic record is very restricted. One needs the following to gain access to the electronic record and authorize the administration of a radionuclide requiring the use of a written directive:

- Username
- Unique Access Code
- Unique Password that is changed every 180 days

Once at the computer screen for the written directive, the physician enters information including radionuclide, and dosage. The authorized user must accept the entry by way of a keystroke. Upon completion of the correct keystroke, the authorized user's name appears on the screen of the written directive. This serves as the electronic signature.

These written directives can be audited for up to three years after they are entered and the authorized user can make revisions to the written directive

10CFR35.5 does allow for records to be stored electronically as long as there are adequate safeguards to prevent tampering. We believe that we meet this condition.

There are no guidelines from the NRC for electronic signature. But we believe that we have a safe and effective method, using established CPOE procedures for written directives for I 131 treatments.

Sincerely,



Robert Berger, M.D.
Radiation Safety Officer

NMSS/RGNI MATERIALS-004

Princeton
HealthCare
System:

University
Medical
Center at
Princeton

Princeton
House
Behavioral
Health

Merwick
Rehab
Hospital &
Nursing
Care

Princeton
HomeCare
Services

Princeton
Surgical
Center

Princeton
Fitness
& Wellness
Center

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HealthCare
System
Foundation