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

September 12, 2005

Docket No. 03002960 License No. 37-00485-04
EA-05-133

Carl J. Seidl
Vice President
Reading Hospital and Medical Center
Sixth Avenue & Spruce Street
West Reading, PA 19612

SUBJECT: INSPECTION 03002960/2005001, READING HOSPITAL AND MEDICAL CENTER

Dear Mr. Seidl:

This letter refers to your August 16, 2005 correspondence, in response to our August 3, 2005 letter. Thank you for informing us of the corrective and preventive actions documented in your letter. With regards to your response in Items A.1 and B, we have no further questions. However, please note that the internal dose calculation for your I-131 Radionuclide Therapy Dose Calculation sheet should be in units of rem instead of millirem. With regards to your response in Item A.2, although we understand that you do not contest the violation, we noted that you raised additional questions and therefore, we offer the following clarifications:

1. Please note that 10 CFR 35.40 allows verbal revisions to written directives under certain circumstances, e.g., a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health. You should review 10 CFR 35.40 to ensure that your procedures written directives for prostate brachytherapy treatments is in accordance with the regulations.

2. Discussions with the authorized medical physicist (AMP) and an authorized user (AU) during the inspection indicated that the AMP would provide a partially completed written directive for intravascular brachytherapy treatments to the authorized user for his signature that did not include time, vessel diameter, and dose (i.e., first half of your form completed only). These remaining components of the written directive were decided during the treatment by the AU and documented by the AMP in the written directive sometime after leaving the cardiac cathertization laboratory. A paper audit of written directives would not have identified this practice.

   In addition, to assure security of radioactive material, 10 CFR 35.406 requires the licensee to maintain accountability for all brachytherapy sources at all times. Therefore, the licensee must record the number of sources removed from the vault, the number of sources implanted, and the number of sources returned to the vault. These records must be maintained according to the requirements in 10 CFR 35.2406.

3. The written directives for gliasite procedures conducted from February 18, 2003 to January 4, 2005, were reviewed during the inspection. For one written directive, the inspector noted that the activity administered was not included on the written directive. The AMP reviewed the written directive and other documentation for the treatment, determined the activity administered from another document, and corrected the written directive during the inspection. Therefore, a paper audit of written directives after the inspection would not have identified this issue.

Your corrective actions for all items will be examined during a future inspection of your licensed program.

Your cooperation with us is appreciated.

Sincerely,

Original signed by Pamela J. Henderson

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

cc:
Walter L. Robinson, Radiation Safety Officer
Commonwealth of Pennsylvania

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