Hospital
HIMA·San Pablo
Caguas

August 14, 2012

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James P. Dwyer, Chief
Medical Branch
Division of Nuclear Materials Safety
U.S Nuclear Regulatory Commission, Region I
2100 Renaissance Blvd, Suite 100
King of Prussia, PA 19406-2713

Docket No. 03030826

Docket No. 03030826
License No. 52-25019-01

SUBJECT: Written Statement Required For Inspection Report NO. 03030826/2012001

Dear Mr. Dwyer:

This letter is in reference to the two Severity Level IV violations found by Mr. Hector Bermudez on March 29, 2012 in our hospital HIMA San Pablo Caguas. We are submitting this statement as required.

In accordance with the NRC Enforcement Policy, the violation and the explanation are listed below:

A. 10 CFR 37.75(c) requires, in part that the licensee maintain a record of the basis for authorizing the release of individuals administered unsealed byproduct materials showing that the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 0.5 rem.

   Contrary to the above, as of march 29. 2012, the licensee did not maintain records of the bases for releasing individuals administered 125 and 150 millicuries of iodine-131 on March 7 and 9, 2012, respectively.

- During the inspection Mr. Carmelo Pérez showed Mr. Hector Bermudez that on the two cases found without the report showing the calculations for the dosage were In compliance with total effective dose equivalent and that they do not exceed 0.5 rem. Even though the calculation report was not found by Mr. Bermudez.

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- As a corrective measure to avoid this incident in the future Mr. Carmelo Pérez trained the immediate supervisor the proper method for calculating and reporting the dosage under Mr. Perez supervision. With this corrective action we will avoid future mistakes or that a patient receives a release without the proper calculations.

B. In reference to the brachytherapy violation cited by the inspector, a commissioning test was performed on the Prowess Brachytherapy Computer on August 12, 2012 with Software Brachy Pro v4.60 Build 3615 dated December 16, 2008. This report shows agreement within acceptable limits for a number of tests including dose from a point source at a series of distances from 0.5 to 7cm, the position o isodose lines relative to their corresponding dose values also over the range from 0.5 to 7cm., and dose volume tests to show that the calculated volumes agree with the known volumes. In addition the scaling of the ultrasound image and the transmission of that image to the Prowess computer were tested. These tests all had acceptable results, and therefore the system is approved for clinical use. Since this system has had the same software since installation, this set of tests also confirms that the system has been correct for patient use since the initial installation.

Please contact Mr. Carmelo Pérez at (787) 432-9320 if you need additional information regarding this matter.

Sincerely,

Claudia V. Guzmán-Rivera, J.D., M.H.S.A.
Hospital HIMA San Pablo-Caguas
P.O. Box 4980
Caguas P.R. 00726-4980