



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

May 25, 2006

Docket No. 03034175  
CAL No. 1-05-003

License No. 52-11832-02

Elyonel Pontón  
Director of Finance and Operations  
Hospital Andrés Grillasca, Inc.  
P. O. Box 1324  
Ponce, PR 00733-1324

SUBJECT: CLOSURE OF CONFIRMATORY ACTION LETTER NO. 1-05-003

Dear Sr. Pontón:

On November 29, 2005, a representative of Hospital Andrés Grillasca, Inc. notified the NRC of a medical event in which a patient received less than 50% of the intended dose during a high dose rate remote afterloader (HDR) fractionated treatment. On December 5, 2005, the NRC issued Confirmatory Action Letter (CAL) No. 1-05-003, delineating certain actions that you had taken or were planning to take in response to that medical event, including plans to cease HDR treatments. On December 8, 2005, and March 8, 2006, respectively, the NRC issued Revision 1 and Revision 2 to the CAL documenting additional and revised commitments, which included plans to treat five additional patients with the HDR.

In two letters, dated March 20, 2006, you submitted your written procedures for compliance with 10 CFR 35.41(b) to assure that HDR treatments are performed in accordance with the written directive, described the contractual agreement with Dr. Correa and Sr. Miguel Rios for continuation of HDR treatments at your facility, submitted a license amendment request to remove the authorized users and authorized medical physicist no longer involved with your program, and submitted a written agreement signed by Dr. Correa indicating that he agrees to continue in his role as Radiation Safety Officer. In addition, on March 21, 2006, the NRC conducted an inspection at your facility and found that all the commitments listed in CAL 1-05-003 have been met. Therefore, no further response is required regarding the CAL. Since you have submitted the information required by the CAL and have taken action to resolve other issues raised during the inspection on March 21, 2006, you may resume HDR treatments without restriction.

Thank you for informing us of the actions documented in your letters. These actions may be examined during a future inspection of your licensed program. Our review of the circumstances surrounding the medical event is continuing and will be addressed in separate correspondence. Your cooperation with us is appreciated.

Current NRC regulations and the NRC Enforcement Policy are available at the NRC web site at <http://www.nrc.gov/materials/miau/mat-toolkits.html> and <http://www.nrc.gov/what-we-do/regulatory/enforcement> or by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 9:00 p.m. EST, Monday through Friday (except Federal holidays).

Sincerely,

***Original signed by George Pangburn***

George Pangburn, Director  
Division of Nuclear Materials Safety

cc:  
Commonwealth of Puerto Rico

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