



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

March 8, 2006

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

License No. 52-11832-02

Elyonel Pontón  
Finance Manager  
Hospital Andrés Grillasca, Inc.  
P.O. Box 1324  
Ponce, PR 00733-1324

**SUBJECT: CONFIRMATORY ACTION LETTER NO. 1-05-003, REVISION 2**

Dear Sr. Pontón:

On December 2, 2005, you informed the NRC Region I Office that you had stopped using the high dose-rate remote afterloader (HDR) unit listed on your license; did not plan to use the HDR unit; and intended to transfer the unit. You also informed the NRC that the HDR authorized users were no longer associated with your hospital, including an authorized user that was listed as your Radiation Safety Officer. Based on these statements, the NRC Region I Office issued Confirmatory Action Letter No. 1-05-003 to you on December 5, 2005, which documented these commitments along with your commitments concerning followup to a medical event that occurred at your facility on November 22, 2005. On December 8, 2005, the NRC issued Revision 1 to the Confirmatory Action Letter to allow completion of HDR treatment for three patients. We understand that the last of the treatments for these three patients was performed on January 31, 2006. The Confirmatory Action Letter also documented your commitment to perform an audit of all HDR treatments conducted at your facility within the past year to confirm that dose calculations were accurate and treatments were conducted in accordance with the written directive. We received a copy of the audit results via electronic mail on February 3, 2006, indicating that no additional medical events were identified during your audit. We will review these results during an upcoming inspection of your facility.

On March 6, 2006, you submitted a written request to the NRC Region I Office to resume HDR treatments at your facility. In your request, you indicated that you have identified two patients that require HDR treatment and these patients do not have the resources to commute to San Juan, Puerto Rico for treatment. You also requested authorization to resume HDR treatments at your facilities until the HDR unit is relocated to another authorized location by the previous consulting group, Radiation Oncology Group, who owns the HDR unit. On March 6, 2006, you informed us that you have an interim agreement in place to allow one member of the previous consulting group, Dr. Correa, to continue HDR treatments at your facility pending completion of construction and application for an NRC license for a new HDR facility in Ponce, Puerto Rico. Based on these statements, we understand that you do not currently intend to amend your NRC license to place the HDR unit into storage only status, with intent to transfer or appoint a new Radiation Safety Officer.

Pursuant to a telephone conversation between you and Penny Lanzisera, Acting Chief of the Medical Branch in this office on March 7, 2006, it is our understanding that you have taken, or will take, the following actions, which will be completed by the dates specified:

- 1) Conduct a course of HDR treatment for the two patients referenced in your letter dated March 6, 2006.
- 2) Refrain from initiating HDR treatment for any patients, other than the two patients described above, pending (a) completion of an NRC inspection to review your corrective actions taken in response to the medical event that occurred on November 22, 2005, and (b) closure of this Confirmatory Action Letter.
- 3) Submit your written procedures for compliance with 10 CFR 35.41(b) to assure that future HDR treatments are performed in accordance with the written directive. These procedures will be submitted to the NRC Region I Office within 14 days of the date of this letter.
- 4) Describe the contractual agreement with Dr. Correa and Sr. Miguel Rios for continuation of HDR patient treatments at your facility. This information will be submitted to the NRC Region I Office within 14 days of the date of this letter.
- 5) Submit a license amendment removing the authorized users and authorized medical physicists no longer involved with your licensed program (e.g., Drs. Sallaberry and Remedios; Sr. Randall). This amendment request will be submitted to the NRC Region I Office within 14 days of the date of this letter.
- 6) Submit the written agreement signed by Dr. Correa indicating that he agrees to continue in his role as your Radiation Safety Officer. This agreement will be submitted to the NRC Region I Office within 14 days of the date of this letter.

Pursuant to Section 182 of the Atomic Energy Act, 42 U.S.C. 2232, you are required to:

- 1) Notify me immediately if your understanding differs from that set forth above;
- 2) Notify me if for any reason you cannot complete the actions within the specified schedule and advise me in writing of your modified schedule in advance of the change; and
- 3) Notify me in writing when you have completed the actions addressed in this Confirmatory Action Letter.

Issuance of the initial Confirmatory Action Letter dated December 5, 2005, Revision 1 to the Confirmatory Action Letter dated December 8, 2005, and this second revision to the Confirmatory Action Letter do not preclude issuance of an order formalizing the above commitments or requiring other actions on the part of the licensee, nor does it preclude the NRC from taking enforcement action for violations of NRC requirements that may have prompted the issuance of this letter. In addition, failure to take the actions addressed in this Confirmatory Action Letter may result in enforcement action.

Current NRC regulations are included on the NRC's website at [www.nrc.gov](http://www.nrc.gov); select **Nuclear Materials; Medical, industrial, and academic uses of nuclear material; then toolkit index page**. The current NRC Enforcement Policy is included on the NRC's website at [www.nrc.gov](http://www.nrc.gov); select **What We Do, Enforcement**, then **Enforcement Policy**. Or you may obtain these documents 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).

To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

Sincerely,

*/RA/*

George Pangburn, Director  
Division of Nuclear Materials Safety

cc:  
Commonwealth of Puerto Rico

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Sincerely,  
*/RA/*  
 George Pangburn, Director  
 Division of Nuclear Materials Safety

cc:  
 Commonwealth of Puerto Rico

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