



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

December 5, 2005

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

License No. 52-11832-02

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

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

Dear Sr. Ponton:

On November 29, 2005, your organization reported to the NRC that your staff identified a medical event that occurred at your facility on November 22, 2005. Your organization determined that a high dose rate remote afterloader (HDR) treatment was delivered to a patient based on a dose calculation performed to a depth of one centimeter rather than to the prescribed depth of two centimeters. As a result, the dose delivered to the intended treatment site was approximately 290 cGy rather than the intended 600 cGy. This event, which occurred during the delivery of the third of five treatment fractions, was discovered on the date of the fourth treatment fraction, November 29, 2005, after your staff noticed the difference in treatment times between the third and fourth fractions. In response to your reporting of the event, the NRC conducted an inspection on November 30, 2005, during which our inspector discovered that you did not have the written procedures required by 10 CFR 35.41 to provide high confidence that each HDR treatment administration is in accordance with the written directive (physician's prescription).

On December 2, 2005, you informed the NRC Region I Office that you have stopped use of the HDR unit; do not plan future use of the HDR unit, and therefore have placed it in safe storage; and intend to transfer the radioactive sources associated with the HDR unit. You also informed the NRC that the HDR authorized users (AUs) are no longer associated with your hospital. Since one of the AUs listed on your license was also the Radiation Safety Officer (RSO), you no longer have an RSO at your facility.

Pursuant to a telephone conversation between you and Pamela Henderson, Chief of the Medical Branch in this office on December 2, 2005, it is our understanding that you have taken, or will take, the following actions, which will be completed by the dates specified:

- 1) Submit to the NRC a license amendment request to:
  - a) Change the HDR unit to storage only status, with intent to transfer.
  - b) Delete from the license the AUs who are no longer associated with your hospital.

- c) Appoint a new RSO, who meets the requirements of 10 CFR 35.50 and agrees, in writing, to be responsible for implementing the radiation protection program.

This amendment request will be submitted to the NRC Region I office within seven days of the date of this letter.

- 2) Transfer the HDR unit's radioactive sources to an authorized recipient. This transfer will be completed within 90 days of the date of this letter and documentation of the transfer will be submitted to the NRC Region I office within seven days of the completion of the transfer.
- 3) 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.

This audit will be completed within 60 days of the date of this letter and a written report documenting the audit results will be submitted to the NRC Region I Office within 15 days of the completion of the audit.

- 4) Pursuant to 10 CFR 35.3045(c), notify by telephone the NRC Operations Center [(301)951-0550] no later than the next calendar day after the discovery of any additional medical events.
- 5) Pursuant to 10 CFR 35.3045(d), submit to the NRC a 15-day, written report for any identified medical event, including all the information required by 10 CFR 35.3045(d)(1) and (2).

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 this Confirmatory Action Letter does 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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OFFICE	ORA/	ORA/	DNMS /	NMSS
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DATE	12/5/05	12/5/05	12/5/05	12/2/05