July 21, 2006

EA No. 06-125

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

SUBJECT: NOTICE OF VIOLATION (NRC Inspection Report No. 03034175/2005001)

Dear Sr. Pontón:

This letter refers to the NRC special inspection conducted at your facility in Ponce, Puerto Rico, on November 30, 2005, and March 21, 2006, in response to a medical event which occurred on November 22, 2005, and reported to the NRC on November 29, 2005. The inspection also included in-office reviews of additional information you provided the NRC through April 20, 2006, including information provided in response to a Confirmatory Action Letter (CAL) sent on December 5, 2005, and revisions dated December 8, 2005, and March 8, 2006, respectively. The results of the inspection were discussed with you and members of your staff during an exit meeting on June 1, 2006, and were described in a letter and subject inspection report dated June 6, 2006.

In your November 29, 2005, report, you indicated 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 from the sources rather than to the prescribed depth of two centimeters from the sources. As a result, the dose delivered to the prescribed depth of two centimeters was 259 centigray rather than the prescribed 600 centigray. This event occurred during the third of five prescribed treatment fractions, and was discovered during the fourth treatment fraction when your staff noted a discrepancy between the calculated treatment times for the third and fourth fractions. The failure to implement the written procedures developed to ensure that doses are administered in accordance with the treatment plan contributed to this medical event.

Based on the information developed during the inspection, the NRC has determined that five violations of NRC requirements occurred. The violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report. The most significant violation involved the failure to implement written procedures, as required by 10 CFR 35.41(a), to ensure that the treatment was in accordance with the written directive. During a telephone conversation on June 1, 2006, Ms. Pamela Henderson of my staff informed you that this violation was being considered for escalated enforcement action. The NRC provided you an opportunity to attend a predecisional

enforcement conference or to provide a written response, prior to the NRC determining appropriate enforcement action. During this telephone conversation, you declined the opportunity to attend a conference or to provide a written response.

You determined that the delivered dose to the patient, that resulted from your staff's dose calculation error, did not result in any adverse health effects. Nonetheless, if your staff involved with the HDR treatment had followed the written procedures developed to ensure that doses are administered in accordance with the treatment plan, the error and resultant medical event might have been precluded. Since your entire staff involved with HDR treatments were not aware of these procedures and, therefore, were not using them, the NRC concluded that this is a programmatic weakness in your HDR program and, therefore, this violation is categorized at Severity Level III in accordance with Supplement VI.C.5 of the Enforcement Policy.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of $3,250 is considered for a Severity Level III violation. Because your facility has not been the subject of escalated enforcement action within the last two years or two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section VI.C.2 of the Enforcement Policy. Credit for corrective actions is warranted because your corrective actions were considered prompt and comprehensive. These corrective actions, which you described during the inspection and in response to the CAL and its revisions, included, but were not limited to: (1) completing all commitments described in the CAL which included, in part, ensuring that your procedures comply with the requirements of 10 CFR 35.41(b) and that future HDR treatments would be delivered in accordance with these requirements; (2) conducting an audit of the HDR program to determine whether additional medical events occurred; and (3) updating the written directive form to include all requirements in 10 CFR 35.40(b).

Therefore, to encourage prompt and comprehensive correction of violations and in recognition of the absence of previous escalated enforcement action, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, you should be aware that significant violations in the future could result in a civil penalty. In addition, issuance of this Severity Level III violation constitutes escalated enforcement action that may subject you to increased inspection effort.

The four additional violations identified as a result of the inspection are included in the enclosed Notice and are categorized at Severity Level IV in accordance with Supplement VI.D of the Enforcement Policy.

The NRC has concluded that information regarding the reasons for the violations, the corrective actions taken to correct the violations and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed in this letter; in additional information you provided in two letters dated March 20, 2006, in response to the CAL and its revisions; and in the inspection report issued on June 6, 2006. Therefore, you are not required to respond to these violations unless those descriptions herein do not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response (if you choose to provide one) will be made available

electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html (the Public Electronic Reading Room). To the extent possible, your response should not include any personal privacy, proprietary or safeguards information so that it can be made available to the public without redaction. The NRC also includes significant enforcement actions on its web site at http://www.nrc.gov; select What We Do, Enforcement, then Significant Enforcement Actions.

Sincerely,

/RA/

Samuel J. Collins
Regional Administrator

Docket No. 030-34175
License No. 52-11832-02

Enclosure: Notice of Violation

cc:
Dr. José N. Correa, Radiation Safety Officer
Commonwealth of Puerto Rico

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response (if you choose to provide one) will be made available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html (the Public Electronic Reading Room). To the extent possible, your response should not include any personal privacy, proprietary or safeguards information so that it can be made available to the public without redaction. The NRC also includes significant enforcement actions on its web site at http://www.nrc.gov; select What We Do, Enforcement, then Significant Enforcement Actions.

Sincerely,

/RA/

Samuel J. Collins
Regional Administrator

Docket No. 030-34175
License No. 52-11832-02

Enclosure: Notice of Violation

cc:
Dr. José N. Correa, Radiation Safety Officer
Commonwealth of Puerto Rico

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ENCLOSURE

NOTICE OF VIOLATION

Hospital Andrés Grillasca, Inc.
Ponce, Puerto Rico

Docket No. 030-34175
License No. 52-11832-02
EA No. 06-125

Based on the special NRC inspection conducted at the Hospital Andrés Grillasca in Ponce, Puerto Rico on November 30, 2005, and March 21, 2006, as well as reviews in the Region I office of additional information provided to the NRC, including information provided in your March 20, 2006, responses to the Confirmatory Action Letter and its revisions, five violations of NRC requirements were identified. The violations were discussed at an exit meeting on June 1, 2006. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. 10 CFR 35.41(a) states, in part, that for any administration requiring a written directive, licensees are required to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. These procedures must, in part, address verifying that the administration is in accordance with the treatment plan and written directive, and checking both manual and computer-generated dose calculations.

Contrary to the above, prior to November 30, 2005, the licensee did not implement written procedures to provide high confidence that each administration is in accordance with the written directive, including verifying that the administration is in accordance with the treatment plan and written directive and checking both manual and computer-generated dose calculations. Specifically, although the licensee had submitted to the NRC written procedures to provide high confidence that each high dose-rate remote afterloading brachytherapy treatment is delivered in accordance with the written directive, licensee personnel involved with HDR treatments were not aware of these procedures and, therefore, were not implementing the requirements of these procedures. As a result, on November 22, 2005, the licensee failed to verify that a high dose-rate remote afterloading brachytherapy treatment was administered in accordance with the written directive in that the dose was calculated and delivered to a depth of one centimeter rather than the prescribed two centimeters, resulting in a 57% underdose for that treatment fraction.

This is a Severity Level III violation (Supplement VI).

B. 10 CFR 35.40(b) requires, in part, that the written directive for high dose-rate remote afterloading brachytherapy must contain the patient or human research subject's name and the following information: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose.

Contrary to the above, prior to November 2005, the licensee's written directives did not contain the information specified in 10 CFR 35.40(b). Specifically, the written directives for high dose-rate remote afterloading brachytherapy did not include the radionuclide, dose per fraction for the full course of treatment, and total dose.

This is a Severity Level IV violation (Supplement VI).

C. 10 CFR 35.633(b) requires, in part, that full calibration measurements of high dose-rate remote afterloader units include determination of timer accuracy and linearity over the typical range of use.

Contrary to the above, prior to March 21, 2006, the licensee's full calibration measurements of the high dose-rate remote afterloader unit did not include determination of timer accuracy and linearity over the typical range of use.

This is a Severity Level IV violation (Supplement VI).

D 10 CFR 35.643(d)(6) requires, in part, that spot-checks of remote afterloader units be performed to assure, in part, proper operation of timer accuracy.

Contrary to the above, prior to March 21, 2006, the licensee performed spot-checks before the first use of a high dose-rate remote afterloader unit on a given day, but did not include a check of timer accuracy.

This is a Severity Level IV violation (Supplement VI).

E. 10 CFR 35.630(a) requires, in part, that (1) the dosimetry system must have been calibrated within the previous two years, or (2) the system must have been calibrated within the previous four years and, 18 to 30 months after that calibration, the system must have been intercompared with another dosimetry system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM.

Contrary to the above, prior to March 21, 2006, the licensee performed full calibration measurements using a dosimetry system that was (1) not calibrated within the previous two years, and (2) although the system had been calibrated within the previous four years, the system had not been intercompared with another dosimetry system eighteen to thirty months after that calibration with a system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. Specifically, on October 18, 2005, the licensee performed full calibration measurements using a dosimetry system that was last calibrated on September 5, 2003, but, as of March 21, 2006, the dosimetry system had not been intercompared with another dosimetry system that was calibrated within the past 24 months.

This is a Severity Level IV violation (Supplement VI).

The NRC has concluded that information regarding the reasons for the violations, the corrective actions taken to correct the violations and prevent recurrence, and the date when full compliance was achieved is already adequately addressed in this letter, in additional information you provided in two letters dated March 20, 2006, in response to the CAL and its revisions; and in the inspection report issued on June 6, 2006. Therefore, no response to this Notice is required. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, EA-06-125" and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you contest the violations, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, D.C. 20555. Under authority of Section 182 of the Act, 42 U. S. C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Because any response will be made available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS), to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html (the Public Electronic Reading Room). 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).

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 21st day of July 2006