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

June 6, 2006

Docket No. 03034175 License No. 52-11832-02
EA No. 06-125

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

SUBJECT: HOSPITAL ANDRÉS GRILLASCA, INC. - NRC SPECIAL INSPECTION REPORT NO. 03034175/2005001

Dear Sr. Pontón:

This refers to the NRC inspection conducted on November 30, 2005, and March 21, 2006, to review the circumstances surrounding a medical event which occurred on November 22, 2005, and was reported to the NRC on November 29, 2005. Followup information provided through April 20, 2006, was also examined as part of this inspection. The enclosed report presents the results of this inspection which were discussed with you at the conclusion of the inspection on June 1, 2006.

Based on the results of this inspection, one apparent violation was identified that is being considered for escalated enforcement. This violation involved the failure to develop, implement and maintain written procedures to provide high confidence that each high dose rate remote afterloader (HDR) administration is in accordance with the written directive. In addition, four apparent violations were identified that are not being considered for escalated enforcement. These violations involved the failure to: (1) include all required information in HDR written directives, (2) determine timer accuracy and linearity over the range of use during HDR full calibration measurements, (3) assure proper operation of timer accuracy during HDR spot checks, and (4) calibrate the HDR dosimetry system as required. The circumstances surrounding these apparent violations, the significance of the issues, and the need for lasting and effective corrective action were discussed with you at the conclusion of the inspection.

On June 1, 2006, Ms. Pamela Henderson, of my staff, informed you that the violation was being considered for escalated enforcement action, and the NRC did not need any additional information to make an enforcement decision. However, Ms. Henderson provided you an opportunity to attend a predecisional enforcement conference or to provide a written response, prior to the NRC determining the appropriate enforcement action. From this conversation we understand that you declined the opportunity to attend a conference or provide a written response. You will be advised by separate correspondence of the results of our deliberations on this matter.

Current NRC regulations are included on the NRC's website at 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;

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.

Sincerely,

/RA/

George Pangburn, Director
Division of Nuclear Materials Safety

Enclosure:
Inspection Report No. 03034175/2005001

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

DISTRIBUTION w/encl:
ADAMS (PARS)
SECY
CA
OEMAIL
OEWEB
L Reyes, EDO
M Virgilio, DEDMRS
M Johnson, OE
B Jones, OGC (Bradley)
L Chandler, OGC
J Strosnider, NMSS
C Miller, NMSS
A. Kock, OEDO
G Morell, NMSS
Enforcement Coordinators
RII, RIII, RIV
S Figueroa, OE
M Elwood, OGC
S Gagner, OPA
H Bell, OIG
J Schlueter, STP
G Caputo, OI
L Tremper, OCFO
D Screnci, PAO-RI
N Sheehan, PAO-RI
G Pangburn, RI
F Costello, RI
DNMS Branch Chief
K Farrar, RI
D Holody, RI
J Wray, RI
R Summers, RI
C O'Daniell, RI
S. Villar, RI
Region I OE Files (with concurrences)

DOCUMENT NAME: C:\MyFiles\Copies\L52-11832-02.2005001.wpd

SISP Review Complete: HBermudez
After declaring this document "An Official Agency Record" it **will** be released to the Public.

To receive a copy of this document, indicate in the box: "**C**" = Copy w/o attach/encl "**E**" = Copy w/ attach/encl "**N**" = No copy

OFFICE	DNMS/RI	N	DNMS/RI		DNMS/RI		ORA/RI	DNMS/RI	
NAME	Hbermudez via email		Sgabriel		Phenderson PAN		Wray	GPangburn	
DATE	6/1/06		6/5/06		6/5/06		6/6/06	6/6/06	

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

EA No.	06-125
Inspection No.	03034175/2005001
Docket No.	03034175
License No.	52-11832-02
NMED No.	050778
Licensee:	Hospital Andrés Grillasca, Inc.
Location:	P.O. Box 1324 Ponce, Puerto Rico
Inspection Dates:	November 30, 2005 and March 21, 2006; by telephone June 1, 2006
Dates Followup Information Received:	December 10, 2005 February 3, March 6, March 20, March 31, and April 20, 2006

Inspectors:

Original signed by: HBermúdez ***June 5, 2006***

Héctor Bermúdez — date
Senior Health Physicist

Original signed by: SGabriel ***June 5, 2006***

Sandra Gabriel — date
Senior Health Physicist

Approved By:

Original signed by PLanzisera ***June 5, 2006***

Pamela J. Henderson, Chief — date
Medical Branch
Division of Nuclear Materials Safety

Document Name: C:\MyFiles\Copies\L52-11832-02.2005001.wpd

EXECUTIVE SUMMARY

Hospital Andrés Grillasca, Inc.
NRC Inspection Report No. 03034175/2005001

A reactive inspection was performed to follow up on the licensee's notification, on November 29, 2005, of a medical event that occurred on November 22, 2005. An additional on-site inspection was conducted on March 21, 2006 to observe a high dose rate remote afterloader (HDR) treatment and follow up on the licensee's actions taken in response to the issuance of a Confirmatory Action Letter (CAL).

The medical event involved a HDR treatment that was delivered to a patient based on a dose calculation performed to a depth of 1 centimeter (cm) from the tandem rather than to the prescribed depth of 2 cm from the tandem. As a result, the dose delivered to the prescription depth 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 staff noticed a discrepancy between the calculated treatment times for the third and fourth treatments.

Within the scope of this inspection, five apparent violations of NRC regulations were identified:

- The licensee did not develop, implement, and maintain written procedures to provide high confidence that each HDR administration is in accordance with the written directive.
- The licensee's HDR written directives did not contain all of the information required by 10 CFR 35.40(b).
- HDR full calibration measurements did not include determination of timer accuracy and linearity over the range of use.
- HDR periodic spot-checks did not assure proper operation of timer accuracy.
- The HDR dosimetry system used for the most recent full calibration was not calibrated within the previous two years. Although it had been calibrated within the previous four years, it had not been intercompared within 18 to 30 months with another dosimetry system that was calibrated within the past 24 months.

REPORT DETAILS

I. Organization and Scope of the Program

a. Inspection Scope

The inspection was limited to a review of licensed activities surrounding a medical event that occured on November 22, 2005, involving the licensee's HDR therapy program. The inspectors toured the licensee's HDR facility, interviewed personnel, and reviewed records.

b. Observations and Findings

License number 52-11832-02 authorizes Hospital Andrés Grillasca to use byproduct materials for medical purposes, including use of sealed sources for HDR brachytherapy. The licensee has performed HDR treatments for gynecological cancers since 1999. Current physics staffing is by a consultant authorized medical physicist (AMP) who comes on-site on the days HDR patients are scheduled. HDR treatments are typically performed one day per week, in the late afternoon and early evening. In calendar year 2005, the licensee treated 39 patients in 151 HDR fractions, with the number of patients per day ranging from one to seven.

c. Conclusions

Licensed activities were limited to the activities authorized by NRC License No. 52-11832-02. No safety concerns were identified.

II. Review of the Medical Event

a. Inspection Scope

The inspectors toured the licensee's HDR facility, interviewed individuals to gain information about the medical event, reviewed the written directive and other records of the patient treatment, and reviewed the licensee's medical event report dated December 6, 2005 (ADAMS Accession No. ML061440433).

b. Observations and Findings

From the interviews and review of records, a chronology of events was developed:

- On November 8 and 15, 2005, following completion of a course of external beam radiation therapy, the patient received the first two of a series of five HDR treatment fractions for cervical carcinoma. The authorized user (AU) prescribed 600 centigray to be delivered to a distance of 2 cm from the sources, in a uterine tandem with 2.5 cm vaginal spacers.

- On November 22, 2005, the patient returned for the third HDR treatment fraction, and again the AU prescribed 600 centigray to be delivered to a distance of 2 cm from the sources in a uterine tandem with 2.5 cm vaginal spacers. Seven HDR patients were scheduled to be treated on this date, beginning in the late afternoon, and this was the first patient to be treated. The dosimetry calculations were performed by the dosimetrist, then checked by the AMP and AU, who approved the treatment. The treatment was delivered at 3:47 p.m.

- On November 29, 2005, the patient returned for the fourth HDR treatment fraction, and again the AU prescribed 600 centigray to a distance of 2 cm from the sources in a uterine tandem with 2.5 cm vaginal spacers. The AMP compared the treatment dwell times with those from the third treatment fraction and noted a large difference. He then compared the calculations and identified that the dosimetry calculations for the third treatment fraction erroneously used a calculation depth of 10 millimeters from the sources instead of a depth of 20 millimeters from the sources. The AMP's preliminary estimate was that the actual treatment dose delivered to the prescription location from the third fraction was 200 centigray. The AMP contacted the NRC Headquarters Operations Office to report the event on the same day that it was identified.

- On November 30, 2005, the AU, who was also the referring physician, notified the patient of the medical event, as required by 10 CFR 35.3045(e).

- On December 6, 2005, the licensee submitted to NRC Region I the written report required by 10 CFR 35.3045(d). The report stated that detailed calculations showed the dose delivered to the prescription location from the third HDR treatment fraction was 259 centigray, rather than the initial estimate of 200 centigray. The licensee stated that the medical event occurred due to a miscommunication between the AU and dosimetrist, in which the dosimetrist misunderstood that the dose was to be delivered to a depth of 10 millimeters. In addition, the AU and AMP did not perform an adequate review of the treatment plan before approving treatment of the patient on November 22, 2005.

- The fifth and final HDR treatment fraction was delivered on December 6, 2005. The AU increased the prescribed dose for this fraction to compensate for the underdose received in the third fraction to obtain the desired biological effectiveness of the full course of treatment.

The licensee stated that there was no adverse effect on the patient from this event. The licensee's stated corrective actions included a verbal second check of the prescription depth with the AU, comparison of the calculated prescription depth with the depth specified in the written prescription, and verification of the treatment time for the previous fraction versus the current fraction.

During the on-site inspection on November 30, 2005, the inspector noted that the licensee's AMP was unaware of 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. Although Region I later determined that on April 13, 1998, the licensee had submitted to the NRC a detailed HDR quality management program, current licensee staff were unaware there was a written program and did not consistently follow the procedures included in this program. Therefore, the licensee did not fulfill the regulatory requirement to "develop, implement, and maintain" procedures to provide high confidence that each administration is in accordance with the written directive.

The inspector also noted that the HDR unit was owned by the radiation oncology private practice to which the AUs belonged, Radiation Oncology Group, that the hospital had recently terminated the contracts of the AUs to provide external beam treatments, and that the licensee's Radiation Safety Officer (RSO) was one of the AU radiation oncologists whose contract had been terminated.

c. Conclusions

One apparent violation was identified: The licensee did not develop, implement, and maintain written procedures to provide high confidence that each HDR procedure is in accordance with the written directive.

III. Confirmatory Action Letter

a. Issuance of the Confirmatory Action Letter (CAL)

Region I issued a CAL to the licensee on December 5, 2005, and revisions to the CAL on December 8, 2005, and March 8, 2006.

b. Contents of the CAL and Licensee's Response

After the on-site inspection, the licensee informed Region I that they were voluntarily terminating their HDR program and that Radiation Oncology Group planned to remove the HDR unit from the licensee's site. On December 5, 2005, Region I issued a CAL confirming the licensee's commitment to submit a license amendment request to change the HDR unit to "storage only" status, delete from the license AUs who were no longer associated with their hospital, and appoint a new RSO. The CAL also required the licensee to transfer the HDR unit's radioactive sources to an authorized recipient and to perform an audit of all HDR treatments conducted within the previous year to confirm that dose calculations were accurate and treatments were conducted in accordance with the written directives.

The licensee subsequently informed Region I that they wished to complete the treatments of three patients who had already begun treatment prior to the medical event. The current RSO would continue to serve as RSO and HDR AU. On December 8, 2005, Region I issued CAL revision 1 to allow completion of treatment for these three patients. This revised CAL also required the licensee to refrain from initiating HDR treatment for any

patients other than the three who had already begun treatment, and to perform certain checks to confirm that the remaining treatments were delivered in accordance with the written directives.

On February 3, 2006, the licensee submitted the audit results, indicating that no additional medical events were identified. On March 6, 2006, the licensee informed Region I that they had identified two new patients who required HDR treatments and were unable to travel to San Juan for treatment. The licensee also requested to resume HDR treatments until the unit was relocated to another authorized location by its owner, Radiation Oncology Group. On March 8, 2006, Region I issued CAL revision 2 to allow treatment for these two patients. This revised CAL also required the licensee to refrain from initiating HDR treatment for any patients other than these two until the NRC completed an inspection to review corrective actions in response to the medical event and the CAL was closed. This revised CAL also required the licensee to submit procedures for compliance with 10 CFR 35.41(a), a description of contractual agreements with the HDR AU and AMP, a license amendment request to remove AUs and AMPs no longer involved with their licensed program, and a signed, written agreement stating that the RSO agreed to continue in this role.

On March 20, 2006, the licensee submitted procedures for compliance with 10 CFR 35.41(a), contractual agreements with the HDR AU and AMP, a license amendment request to remove AUs and AMPs no longer involved with their licensed program, and a signed, written agreement stating that the RSO agreed to continue in this role. On March 21, 2006, Region I inspectors performed an on-site inspection of the licensee's HDR program and the licensee's actions in response to the CAL. The inspectors confirmed that the licensee had completed all corrective actions required by the CAL, and conducted a comprehensive inspection of the licensee's HDR program. See Section IV, below, for further discussion of this inspection. On May 25, 2006, Region I closed the CAL.

c. Conclusions

The licensee's response to the CAL and it's revisions was adequate. No safety concerns were identified.

IV. Review of the Licensee's HDR Program

a. Inspection Scope

The inspectors reviewed documentation obtained during the November 30, 2005, on-site inspection. During the March 21, 2006, on-site inspection, the inspectors toured the licensee's HDR facility, interviewed the AU/RSO and AMP, observed daily spot-checks and an HDR treatment, and reviewed HDR program records.

b. Observations and Findings

On December 8, 2005, Region I staff reviewed a copy of the written directive form for the patient involved in the medical event and identified that it did not include all of the elements required by 10 CFR 35.40(b)(5). The written directive did not include the radionuclide, and while it did include the total number of fractions, it did not include the total dose to be delivered for the full treatment course or the dose per fraction to be used for the full treatment course. Instead, on the day of each treatment fraction, the AU wrote an individual prescription for that day's treatment, including the dose per fraction.

Region I staff informed the AMP of the apparent violation of 10 CFR 35.40(b)(5). On December 10, 2005, the AMP submitted a new written directive form that did include all of the required elements required by 10 CFR 35.40(b)(5).

During the on-site inspection on March 21, 2006, the inspectors determined that the AU and AMP came on-site in the late afternoon to perform the HDR treatment after linear accelerator treatments were finished for the day. The inspectors noted that the HDR unit was located in a former cobalt-60 teletherapy vault, now used as a simulator room. The simulator/HDR room was locked when unattended, and HDR console keys were inaccessible to unauthorized individuals. A two-way switch prevented operation of both the simulator and HDR unit at the same time. Emergency response equipment was present in the HDR treatment room and staff were trained in emergency response. A continuous viewing and intercom system was provided, the treatment room door was properly posted, the door interlock was functional, an area radiation monitor was present and functional, and a calibrated survey meter was present and functional.

The AMP performed daily spot-checks prior to treatment, however, prior to the day of the inspection, spot-checks did not assure proper operation of timer accuracy. This is an apparent violation of 10 CFR 35.643(d)(6). At the request of the inspectors, the AMP immediately implemented a check to assure proper operation of timer accuracy. The AU completed and signed a written directive and participated in the patient simulation and treatment planning. The AMP performed the dose calculation and the AU approved it prior to treatment. The AU and AMP remained at the HDR control panel throughout the treatment. At the conclusion of the treatment, the AMP surveyed the patient to confirm that the source returned to the safe, shielded position.

The inspectors also reviewed records of full calibrations and calibration of the dosimetry system. The inspectors noted that full calibration measurements did not include determination of timer accuracy and linearity. This is an apparent violation of 10 CFR 35.633(b). The inspectors also noted that the last full calibration was performed on October 18, 2005, however the dosimetry system was last calibrated on September 5, 2003. 10 CFR 35.630(a) requires, in part, that the dosimetry system must have been calibrated within the previous two years, or 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. The licensee's dosimetry system was not calibrated within the previous two years. In addition, more than 30 months had passed since the last dosimetry

system calibration and it had not been intercompared with another calibrated dosimetry system. This is an apparent violation of 10 CFR 35.630(a).

On April 20, 2006, the AMP provided corrective actions including a written procedure for daily spot-checks to assure proper operation of timer accuracy, a written procedure for full calibration tests of timer accuracy and linearity over the range of use, and a commitment to recalibrate the dosimetry system.

During the on-site inspection, the RSO/AU stated that the reason the radiation oncologists' contracts were terminated was because the licensee now requires physicians to have exclusive contracts to provide services only at this location. The Radiation Oncology Group physicians were unwilling to discontinue providing services at another freestanding site. Another group of radiation oncologists now provides external beam services for the licensee. Although the RSO/AU no longer provides external beam services at this location, the inspectors observed that the relationship between the RSO/AU and current full-time licensee staff members appears to be cordial and cooperative.

The RSO/AU and licensee management both stated that Radiation Oncology Group still intends to apply for an NRC license to move the HDR unit to their freestanding site. At that time, the licensee will submit an amendment request to terminate their HDR program.

c. Conclusions

The inspectors identified four apparent violations: (1) written directives did not include all elements required by 10 CFR 35.40(b)(5); (2) daily spot-checks did not assure proper operation of timer accuracy; (3) full calibration measurements did not include determination of timer accuracy and linearity over the range of use; and (4) the HDR dosimetry system had not been calibrated within the required time frame.

V. Exit Meeting

An exit meeting was conducted on November 30, 2005, and again on March 24, 2006, to discuss the preliminary inspection findings with the licensee's Director of Finance and Operations. On June 1, 2006, at the conclusion of the inspection, the apparent violations were discussed with the licensee's Director of Finance and Operations by telephone.

PARTIAL LIST OF PERSONS CONTACTED

Licensee

Miguel Rios Gerena, M.S., Authorized Medical Physicist
José N. Correa, M.D., Authorized User and Radiation Safety Officer
*+Elyonel Pontón, Director of Finance and Operations

*Present at exit meetings conducted on November 30, 2005 and March 24, 2006
+Present at exit meeting conducted on June 1, 2006