



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PENNSYLVANIA 19406-2713

September 28, 2012

Docket No. 03034175

License No. 52-11832-02

Manuel Vázquez
Executive Director
Hospital Andrés Grillasca, Inc.
P.O. Box 1324
Ponce, PR 00733-1324

SUBJECT: NRC INSPECTION REPORT NO. 03034175/2012001, HOSPITAL ANDRÉS GRILLASCA, INC., PONCE, PUERTO RICO SITE AND NOTICE OF VIOLATION

Dear Mr. Vázquez:

On September 12, 2012, Héctor Bermúdez of this office conducted a safety inspection at the above location of activities authorized by your NRC license. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selective examination of representative records. The findings of the inspection were discussed with you and your Radiation Safety Officer (RSO), Mr. Pedro Montes, at the conclusion of the inspection.

Based on the results of this inspection, and in accordance with the NRC Enforcement Policy, the NRC has determined that two Severity Level IV violations of NRC requirements occurred. The violations involved: 1) the failure to inventory three sealed radiation sources at the required interval; and, 2) the failure to designate a RSO after the previous RSO left your employment in 2009.

The violations are cited in the enclosed Notice of Violation (Notice) because the violations were identified by the NRC. Also, Item A, as listed in the Notice, is a repeat violation that was identified during the previous inspection of your licensed program. This violation was documented in the NRC Form 591 dated January 21, 2011. The current violation is of special concern because your previous actions were not effective in preventing recurrence.

During our inspection exit meeting on September 12, 2012, you indicated that the sealed sources will be moved to a secure area within the Radiation Therapy Department which is more accessible to your RSO. In addition, we note that you have recently hired a new RSO. You stated that you have taken corrective and preventative actions to address each violation. You are required to respond to this letter and should follow the instructions in the Notice when preparing your response.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC document system (ADAMS), accessible from the

NRC website at <http://www.nrc.gov/reading-rm/adams.html>. 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.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses**; then **Regulations, Guidance and Communications**. The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **About NRC, Organizations & Functions; Office of Enforcement; Enforcement documents**; then **Enforcement Policy (Under 'Related Information')**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

Please note that the office of the Region I Division of Nuclear Materials Safety has moved effective May 9, 2012. Our new address is:

U. S. Nuclear Regulatory Commission
Region I
2100 Renaissance Blvd, Suite 100
King of Prussia, PA 19406-2713

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

M. Vázquez

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Please contact Mr. Héctor Bermúdez at (404) 997-4734 if you have any questions regarding this matter.

Sincerely,

Original signed by James P. Dwyer

James P. Dwyer, Chief
Medical Branch
Division of Nuclear Materials Safety

Enclosure:
Notice of Violation

cc:
Mr. Pedro Montes, Radiation Safety Officer
Commonwealth of Puerto Rico

M. Vázquez

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Please contact Mr. Héctor Bermúdez at (404) 997-4734 if you have any questions regarding this matter.

Sincerely,

Original signed by James P. Dwyer

James P. Dwyer, Chief
Medical Branch
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Enclosure:
Notice of Violation

cc:
Mr. Pedro Montes, Radiation Safety Officer
Commonwealth of Puerto Rico

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OFFICE	DNMS/RI	N	DNMS/RI		DNMS/RI			
NAME	HBermúdez/hb		JDwyer/jd					
DATE	9/28/12		9/28/12					

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NOTICE OF VIOLATION

Hospital Andrés Grillasca, Inc.
Ponce, PR

Docket No. 03034175
License No. 52-11832-02

During an NRC inspection conducted on September 12, 2012, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 35.67(g) requires, in part, that the licensee conduct a semi-annual physical inventory of all sealed sources in its possession. The licensee shall retain each inventory record for three years.

Contrary to the above, as of September 12, 2012, the licensee had not conducted a semi-annual physical inventory of all sealed sources in its possession. Specifically, the licensee had not inventoried three dose calibrator sealed sources stored in the Nuclear Medicine Department since the Department closed in 2009.

This is a repeat Severity Level IV violation (Section 6.3).

- B. Condition 11 of License No. 52-11832-02 designated an individual as the Radiation Safety Officer (RSO) for the license.

Contrary to the above, between 2009 and September 5, 2012, the individual designated as the RSO did not perform the functions of the RSO. On September 5, 2012, Condition 11 of the license was amended by NRC to designate a new RSO.

This is a Severity Level IV violation (Section 6.3).

Pursuant to the provisions of 10 CFR 2.201, Hospital Andrés Grillasca, Inc., is hereby required to submit a written statement or explanation 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). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an Order or a Demand For Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington,

DC 20555-0001. Under the 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.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publically available without redaction.

However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

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

Dated This 28 day of September 2012