



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

November 27, 2015

Docket No. 03030826

License No. 52-25019-01

Ms. Claudia Guzmán
Executive Director
Hospital HIMA San Pablo - Caguas
P.O. Box 4980
Caguas, PR 00726-4980

SUBJECT: NRC INSPECTION REPORT NO. 03030826/2015001, HOSPITAL HIMA SAN PABLO - CAGUAS, CAGUAS, PUERTO RICO SITE AND NOTICE OF VIOLATION

Dear Ms. Guzmán:

On January 28, 2015, Héctor Bermúdez of this office conducted a safety inspection at the above address of activities authorized by the above listed NRC license. The inspection was limited to a review of your newly implemented High Dose Rate (HDR) Remote Afterloader brachytherapy program. The findings of the inspection were discussed with Dra. Mayra M. Collazo Castro of your organization at the conclusion of the onsite inspection. A final exit interview was conducted via telephone with your Radiation Safety Officer, Mr. Carmelo Pérez, on September 30, 2015.

Based on the results of this inspection and in accordance with the NRC Enforcement Policy, the NRC has determined that one Severity Level IV violation of NRC requirements occurred. The violation involved the failure to secure the HDR unit's console keys when not in use or unattended. The violation is cited in the enclosed Notice of Violation, because the violation was identified by the NRC. During our inspection onsite exit meeting on January 28, 2015, Dra. Collazo indicated that the keys will be secured from now on. It was stated that you have taken corrective and preventative actions to address the violation and that Hospital HIMA San Pablo – Caguas is committed to radiation safety and to compliance with NRC regulations and license conditions. You are required to respond to this letter and should follow the instructions specified in the Notice of Violation when preparing your response. The guidance in the enclosed Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful.

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

Sincerely,

/RA/

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

Enclosures:
Notice of Violation
Information Notice 96-28

cc:
Mr. Carmelo Pérez, Radiation Safety Officer
Commonwealth of Puerto Rico

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Enclosures:
Notice of Violation
Information Notice 96-28

cc:
Mr. Carmelo Pérez, Radiation Safety Officer
Commonwealth of Puerto Rico

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OFFICE	DNMS/RI	N	DNMS/RI	DNMS/RI		
NAME	HBermúdez /RA/		JDwyer/jpd			
DATE	9/30/2015		11/27/2015			

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NOTICE OF VIOLATION

Hospital HIMA San Pablo - Caguas
Caguas, PR

Docket No. 03030826
License No. 52-25019-01

During an NRC inspection conducted on January 28, 2015, with a subsequent telephone exit interview on September 30, 2015, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 35.610(a)(1) requires, in part, that the licensee secure the HDR unit's console keys when not in use or unattended.

Contrary to the above, on January 28, 2015, the licensee failed to secure the console keys when personnel left the area for a lunch break.

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

Pursuant to the provisions of 10 CFR 2.201, Hospital HIMA San Pablo - Caguas 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 (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 27th day of November 2015