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

June 17, 2012

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

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

SUBJECT: NRC INSPECTION REPORT NO. 03030826/2012001, HOSPITAL HIMA SAN PABLO-CAGUAS, CAGUAS, PUERTO RICO SITE AND NOTICE OF VIOLATION

Dear Ms. Guzmán:

On March 29, 2012, 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 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. Additional information provided in telephone conversations on April 30, and May 25, 2012, by Mr. Carmelo Pérez, your Radiation Safety Officer (RSO), was also examined as part of the inspection. The preliminary findings of the onsite inspection were discussed with you. The final findings were discussed with Mr. Pérez at the conclusion of the inspection. Mr. Pérez indicated that he would discuss the final findings with you and your staff.

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 maintain records of the basis for authorizing the release of iodine-131 therapy patients released on March 7 and 9, 2012; and 2) the failure to perform acceptance testing on the treatment planning system of the therapy-related computer system used in your permanent implant brachytherapy program.

The violations are cited in the enclosed Notice of Violation (Notice), because the violations were identified by the NRC. Please note that Item A as listed in the Notice is a repeat violation that was identified during the previous inspection of your licensed program. This was documented in the Notice of Violation on our NRC Form 591M Part 1 dated September 16, 2008. Although your staff committed to correct the violation during that inspection’s exit meeting, the current violation is of concern because your preventative actions were not effective in preventing recurrence. Also, regarding Item B in the Notice, your RSO stated that acceptance testing of the referenced system was promptly performed after the inspection in accordance with a published protocol accepted by a nationally recognized body and that no discrepancies were identified. Therefore, it is our conclusion that your brachytherapy patients treated through the day of the onsite inspection were treated as intended by the authorized user physicians. Please confirm that our conclusion is valid in your required response to this letter and Notice of Violation.

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 USNRC 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

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:
Carmelo Pérez, Radiation Safety Officer
Commonwealth of Puerto Rico

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Sincerely,

Original signed by James P. Dwyer

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

Enclosure:
Notice of Violation

cc:
Carmelo Pérez, Radiation Safety Officer
Commonwealth of Puerto RicoDistribution:
D. J. Holody, RI

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OFFICE	DNMS/RI	N	DNMS/RI					
NAME	HBermúdez HB		JDwyer/jpd					
DATE	6/12/2012		6/17/2012					

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Hospital HIMA San Pablo-Caguas
Caguas, PR

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

During an NRC inspection conducted on March 29, 2012, with subsequent telephone conversations through May 25, 2012, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. 10 CFR 37.75(c) requires, in part, that the licensee maintain a record of the basis for authorizing the release of individuals administered unsealed byproduct materials showing that the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 0.5 rem.

   Contrary to the above, as of March 29, 2012, the licensee did not maintain records of the bases for releasing individuals administered 125 and 150 millicuries of iodine-131 on March 7 and 9, 2012, respectively.

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

B. 10 CFR 35.457 requires, in part, that the licensee perform acceptance testing of the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies.

   Contrary to the above, the licensee resumed performing permanent implant brachytherapy treatments using a new treatment planning software after the previous inspection on August 7, 2008 and, as of March 29, 2012, the licensee had not performed acceptance testing of its treatment planning system.

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

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 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 17th day of June 2012