

## UNITED STATES NUCLEAR REGULATORY COMMISSION

REGION I 475 ALLENDALE ROAD KING OF PRUSSIA, PENNSYLVANIA 19406-1415

April 24, 2006

Docket No. 03036635 License No. 52-30937-01

Jorge Matta
Administrator
Centro de Radioterapia at
Hospital Auxilio Mutuo
Stop 37 ½
Avenida Ponce de León #725
Hato Rey, PR 00918

SUBJECT: INSPECTION 03036635/2006001, CENTRO DE RADIOTERAPIA AT

HOSPITAL AUXILIO MUTUO, HATO REY, PUERTO RICO SITE, AND NOTICE

OF VIOLATION

Dear Mr. Matta:

On March 24, 2006, Héctor Bermúdez and Sandy Gabriel 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 inspectors, interviews with personnel, and a selected examination of representative records. The findings of the inspection were discussed with Dra. Vanessa Marcial of your organization at the conclusion of the inspection.

Based on the results of this inspection, it appears that your activities were not conducted in full compliance with NRC requirements. A Notice of Violation is enclosed that categorizes each violation by severity level. You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

Current NRC regulations are included on the NRC's website at <a href="www.nrc.gov">www.nrc.gov</a>; select Nuclear Materials; Medical, Industrial, and Academic Uses of Nuclear Material; then Toolkit Index Page. The current Enforcement Policy is included on the NRC's website at <a href="www.nrc.gov">www.nrc.gov</a>; 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).

J. Matta 2 Centro de Radioterapia at Hospital Auxilio Mutuo

Your cooperation with us is appreciated.

Sincerely,

Original signed by Penny Lanzisera

Penny Lanzisera, Acting Chief Medical Branch Division of Nuclear Materials Safety

Enclosure: Notice of Violation

CC:

Miguel Ríos, Radiation Safety Officer Commonwealth of Puerto Rico

J. Matta 3 Centro de Radioterapia at Hospital Auxilio Mutuo

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SISP Review Complete: <u>HBermúdez</u>
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OFFICE	DNMS/RI	Ν	DNMS/RI	n	DNMS/RI	n	
NAME	Hbermúdez via email		Sgabriel via email		PLanzisera/PL		
DATE	4/20/06		4/20/06		4/20/06		

## **NOTICE OF VIOLATION**

Centro de Radioterapia at Hospital Auxilio Mutuo Hato Rey, PR

Docket No. 03036635 License No. 52-30937-01

During an NRC inspection conducted on March 24, 2006, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. 10 CFR 35.610(e) requires that the licensee ensure that operators, authorized medical physicists and authorized users participate in drills of the emergency procedures required by 10 CFR 35.610(a)(4) initially and at least annually.

Contrary to the above, on March 24, 2006, the licensee began licensed activities but had not ensured that its operators, authorized medical physicist and authorized user participated in drills of the emergency procedures required by 10 CFR 35.610(a)(4).

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

B. License Condition No. 14 requires, in part, that the licensee conduct its program in accordance with the representations contained in the application dated August 5, 2004. Item 9 of the application, "Facility Design and Safety Equipment," states, in part, that beam-on indicators are located at the door and control stations.

Contrary to the above, as of March 24, 2006, the licensee did not have a beam-on indicator at the door to the treatment room. Specifically, the beam-on indicator wiring had not been installed.

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

Pursuant to the provisions of 10 CFR 2.201, Centro de Radioterapia at Hospital Auxilio Mutuo 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,

Notice of Violation 2 Centro de Radioterapia at Hospital Auxilio Mutuo

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.

Dated This 24th day of April 2006