



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

January 11, 2005

Docket No. 030-30003

License No. 52-24916-01

Gilberto Gonzalez
Administrator
Alejandro Otero Lopez Hospital
Urbanizacion Atenas
PO Box 1142
Manati, PR 00674

**SUBJECT: INSPECTION 03030003/2004001, ALEJANDRO OTERO LOPEZ HOSPITAL,
MANATI, PUERTO RICO SITE AND NOTICE OF VIOLATION**

Dear Sr. Gonzalez:

On December 13, 2004, Steve Hammann and Andy Miller 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 circumstances regarding your facilities reported loss of four I-125 brachytherapy seeds. The findings of the inspection were discussed with Dr. Eduardo Pascual Ferrer 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 in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG 1600. 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.

Please note that on October 25, 2004, the NRC suspended public access to ADAMS, and initiated an additional security review of publicly available documents to ensure that potentially sensitive information is removed from the ADAMS database accessible through the NRC's web site. Interested members of the public may obtain copies of the referenced documents for review and/or copying by contacting the NRC Public Document Room pending resumption of public access to ADAMS. The NRC Public Document Room is located at NRC Headquarters in Rockville, MD, and can be contacted at 800-397-4209 or 301-415-4737 or pdr@nrc.gov.

G. Gonzalez
Alejandro Otero Lopez Hospital

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Your cooperation with us is appreciated.

Sincerely,

Original signed by Pamela J. Henderson

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

Enclosure:
Notice of Violation

cc:
Eduardo Pascual Ferrer, M.D., Radiation Safety Officer
Commonwealth of Puerto Rico

G. Gonzalez
Alejandro Otero Lopez Hospital

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D. J. Holody, RI

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DATE	1/5/05		1/6/05		1/6/05			

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NOTICE OF VIOLATION

Alejandro Otero Lopez Hospital
Manati, PR

Docket No. 030-30003
License No. 52-24916-01

During an NRC inspection conducted on December 13, 2004, two violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG-1600, the violations are listed below:

- A. 10 CFR 20.2201(a)(1)(ii) requires that each licensee shall report by telephone within 30 days after the occurrence of any lost, stolen, or missing licensed material becomes known to the licensee, all licensed material in a quantity greater than 10 times the quantity specified in Appendix C to Part 20 that is still missing at this time.

Contrary to the above, the licensee did not report by telephone within 30 days after an occurrence of missing licensed material, greater than 10 times the quantity specified in Appendix C to Part 20, became known to them. Specifically, the licensee identified on September 20, 2004, that four I-125 brachytherapy seeds were missing and did not report this to the commission until December 8, 2004, a period exceeding 30 days.

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

- B. 10 CFR 35.406(a) requires that each licensee shall maintain accountability at all times for all brachytherapy sources in storage or use.

Contrary to the above, the licensee did not maintain accountability at all times for all brachytherapy sources in storage or use. Specifically, four I-125 brachytherapy sources believed to have been in storage were discovered to be missing on September 10, 2004.

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

Pursuant to the provisions of 10 CFR 2.201, Alejandro Otero Lopez Hospital 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.

Notice of Violation
Alejandro Otero Lopez Hospital

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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 at <http://www.nrc.gov/reading-rm.html>. 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 11th day of January 2005