

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



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April 19, 2010

Docket No. 03036979

License No. 52-31065-01

José E. Meléndez, M.D.
Radiation Safety Officer
100 Roseville Drive, Box 22
San Juan, PR 00926

SUBJECT: NRC INSPECTION REPORT NO. 03036979/2010002, JOSÉ E. MELÉNDEZ, M.D., RÍO GRANDE NUCLEAR MEDICINE, RÍO GRANDE, PUERTO RICO AND NOTICE OF VIOLATION

Dear Dr. Meléndez:

On March 23, 2010, Tara Weidner and Carmen Rivera of this office conducted a safety inspection at Río Grande Nuclear Medicine, Río Grande, Puerto Rico 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 review of records. The findings of the inspection were discussed with you at the conclusion of the inspection.

Based on the results of this inspection and in accordance with the NRC Enforcement Policy, the NRC identified two violations of NRC requirements. The violations involved; (1) the failure to control and maintain constant surveillance of licensed material that is in a controlled area and that is not in storage as required by 10 CFR 20.1802; and (2) the failure to post a controlled area in which licensed material is used or stored as required by 10 CFR 20.1902(e). Therefore, the violations are categorized, in accordance with the NRC Enforcement Policy, at a Severity Level IV. These violations are being cited in the enclosed Notice of Violation (Notice) because they were not licensee identified. 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.

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 are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material**; then **Regulations, Guidance, and Communications Page**. The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **About NRC; How We Regulate; Enforcement**; then **Enforcement Policy**. 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 7:00 a.m. to 6:30 p.m. EST, Monday through Friday (except Federal holidays).

Please contact Tara Weidner at 610-337-5272 if you have any questions regarding this matter.

Sincerely,

Original signed by Marc Ferdas

Marc Ferdas, Chief
Medical Branch
Division of Nuclear Materials Safety

Enclosure:
Notice of Violation

cc:
Denis Ruiz, M.D., Owner, Río Grande Nuclear Medicine
Commonwealth of Puerto Rico

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Sincerely,

Original signed by Marc Ferdas

Marc Ferdas, Chief
Medical Branch
Division of Nuclear Materials Safety

Enclosure:
Notice of Violation

cc:
Denis Ruiz, M.D., Owner, Río Grande Nuclear Medicine
Commonwealth of Puerto Rico

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DATE	4.16.2010		4/19/10			

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NOTICE OF VIOLATION

José E. Meléndez, M.D.
Río Grande, PR

Docket No. 03036979
License No. 52-31065-01

During an NRC inspection conducted on March 23, 2010, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 20.1802 requires that the licensee control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

Contrary to the above, on March 23, 2010, the licensee did not maintain constant surveillance of approximately 100 millicuries of Technetium-99m, which was located in the licensee's Hot Lab, a controlled area.

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

- B. 10 CFR 20.1902(e) states that the licensee shall post each area or room in which there is used or stored an amount of licensed material exceeding 10 times the quantity of such material specified in appendix C to part 20 with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)."

Contrary to the above, on March 23, 2010, the licensee did not post each area or room in which there is used or stored an amount of licensed material exceeding 10 times the quantity of such material specified in appendix C to part 20 with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)." Specifically, the Hot Lab, a room in which approximately 100 millicuries of Technetium-99m was used or stored, was not posted with the appropriate sign.

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

Pursuant to the provisions of 10 CFR 2.201, José E. Meléndez, M.D. 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,

José E. Meléndez, M.D
Notice of Violation

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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.

Dated This 19th day of April 2010