



March 2, 2010

Docket No. 03036979
EA-10-033

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. 03036979/2010001, JOSÉ E. MELÉNDEZ, M.D., RÍO GRANDE NUCLEAR MEDICINE, RÍO GRANDE, PUERTO RICO SITE AND NOTICE OF VIOLATION

Dear Dr. Meléndez:

On January 28, 2010, Héctor Bermúdez and MaryAnn Abogunde of this office attempted to conduct a safety inspection of activities authorized by the above listed NRC license at your Río Grande Nuclear Medicine facility. The inspection was scheduled to be an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and license conditions. The facility was closed for the day at the time of inspection. Therefore, the inspection was limited to a verification of facility location and operational status. In addition, information provided during telephone conversations with Diana Carrillo, Nuclear Medicine Technologist, David Rhoe, Radiation Safety Officer, and you on January 28, 29, and February 1, 2010, respectively, were examined as part of the inspection. The findings of the inspection were discussed with you on February 1, 2010.

Based on the results of this inspection and in accordance with the NRC Enforcement Policy, the NRC identified one violation of NRC requirements. The violation involved the failure to use byproduct material for the purposes authorized in the license as required by 10 CFR 30.34(c). Specifically, although your license authorized possession and storage of licensed materials, the inspectors identified that you were using byproduct material for medical use. Normally, the unauthorized use of radioactive materials on humans is considered for escalated enforcement. The NRC assessed the unique circumstances involved in the above violation, including: (1) between December 2006 and September 8, 2008, your license authorized the medical use of licensed materials and you were in compliance with all NRC requirements; (2) as of September 8, 2008 your license was amended to authorize possession/storage only due to renovations being conducted at your facilities; (3) the byproduct material used between December 3, 2009 and February 1, 2010 was not of the quantity or type requiring a written directive; and (4) the authorized user was qualified for the uses in accordance with NRC regulations and has used such materials in the past. Therefore, the violation is categorized, in accordance with the NRC Enforcement Policy, at Severity Level IV. This violation is being cited in the Notice because it was not licensee identified.

The NRC has concluded that it has sufficient information on the docket regarding the reason for the violation, the corrective actions taken to correct the violation and prevent recurrence, and the date when full compliance was achieved. Specifically, on February 3, 2010, the NRC received

an amendment request to reinstate your medical use license for authorized use of byproduct material, and approval was granted on February 5, 2010. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, if you choose to provide one, 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 Héctor Bermúdez at 404-562-4734 if you have any questions regarding this matter.

Sincerely,

Original signed by Marc Ferdas

Marc S. Ferdas, Chief
Medical Branch
Division of Nuclear Materials Safety

Enclosure:
Notice of Violation

cc:
Commonwealth of Puerto Rico

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Commonwealth of Puerto Rico

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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 January 28, 29, and February 1, 2010, for which a telephonic exit meeting was conducted on February 1, 2010, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR Part 30.34(c) requires, in part, that each licensee confine its use of byproduct material to the purposes authorized in the license.

Condition 9 of License No. 52-31065-01, Amendment 2, dated September 8, 2008, authorized possession and storage only until the license is amended to authorize medical use approved in 10 CFR 35.100, 10 CFR 35.200, and/or 35.300.

Contrary to the above, from December 3, 2009 through February 1, 2010, José E. Meléndez, M.D. did not confine the use of byproduct material to the purposes authorized in the license. Specifically, José E. Meléndez, M.D., used byproduct material for uptake, dilution and excretion studies permitted by 10 CFR 35.100 and imaging and localization studies permitted by 10 CFR 35.200, activities not authorized by their license.

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

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence and the date when full compliance was achieved is already adequately addressed on the docket. Therefore, José E. Meléndez, M.D., is not required to respond to this Notice of Violation. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation," and send it 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).

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.

Notice of Violation
José E. Meléndez, M.D.

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In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated This 2nd day of March 2010