



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PENNSYLVANIA 19406-2713

December 17, 2013

Docket No. 03037326

License No. 52-31182-01

Luis A. Rosado Carrillo, M.D.
Director
Clínica Cardiovascular de Guaynabo
P.O. Box 965
Guaynabo, PR 00970-0965

**SUBJECT: NRC INSPECTION REPORT NO. 03037326/2013001, CLÍNICA
CARDIOVASCULAR DE GUAYNABO, GUAYNABO, PUERTO RICO SITE AND
NOTICE OF VIOLATION**

Dear Dr. Carrillo:

On October 28, 2013, Maryann Abogunde of this office conducted a safety inspection at the above address of activities authorized by your 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 an examination of records. The preliminary findings of the inspection were discussed with Roberto P. Bordewyk, M.D.; Wanda Cruz; and David Rhoe of your organization at the conclusion of the inspection. A telephonic exit meeting was conducted on November 20, 2013, between you and Maryann Abogunde of this office, to discuss the findings of this inspection.

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 notify the Commission prior to using an area that was not specifically identified in the application for 10 CFR 35.200 uses and 2) the failure to secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas. The violations are cited in the enclosed Notice of Violation (Notice), because the violations were identified by the NRC.

During our telephonic inspection exit meeting on November 20, 2013, you stated that you have taken the following corrective and preventative actions to address each violation and that Clínica Cardiovascular de Guaynabo is committed to radiation safety and to compliance with NRC regulations and licensed conditions:

1. You immediately contacted the radiopharmacy to have all radiopharmaceutical packages directly delivered only to the nuclear medicine technologist;
2. You discussed with the nuclear medicine technologist the new change to the delivery of all radiopharmaceutical packages process outside normal business hours; and

3. You made plans to use the secured hot lab room that is part of your current facilities, as the delivery location for radiopharmaceutical packages by the end of November. Until that time, the nuclear medicine technologist will continue to be available to accept packages directly from the radiopharmacy and have them delivered and stored in the hot lab room.

In addition, you stated that the building in which your facility is located is shared with other offices so, in order for the radiopharmacy to have access to the hot lab room, the current alarm system would be disabled, a new access key pad with a specific code outside the building would be installed, and a new set of keys into the hot lab room would be made available to the radiopharmacy for direct entry.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with 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, 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).

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

L. Carrillo, M.D.

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Please contact Maryann Abogunde at (610) 337-5090 if you have any questions regarding this matter. Thank you for your cooperation.

Sincerely,

Original signed by James P. Dwyer

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

Enclosure:
Notice of Violation

cc: Roberto P. Bordewyk, M.D., Radiation Safety Officer
Commonwealth of Puerto Rico

L. Carrillo, M.D.

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Please contact Maryann Abogunde at (610) 337-5090 if you have any questions regarding this matter. Thank you for your cooperation.

Sincerely,

Original signed by James P. Dwyer

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

Enclosure:
Notice of Violation

cc: Roberto P. Bordewyk, M.D., Radiation Safety Officer
Commonwealth of Puerto Rico

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NAME	MAbogunde\jpd fl		JDwyer\jpd					
DATE	12/17/2013		12/17/2013					

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NOTICE OF VIOLATION

Clínica Cardiovascular de Guaynabo
Guaynabo, PR

Docket No. 03037326
License No. 52-31182-01

During an NRC inspection conducted on October 28, 2013, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 35.14(b)(5) requires, in part, that a licensee notify the Commission no later than 30 days after the licensee has added to or changed the areas of use identified in the application or on the license where byproduct material is used in accordance with either 10 CFR 35.100 or 35.200.

Contrary to the above, as of October 28, 2013, Clínica Cardiovascular de Guaynabo did not notify the Commission prior to using an area that was not specifically identified in the application for 10 CFR 35.200 uses. Specifically, for several years, a stairwell area outside of the facility was used for storage of radiopharmaceutical packages delivered by the radiopharmacy outside of normal business hours, without notification to the Commission.

This is a Severity Level IV violation (Enforcement Policy Section 6.3.d).

- B. 10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

Contrary to the above, as of October 28, 2013, Clínica Cardiovascular de Guaynabo did not secure from unauthorized removal or access licensed materials that were stored in controlled or unrestricted areas. Specifically, radiopharmaceutical packages containing no more than 100 millicuries of Technetium-99m and used for nuclear cardiology studies, were unsecured from unauthorized removal or access of individuals other than licensee and radiopharmacy personnel that share the same building facility. The packages were delivered by the radiopharmacy to a stairwell area outside of the facility during non-business hours, at about 6 a.m., and remained there until about 8 a.m., when the nuclear medicine technologist arrived for the day. The stairwell area is normally key-locked during non-business hours, but individuals other than licensee and radiopharmacy personnel that share the building facility also have access to the area during non-business hours.

This is a Severity Level IV violation (Enforcement Policy Section 6.3.d).

Pursuant to the provisions of 10 CFR 2.201, Clínica Cardiovascular de Guaynabo 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.

Dated This 17 day of December 2013