

UNITED STATES NUCLEAR REGULATORY COMMISSION REGION I 2100 RENAISSANCE BLVD. KING OF PRUSSIA, PA 19406-2713

September 17, 2019

Luis A. Rosado Carillo, M.D., President Clinica Cardiovascular de Guaynabo P.O. Box 965 Guaynabo, Puerto Rico 00970-0965

SUBJECT: CLINICA CARDIOVASCULAR DE GUAYNABO – NRC INSPECTION NO. 03037326/2019001, AND NOTICE OF VIOLATION

Dear Dr. Rosado Carillo:

This letter refers to the licensing review of the letter received April 16, 2019, requesting a direct transfer of control of your license to Nuclear Scan, PSC. Based on the results of our reveiw, the NRC has determined that one Severity Level IV violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at <u>https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html</u>. The violation is cited in the enclosed Notice of Violation (Notice) because the violation was identified by the NRC.

The NRC has concluded that information regarding: (1) the reason for the violation; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance will be (was) achieved is already adequately addressed on the docket and included giving a verbal commitment to notify the NRC in writing of any future transfers of control of this license. Therefore, you are not required to respond to this letter unless the description herein 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 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 Web site at <u>http://www.nrc.gov/reading-rm/adams.html</u>. 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.

If you have any questions regarding this matter, please contact Shawn Seeley of my staff at 610-337-5102 or via electronic mail at <u>shawn.seeley@nrc.gov</u>.

Thank you for your cooperation.

Sincerely,

Ronna M. Junka

Donna M. Janda, Chief Medical and Licensing Assistance Branch Division of Nuclear Materials Safety

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

Enclosure: Notice of Violation

cc w/Encl: Juan Fontanez, MD, Nuclear Scan PSC David Rhoe, Radiation Safety Officer Commonwealth of Puerto Rico

CLINICA CARDIOVASCULAR DE GUAYNABO - NRC INSPECTION NO. 03037326/2019001, AND NOTICE OF VIOLATION DATED September 17, 2019

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NOTICE OF VIOLATION

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Clinica Cardiovascular de Guaynabo Guaynabo, Puerto Rico Docket No. 03037326 License No. 52-31182-01

Based on the licensing review of the letter dated April 16, 2019, for a transfer of control, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 30.34(b)(1) requires that no license issued or granted pursuant to the regulations in this part and parts 31 through 36, and 39 nor any right under a license shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Commission shall, after securing full information, find that the transfer is in accordance with the provisions of the Act and shall give its consent in writing.

Contrary to the above, on April 5, 2019, Clinica Cardiovascular de Guaynabo underwent a direct transfer of control of the NRC radioactive materials license to another entity before the Commission found that the transfer was in accordance with the provisions of the Act and gave its consent in writing. Specifically, Clinica Cardiovascular de Guaynabo transferred all activities conducted under license number 52-31182-01 to Nuclear Scan, PSC.

This is a Severity Level IV violation (Enforcement Policy Example 6.3.d.7).

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.

If you decide to include a response, 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 of receipt.

Dated This 17th day of September 2019