



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

June 6, 2019

José M. Talavera, Chief Executive Officer
Hospital Metropolitano
Caparra Heights Station
P.O. Box 11981
San Juan, Puerto Rico 00922-1981

**SUBJECT: HOSPITAL METROPOLITANO - NRC INSPECTION NO. 03011155/2018001
AND NOTICE OF VIOLATION**

Dear Mr. Talavera:

This letter refers to the inspection conducted on October 3, 2018, with in-office review through May 8, 2019, at your facility. This inspection examined activities conducted under your license as they relate to public health and safety, and to confirm compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel. The findings of the inspection were provided to you during the formal exit meeting held by telephone on May 11, 2019.

Based on the results of this inspection, 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 <https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. 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 was achieved is already adequately addressed on the docket and includes revising the written directives used for brachytherapy procedures to include all of the information required by 10 CFR 35.40(6)(ii). 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 <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.

J. Talavera

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If you have any questions regarding this matter, please contact Robert Gallagher of my staff at (610) 337-5182 or via electronic mail at robert.gallagher@nrc.gov.

Thank you for your cooperation.

Sincerely,

A handwritten signature in black ink, appearing to read "Donna Janda". The signature is fluid and cursive, with the first name "Donna" being more prominent than the last name "Janda".

Donna Janda, Chief
Medical and Licensing Assistance Branch
Division of Nuclear Materials Safety
Region I

Docket No. 03011155
License No. 52-16033-01

Enclosure:
Notice of Violation

cc w/ enclosure
David Rhoe, Radiation Safety Officer
Commonwealth of Puerto Rico

J. Talavera

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HOSPITAL METROPOLITANO - NRC INSPECTION NO. 03011155/2018001 AND NOTICE
OF VIOLATION DATED 6/6/19

DISTRIBUTION:

JTrapp, DNMS

JNick, DNMS

R1Enforcement

DJanda, DNMS

RGallagher, DNMS

DOCUMENT NAME: G:\WBL Documents\WBL Inspection Letter\L52-16033-01.2018001.NOV.Public.docx

<input checked="" type="checkbox"/> SUNSI Review		<input checked="" type="checkbox"/> Non-Sensitive Sensitive		<input checked="" type="checkbox"/> Publicly Available Non-Publicly Available	
OFFICE	DNMS/RI	DNMS/RI			
NAME	RGallagher/rg	DJanda/dmj			
DATE	6/5/19	6/6/19			

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Hospital Metropolitano
San Juan, Puerto Rico

Docket No. 03011155
License No. 52-16033-01

During an NRC inspection conducted on October 3, 2018, with in-office review through May 8, 2019, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 35.40 requires, in part, that a written directive must be dated and signed by an authorized user before any administration of a therapeutic dose of radiation from byproduct material. 10 CFR 35.40 (b)(6)(ii) requires that the written directive, after implantation but before completion of the procedure, must contain: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or total dose).

Contrary to the above, the inspector reviewed 10 written directives and identified that all 10 did not contain the information required by 10 CFR 35.40 (b)(6)(ii). Specifically, the written directives in use at the time of the inspection did not include post-implantation documentation of the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).

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

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 will be achieved is already adequately addressed on the docket. 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.

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

Dated This 6th day of June 2019