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UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION I  
475 ALLENDALE RD, SUITE 102  
KING OF PRUSSIA, PA 19406-1415

August 21, 2024

EA-24-009

Jorge Matta Gonzalez, Executive Director  
Puerto Rico Medical Services Administration  
P.O. Box 2129  
San Juan, PR 00922-2129

SUBJECT: NOTICE OF VIOLATION – PUERTO RICO MEDICAL SERVICES  
ADMINISTRATION NRC INSPECTION REPORT 030-37829/2023-001

Dear Jorge Matta Gonzalez:

This letter refers to the inspection conducted by the U.S. Nuclear Regulatory Commission (NRC) at the Puerto Rico Medical Services Administration (PRMSA) facility in San Juan, Puerto Rico on October 16, 2023, with additional on-site follow-up on December 6, 2023, followed by an in-office review through February 6, 2024. The purpose of the inspection was to examine the activities conducted under your license as they relate to public health and safety, to confirm compliance with the NRC's rules, regulations, and with the conditions of your license.

Based on the results of the inspection, the NRC identified one apparent violation related to NRC health-and-safety requirements for PRMSA's apparent failure to retain documentation associated with the annual review of the PRMSA radiation protection program. In addition, one or more apparent security-related violation(s) were identified. The NRC discussed the apparent violations with members of your staff during a telephonic exit meeting on April 4, 2024. The details of the health-and-safety violation were described in the public portion of the NRC inspection report enclosed with the letter dated April 15, 2024 (ML24106A017)<sup>1</sup>. The details of the security-related violations were described in the non-public portion of the inspection report.

In the April 15, 2024, letter transmitting the inspection report, we provided PRMSA with the opportunity to address the apparent violations identified in the report by either attending a pre-decisional enforcement conference or by providing a written response before we made our final enforcement decision. In a letter dated May 10, 2024, PRMSA agreed with the NRC's description of the apparent violations and the corrective actions taken to address them.

The enclosure contains Sensitive Unclassified Non-Safeguards Information. Upon separation, this cover letter is DECONTROLLED.

<sup>1</sup> Designation in parentheses refers to an Agency-wide Documents Access and Management System (ADAMS) accession number. Documents referenced in this letter are publicly-available using the accession number in ADAMS.

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Based on the information developed during the inspection and in the May 10, 2024, letter, the NRC has determined that one violation related to NRC health-and-safety requirements occurred. The violation is cited in the enclosed public Notice of Violation (Notice) (Enclosure 1) and the circumstances surrounding it is described in detail in the public inspection report.

In addition to the health-and-safety violation, one or more violations of NRC security requirements occurred and are subject to escalated enforcement action. The non-public Notice is included in this document as Enclosure 2. The circumstances surrounding the violations are described in detail in the subject non-public inspection report.

In accordance with the NRC Enforcement Policy, a base civil penalty is considered for any escalated violation. However, because your facility has not been the subject of escalated enforcement action within either the last two years or the two most recent inspections, the NRC considered whether credit was warranted for Corrective Action in accordance with the civil penalty assessment process in Section 2.3.4 of the NRC Enforcement Policy. The NRC has concluded that credit is warranted because PRMSA took prompt and comprehensive corrective actions to address the violations.

In recognition of these prompt and comprehensive corrective actions, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty. However, significant violations in the future could result in a civil penalty. In addition, issuance of a Notice of Violation that includes escalated enforcement action may subject PRMSA to increased inspection effort.

The NRC has concluded that information regarding: (1) the reason for the violations; (2) the actions planned or already taken to correct the violations and prevent recurrence; and, (3) the date when full compliance was achieved, is already adequately addressed on the docket in the Inspection Report No. 030-37829/2023-001 and your letter dated May 10, 2024. 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.

However, the material enclosed herewith contains Security-Related Information in accordance with 10 CFR 2.390(d)(1) and its disclosure to unauthorized individuals could present a security vulnerability. Therefore, the material in the enclosure will not be made available electronically for public inspection in the NRC Public Document Room or in the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. If Security Related Information is necessary to provide an acceptable response, please mark your entire response Security-Related Information in accordance with 10 CFR 2.390(d)(1) and follow the instructions for withholding in 10 CFR 2.390(b)(1). In accordance with 10 CFR 2.390(b)(1)(ii), the NRC is waiving the affidavit requirements for your response.

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If you have any questions related to this matter, please contact Anne DeFrancisco of my staff at (610) 337-5078 or [Anne.DeFrancisco@nrc.gov](mailto:Anne.DeFrancisco@nrc.gov).

Sincerely,

Raymond K. Lorson  
Regional Administrator

Enclosure:

1. Notice of Violation (Public)
2. Notice of Violation (Non-public)

Docket No. 030-37829  
License No. 52-31281-02

cc w/ Enclosure:

Adriana Cordova Ayuso, M.S., DABR, Radiation Safety Officer

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SUBJECT: NOTICE OF VIOLATION – PUERTO RICO MEDICAL SERVICES  
 ADMINISTRATION NRC INSPECTION REPORT 030-37829/2023-001;  
 August 21, 2024

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ADAMS Document Accession NO.: ML24232A163 (Public)

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NAME						R Lorson
DATE						8/21/2024

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ENCLOSURE

NOTICE OF VIOLATION

Puerto Rico Medical Services Administration  
San Juan, Puerto Rico

Docket No.: 030-37829  
License No.: 52-31281-02  
EA-24-009

During an NRC routine inspection conducted on October 16, 2023, and an on-site follow-up inspection conducted on December 6, 2023, with continued in-office review through February 6, 2024, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violation is listed below.

10 CFR 20.2102(b) requires, in part, that each licensee shall retain the records of the radiation protection program required by 10 CFR 20.2102(a)(2) including audits and other reviews of program content and implementation, for 3 years after record creation.

Contrary to the above, from or about April 28, 2023, through October 16, 2023, the licensee failed to retain the records of its radiation protection program, including audits and other reviews of program content and implementation, for the required period of 3 years post-record creation. Specifically, the licensee performed an annual radiation safety program review for calendar year 2022 between January 1, 2023, and April 28, 2023, and failed to maintain a record of that review following the deletion of the record on or about April 28, 2023.

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

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 in Inspection Report No. 030-37829/2023-001 and your letter dated May 10, 2024. However, if the description therein does not accurately reflect your position or your corrective actions, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 within 30 days of the date of the letter transmitting this Notice of Violation. In that case, or if you choose to respond, clearly mark your response as a Reply to a Notice of Violation, EA-24-009, and send it to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville, MD 20852-2738, with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region I, 475 Allendale Road, Suite 102, King of Prussia, PA 19406, and the Document Control Desk, Washington, DC 20555-0001.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.]

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

Dated this 21<sup>st</sup> day of August, 2024.

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Enclosure