



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

April 26, 2016

Docket No. 03037829
EA-16-059

License No. 52-31281-02

Myria Roque
Radiation Safety Officer and
Reviewing Official
Puerto Rico Medical Services
Administration
P.O. Box 2129
San Juan, PR 00922-2129

SUBJECT: NRC INSPECTION REPORT NO. 03037829/2016002, PUERTO RICO
MEDICAL SERVICES ADMINISTRATION, PUERTO RICO MEDICAL CENTER,
SAN JUAN, PUERTO RICO

Dear Ms. Roque:

On January 28, 2016, with continued in-office review through April 22, 2016, Penny Lanzisera of this office conducted a routine inspection of your facility at the Puerto Rico Medical Center on the Centro Medico Campus, San Juan, Puerto Rico. 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 a selective examination of representative records. Additional information provided in the telephone conversations with you on February 2, 9, and 23, 2016, was also examined as part of the inspection. The preliminary inspection findings were discussed with you and Dr. Julio J. Diaz-Padilla at the conclusion of the on-site portion of the inspection on January 28, 2016. A final exit meeting was conducted (telephonically) with you and Mr. Edwin Carrasquillo, your Security Director, on March 17, 2016, with clarifications discussed on April 22, 2016. The enclosed report presents the results of the inspection.

Based on the results of the inspection, the NRC determined that one or more apparent violations of NRC requirements occurred and are being considered for escalated enforcement. The apparent violation(s) were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. Because of the security-related nature of any such apparent violation, the number and characterization will not be provided in this letter, but instead described in the nonpublic inspection report. The circumstances surrounding these apparent violations, the significance of the issues, and the need for lasting and effective corrective action

<p>Enclosure contains Sensitive Unclassified Non-Safeguards Information. Upon separation, this cover letter is decontrolled.</p>

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were discussed with members of your staff at the inspection exit meeting at the conclusion of the on-site inspection and on March 17 and April 22, 2016. As a result, it may not be necessary to conduct a pre-decisional enforcement conference in order to enable the NRC to make an enforcement decision. However, a Notice of Violation is not presently being issued for these inspection findings.

In addition, since your facility has not been the subject of escalated enforcement actions within the last two inspections, and based on our understanding of your corrective action, a civil penalty may not be warranted in accordance with Section 2.3.4 of the Enforcement Policy.

We believe we have sufficient information to make an enforcement decision regarding the apparent violations. Therefore, you may accept the violation(s) as characterized in this letter and notify us of that decision within **10** days. Alternatively, before the NRC makes its final enforcement decision, you may choose to provide your perspective on this matter, including the significance, cause, and corrective actions, as well as any other information that you believe the NRC should take into consideration by: (1) requesting a pre-decisional enforcement conference (PEC) to meet with the NRC and provide your views in person; or (2) responding in writing to the apparent violations addressed in this inspection report within 30 days of the date of this letter. Please contact James P. Dwyer at (610) 337-5309 within **10** days of the date of this letter to notify NRC whether you are interested in attending a PEC, providing a written response, or accepting the violations.

If you choose to provide a written response, it should be clearly marked as a "Response to Apparent Violations in Inspection Report No. 03037829/2016002; EA-16-059" and should be sent to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region I, 2100 Renaissance Boulevard, Suite 100, King of Prussia, PA 19406. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a PEC.

If you choose to request a PEC, the meeting should be held in our office in King of Prussia, PA within 30 days of the date of this letter. The PEC will afford you the opportunity to provide your perspective on the apparent violation(s) and any other information you believe the NRC should take into consideration before making an enforcement decision. The topics discussed during the conference may include the following: information to determine whether the violation(s) have occurred, information to determine the significance of the violation(s), information related to the identification of the violation(s), and information related to any corrective actions taken or planned to be taken. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," is included on the NRC's Web site at:

<http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notice/1996/in96028.html>, may

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be helpful. Please note that if a PEC is held, the NRC will issue a press release to announce the time and date of the conference; however the PEC will be closed to public observation since Security-Related information will be discussed.

In addition, please be advised that the number and characterization of apparent violations described in the enclosed inspection report may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be made available electronically for public inspection in the NRC Public Document Room located at NRC Headquarters in Rockville, MD, and from the NRC's document system, the Agency-wide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. 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 from the NRC's document 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 the top of each page of your response, "Security-Related Information – Withhold Under 10 CFR 2.390." To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information. In accordance with 10 CFR 2.390(b)(1)(ii), the NRC is waiving the affidavit requirements for your response.

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.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses**; then **Regulations, Guidance and Communications**. The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **About NRC, Organizations & Functions; Office of Enforcement; Enforcement documents**; then **Enforcement Policy (Under 'Related Information')**. 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 8:00 a.m. to 5:30 p.m. EST, Monday through Friday

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(except Federal holidays). To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction.

Sincerely,

/RA/

James M. Trapp, Director
Division of Nuclear Materials Safety

Enclosure:
Inspection Report No. 03037829/2016002
(Non-public)

cc with enclosure:
Edwin Carrasquillo, Security Director

cc without enclosure:
Commonwealth of Puerto Rico

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