



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

October 26, 2016

Docket No. 03033911

License No. 52-25344-01

Jose Alsina Cardona
Vice President and COO
Banco de Sangre de Servicios Mutuos
662 Ponce de Leon Avenue
Hato Rey, Puerto Rico 00918

SUBJECT: NRC INSPECTION REPORT NO. 03033911/2016002, BANCO DE SANGRE DE SERVICIOS MUTUOS, INC., PUERTO RICO, SITE AND NOTICE OF VIOLATION

Dear Mr. Cardona:

On June 9, 2016, Randolph Ragland of this office conducted a security inspection at your facility in Hato Rey, Puerto Rico. The inspection continued in-office until October 20, 2016. The inspection was limited to a review of your implementation of 10 CFR 37 security requirements. The inspection consisted of observations by the inspector, interviews with personnel, and selective examination of representative records. Additional information provided in emails dated September 23 and October 13, 2016, between Edwin Velez of your staff and Randolph Ragland of this office was also examined as part of the inspection. The findings of the inspection were discussed with you, Edwin Velez and Ailed Marcano of your organization, at the conclusion of the inspection on October 20, 2016.

Based on the results of this inspection and in accordance with the NRC Enforcement Policy, the NRC has determined that two violations of NRC requirements occurred. Because these violations had the same root cause, they have been characterized collectively as one Severity Level IV problem. The current Enforcement Policy is included on NRC's website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The violations are cited because they were identified by the NRC. Enclosure 2 provides a determination of the severity level and a description of the corrective and preventative actions taken by Banco de Sangre de Servicios Mutuos, Inc., to address the violations.

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence are already adequately addressed in our records. Therefore, you are not required to respond to this letter unless the description of your corrective actions in this letter 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.

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

J. Cardona

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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 Agencywide Documents Access and Management System (ADAMS), accessible from the NRC website at <http://www.nrc.gov/reading-rm/adams.html>. However, the material enclosed herewith contains Security-Related Information in accordance 10 CFR 2.390(d)(1) and its disclosure to unauthorized individuals could present a security vulnerability. Therefore, the material in the enclosures will not be made available electronically for public inspection. If Security-Related Information is necessary to provide an acceptable response, if you choose to submit one, 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.

In accordance with 10 CFR Part 19.11, you may be required to post this Notice within two working days. However, you are reminded to review NRC security requirements that limit the release of such information.

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 (except Federal holidays).

J. Cardona

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Please contact Randolph Ragland at 610-337-5083 if you have any questions regarding this matter.

Sincerely,

/RA/

Blake D. Welling, Chief
Commercial, Industrial, R&D
and Academic Branch
Division of Nuclear Materials Safety

Enclosures:

1. Notice of Violation (Non-Public)
2. Determination of Severity Level and
Description of Corrective Actions (Non-Public)

cc with Enclosures: Adalgisa Coste, Radiation Safety Officer

cc w/o Enclosures: Commonwealth of Puerto Rico

J. Cardona

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DATE	10/26/16		10/26/16				

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