



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

March 3, 2017

Gladys Colon
Site Lead
Cruz Roja Americana
PO Box 366046
San Juan, Puerto Rico 00936-6046

SUBJECT: NRC INSPECTION REPORT NO. 03032967/2016001, CRUZ ROJA
AMERICANA, PUERTO RICO, AND NOTICE OF VIOLATION

Dear Ms. Colon:

On June 8, 2016, Randolph Ragland of this office commenced a safety inspection at your Rios Piedras, Puerto Rico, facility, and on November 9, 2016, Mr. Ragland conducted additional interviews and document reviews at the American Red Cross facility in Philadelphia, Pennsylvania. The inspection continued in-office until March 1, 2017. 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. The findings of the inspection were discussed with you, Ada Diaz, and Edda Rodriguez of your organization at the conclusion.

Based on the results of this inspection and in accordance with the NRC Enforcement Policy, the NRC has determined that one Severity Level IV violation of NRC requirements occurred. The violation involved the failure to maintain a Radiation Safety Officer for your NRC license.

The violation is cited in the enclosed Notice of Violation (Notice), because the violation was identified by the NRC.

During our inspection exit meeting on March 1, 2017, you stated that Cruz Roja Americana is committed to radiation safety and to compliance with NRC regulations and license conditions. Further, you stated that as a corrective action you named a new Radiation Safety Officer in August of 2016, and that as a preventative measure, the American Red Cross Regional Director of Quality Assurance will provide enhanced oversight of Cruz Roja Americana's NRC licensed activities until your license is terminated.

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. Therefore, you are not required to respond to this letter unless the description herein does not accurately reflect your corrective actions or your position. If you contest this violation or its significance, you should provide a response within 30 days of the date of this inspection report, with the basis for your denial, to the Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington DC 20555-0001, with copies to: (1) the Regional Administrator, Region I and (2) the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, 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 website 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.

Current NRC regulations and guidance are included on the NRC's Web Site 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 Web Site 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).

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

Sincerely,



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

Docket No. 03032967
License No. 52-25220-01

Enclosure:
Notice of Violation

cc w/encl: Edda L. Rodriguez, Radiation
Safety Officer
Karey-Ann Schmidt, Regional
Director of QA
Commonwealth of Puerto Rico

NOTICE OF VIOLATION

Cruz Roja Americana
San Juan, Puerto Rico

Docket No. 03032967
License No. 52-25220-01

During an NRC inspection conducted on June 8, 2016, November 9, 2016, and continued in-office until March 1, 2017, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

Cruz Roja Americana, Inc., NRC License No. 52-25220-01, Condition 12, Amendment 7, dated November 17, 2015, authorized a named individual to fulfil the duties and responsibilities of the Radiation Safety Officer (RSO).

Contrary to the above, from August 25, 2015, until August 23, 2016, the named individual specifically authorized in Condition 12 of the license to fulfill the duties and responsibilities of the Radiation Safety Officer, did not fulfil the duties and responsibilities of the Radiation Safety Officer for the license. Specifically, Cruz Roja Americana, Inc. facility management terminated the Radiation Safety Officer on August 25, 2015, and did not submit a license amendment request to NRC to replace the Radiation Safety Officer until August, 23, 2016.

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 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 3rd day of March 2017