



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

July 24, 2015

Docket No. 03036911

License No. 52-25430-03

David M. Rhoe, CEO
CRMI
Paseo de la Fuente
D-4 Calle Tivoli
San Juan, PR 00926-6459

SUBJECT: NRC INSPECTION REPORT NO. 03036911/2015001, CRMI, AND NOTICE OF VIOLATION

Dear Mr. Rhoe:

On February 24 through July 9, 2015, Robin Elliott of this office conducted a safety inspection of activities authorized by the above listed NRC license. 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 correspondence dated March 2, May 20, June 2 and July 10, 2015, was examined as part of the inspection. The findings of the inspection were discussed with you at the conclusion of the inspection.

Based on the results of this inspection and in accordance with the NRC Enforcement Policy, the NRC has determined that three Severity Level IV violations of NRC requirements occurred. The violations involved: 1) the failure to conduct an adequate survey of the hot lab to identify a radiation area at the Cayey, Puerto Rico location; 2) the failure of the licensee, as shipper, to include an emergency response telephone number on the shipping papers used for the transportation of the dose of iodine-131 from the hospital in Cayey, Puerto Rico to a patient's residence; and 3) the failure of the licensee, as shipper, to certify on the shipping paper used for the transportation of the dose of iodine-131 from the hospital in Cayey, Puerto Rico to a patient's residence, that the material was offered for shipment in accordance with 49 CFR 172.204(a). The violations are cited in the enclosed Notice of Violation (Notice), because the violations were identified by the NRC.

The NRC has concluded that the information regarding the reasons for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence are already adequately addressed on the docket and in your correspondence dated July 10, 2015. Specifically, CRMI: (1) conducted a training session with the Nuclear Medicine Technologist at the Cayey, Puerto Rico location on March 2, 2015, to review proper surveying techniques; and (2) reviewed DOT shipping requirements with the individual responsible for the shipment made on November 21, 2014, specifically 49CFR172.201(d) and 49CFR172.204(a). In addition, during a telephone conversation on July 9, 2015, CMRI committed to compliance with NRC regulations and license conditions. 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 in the enclosed Notice.

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

Please contact Robin Elliott at (610) 337-5076 if you have any questions regarding this matter.

Sincerely,

/RA/

James P. Dwyer, Chief
Medical Branch
Division of Nuclear Materials Safety

Enclosure:
Notice of Violation

cc:
Commonwealth of Puerto Rico

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Division of Nuclear Materials Safety

Enclosure:
Notice of Violation

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OFFICE	DNMS/RI	N	DNMS/RI				
NAME	RElliott/re		JPDwyer/jpd				
DATE	07/15/2015		07/24/2015				

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NOTICE OF VIOLATION

CRMI
San Juan, PR

Docket No. 03036911
License No. 52-25430-03

During an NRC inspection conducted on February 24 through July 9, 2015, three violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 20.1501 requires, in part, that each licensee shall make or cause to be made, surveys that may be necessary for the licensee to comply with the regulations in this part.

10 CFR 20.1003 defines "Survey" as an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal or presence of radioactive material or other sources of radiation. When appropriate, such an evaluation includes a physical survey of the location of radioactive material and measurements or calculations of levels of radiation or concentrations or quantities of radioactive material present.

10 CFR 20.1003 defines "Radiation Area" as an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.005 rem (0.05 mSv) in 1 hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

10 CFR 20.1902(a) requires, in part, that the licensee post each radiation area with a conspicuous sign bearing the radiation symbol and the words "Caution Radiation Area."

Contrary to the above, on February 24, 2015, CRMI did not perform an adequate survey to identify an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.005 rem (0.05 mSv) in 1 hour at 30 centimeters from the radiation source and therefore, did not post the area with the words "Caution Radiation Area." Specifically, the licensee failed to conduct an adequate survey in the hot lab/injection area of the Cayey, Puerto Rico, facility to evaluate the radiation levels (>15 milliRoentgen/hour) emanating from a wall mounted sharps container and did not post the sharps container with the words, "Caution Radiation Area," as required by 10 CFR 20.1902(a).

This a Severity Level IV violation, Enforcement Policy Section 6.7

- B. 10 CFR 71.5 requires, in part, that each licensee who transports licensed material outside the site of usage, as specified in the NRC license, or where transport is on public highways, shall comply with applicable requirements of the DOT regulations in 49 CFR parts 107, 171 through 180, and 390 through 397, appropriate to the mode of transport.

1. 49 CFR 172.201(d) requires, in part, that a shipping paper must contain an emergency response telephone number and, if utilizing an emergency response information telephone number service provider, identify the person who has a contractual agreement with the service provider as prescribed in subpart G of this part.

Contrary to the above, on November 21, 2014, CRMI transported radioactive material using a shipping paper that did not contain an emergency response telephone number as prescribed in subpart G of this part. Specifically, the licensee transported 9.558 GBq of I-131 from the hospital in Cayey, Puerto Rico to a patient's home by public highway using a shipping paper that listed a service provider's emergency response information telephone number for which the licensee no longer had a contractual agreement.

This is a Severity Level IV violation, Enforcement policy Section 6.8

2. 49 CFR 172.204(a) requires, in part, that each person who offers a hazardous material for transportation shall certify that the material is offered for transportation in accordance with this subchapter by printing on the shipping paper containing the shipping description the certification contained in paragraph (a)(1) of this section or the certification containing the language contained in paragraph (a)(2) of this section.

Contrary to the above, on November 21, 2014, CRMI did not certify that the material was offered for transportation in accordance with 49 CFR 172.204(a) by printing on the shipping paper containing the shipping description the certification contained in paragraph (a)(1) of this section or the certification containing the language contained in paragraph (a)(2) of this section. Specifically, the licensee transported 9.558 GBq of I-131 from the hospital in Cayey, Puerto Rico to a patient's home by public highway using a shipping paper prepared and certified by the previous shipper.

This is a Severity Level IV violation, Enforcement Policy Section 6.8

The NRC has concluded that information regarding the reason for the violations, 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 24 day of July 2015