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

November 6, 2008

Docket No. 030-37454 License No. 52-31241-01
EA-08-226

Edwin Marshall, M.D.
Centro Cardiovascular del Este, CSP
PMB 202
P.O. Box 70005
Fajardo, PR 00738

SUBJECT: INSPECTION NO. 03037454/2007001, CENTRO CARDIOVASCULAR DEL ESTE, CSP, FAJARDO, PUERTO RICO SITE; NRC OFFICE OF INVESTIGATIONS (CASE NO. 1-2008-012); AND NOTICE OF VIOLATION

Dear Dr. Marshall:

On November 15, 2007, Todd Jackson and Lizette Roldán of this office conducted a safety inspection at 375 General Valero Avenue, Suite 102, Fajardo, Puerto Rico, 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 inspectors, interviews with personnel, and a selective examination of representative records. The interviews included a telephone discussion with your authorized user, Dr. Rene Baez-Carattini, on November 26, 2007. The preliminary findings of the inspection were discussed with you and other members of your organization at the conclusion of the inspection on November 15, 2007. An exit meeting was conducted during a telephone discussion between Mr. Garcia-Alvarez of your staff and Mr. James P. Dwyer of my staff on October 8, 2008.

Based on the results of this inspection, it appears that your activities were not conducted in full compliance with NRC requirements. The inspection findings, described in the enclosed report, include: (1) an apparent violation of 10 CFR 35.27(b) and 10 CFR 35.63(d) for failure to follow the instructions of the Authorized User regarding the preparation of byproduct material for medical use; and (2) an apparent violation of 10 CFR 35.2063 for failure to record, in the record of dosage determinations, the dosage and the date and time of dosage determination. Following the inspection, the NRC Office of Investigations conducted an investigation to determine if three members of your organization deliberately violated these regulatory requirements. Deliberate violations are accorded much higher significance when enforcement action is considered. Onsite interviews to support the investigation were performed on February 5 and 6, 2008. NRC concluded from the investigation that these three individuals did not act deliberately when they violated NRC requirements.

A Notice of Violation is enclosed that categorizes each violation by severity level. You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. In addition, your response should indicate how you will improve your oversight of the licensed program and how

you will improve communications between your Authorized User, your Nuclear Medicine Technologist and your Radiation Safety Officer to ensure that your licensed program is operated safely and in accordance with requirements. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

Current NRC regulations are included on the NRC's website at www.nrc.gov ; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material;** then **Regulations, Guidance, and Communications Page.** The current Enforcement Policy is included on the NRC's website at www.nrc.gov ; select **About NRC; Organization and Functions; Office of Enforcement; About Enforcement;** then **Enforcement Policy.** 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 7:00 a.m. to 6:30 p.m. EST, Monday through Friday (except Federal holidays).

Please contact Mr. Dwyer at 610-337-5309 if you have any questions regarding this matter.

Sincerely,

/RA E. W. Cobey for/

John D. Kinneman, Director
Division of Nuclear Materials Safety

Enclosures:
Notice of Violation
Inspection Report No. 03037454/2007001

cc w/ enclosures:
David Rhoe, Radiation Safety Officer
Commonwealth of Puerto Rico

you will improve communications between your Authorized User, your Nuclear Medicine Technologist and your Radiation Safety Officer to ensure that your licensed program is operated safely and in accordance with requirements. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

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Division of Nuclear Materials Safety

Enclosures:
Notice of Violation
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cc w/ enclosures:
David Rhoe, Radiation Safety Officer
Commonwealth of Puerto Rico

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DATE	10/20/08		10/20/08		10/28/08		10/29/08	
OFFICE	OI		FSME		OGC		OE	
NAME	EWilson/EW		MBurgess		M. Barkman NLO		L. Sreenivas for NHilton	
DATE	10/30/08		11/4/2008		10/31/08		11/05/08	
~~OFFICE~~	RI/DNMS							
~~NAME~~	Kinneman/ewc f/							
~~DATE~~	11/06/08							

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NOTICE OF VIOLATION

Centro Cardiovascular del Este, CSP
Fajardo, PR

Docket No. 03037454
License No. 52-31241-01

During an NRC inspection conducted on November 15, 2007, and February 5-6, 2008, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. 10 CFR 35.27(b) requires, in part, that a licensee that permits the preparation of byproduct material for medical use by an individual under the supervision of a physician who is an authorized user, as allowed by 10 CFR 35.11(b)(2), shall require the supervised individual to follow the instructions of the supervising authorized user regarding the preparation of byproduct material for medical use, written radiation protection procedures established by the licensee, the regulations of this chapter, and license conditions.

   10 CFR 35.63(d) requires that unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent.

   The supervising authorized user provided a written procedure that required patient dosages for a specific diagnostic scan range between 8 and 12 millicuries of technetium-99m for the resting portion of the scan and between 25 and 30 millicuries of technetium-99m for the stress portion of the scan.

   Contrary to the above, on several occasions including, but not limited to, August 27, 29, September 10, 14, 20, and November 8, 2007, the licensee's technologist ordered dosages within the prescribed range for scheduled scan, however, prior to the administration of the dosages, the technologist split the dosages so that additional unscheduled patients could be accommodated. The dosages administered were not recorded; however, all of the dosages administered could not have fallen within the prescribed range.

   This is a Severity Level IV violation (Supplement VI).

B. 10 CFR 35.2063 requires a licensee to retain a record of dosage determinations required by 10 CFR 35.63 for a period of 3 years and that the record contain the radiopharmaceutical; the patient's name, or identification number if one has been assigned; the prescribed dosages and the determined dosage; the date and time of the dosage determination; and the name of the individual who determined the dosage.

   Contrary to the above, on several occasions including, but not limited to, August 27, 29, September 10, 14, 20, and November 8, 2007, the record of dosage determinations did not contain the determined dosage or the date and time of dosage determination.

   This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Centro Cardiovascular del Este, CSP is hereby required to submit a written statement or explanation 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). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

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.

Dated This 6th day of November 2008