

NRC FORM 591M PART 1
(10-2008)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:
Cardiovascular Associates of Puerto Rico
 Nuclear Medicine Division
 P.O. Box 6480, Santa Rosa Unit
 Bayamón, Puerto Rico 00960-9004
 @ Instituto San Pablo, Santa Cruz Street, Bayamón
 REPORT No. 2009-001

2. NRC/REGIONAL OFFICE
U.S. Nuclear Regulatory Commission
 Region I, 475 Allendale Road
 King of Prussia, Pennsylvania 19406-1415

3. DOCKET NUMBER(S)
030-30966

4. LICENSE NUMBER(S)
52-25033-01

5. DATE(S) OF INSPECTION
January 14 & February 12, 2008

LICENSEE:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, NUREG-1600, to exercise discretion, were satisfied.
- Non-Cited Violation(s) was/were discussed involving the following requirement(s) and Corrective Action(s):

4. During this inspection certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.

10 CFR §35.60(a) states in part, for direct measurements performed in accordance with §35.63, a licensee shall possess and use instrumentation to measure the activity of unsealed byproduct material. 10 CFR §35.60(b) states, a licensee shall calibrate the instrumentation required in paragraph (a) of this section in accordance with nationally recognized standards or the manufacturer's instructions. 10 CFR §35.60(c) states, a licensee shall retain a record of each instrument calibration required by this section in accordance with §35.2060.

Contrary to the above, the licensee did not calibrate their dose calibrator nor did they have a record of the calibration, specifically they did not perform quarterly linearity test in accordance to manufacturer's instructions.

Corrective Actions: Licensee performed linearity test on dose calibrator and has committed to performing quarterly linearity test in accordance with the manufacturer's instructions. They also commit to retaining the linearity records for their dose calibrator.

Licensee's Statement of Corrective Actions for Item 4, above.

I hereby state that, within 30 days, the actions described by me to the inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

TITLE	Printed Name	Signature	Date
LICENSEE'S REPRESENTATIVE	Dr. René Pérez-Ríos, Director	<i>René Pérez-Ríos</i>	2/23/09
NRC INSPECTOR	Lizette Roldán, Ph.D./Health Physicist	<i>Lizette Roldán</i>	02/23/09