NRC FORM 591M PART 1
(06-2010)
10 CFR 2.201

U.S NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Cardiology Associates, Inc. 621 Memorial Drive, Suite 502 South Bend, IN 46601 REPORT NUMBER(S): 11-01	U.S. Nuclear Regulatory Commission, Region III 2443 Warrenville Road, Suite 210 Lisle, Illinois 60532

3. DOCKET NUMBER(S)	4. LICENSEE NUMBER(S)	5. DATE(S) OF INSPECTION
030-36946	13-32580-01	June 13, 2011

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) were discussed involving the following requirement(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

Statement of Corrective Actions

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			
NRC INSPECTOR	Andrew M. Bramnik	Andrew M Bramnik	6/13/2011
Branch Chief	Tamara E. Bloomer	TE Bloomer	6/22/11

NRC FORM 591 M PART 3
(06-2010)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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1. LICENSEE	2. NRC/REGIONAL OFFICE
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6. INSPECTION PROCEDURES	7. INSPECTION FOCUS AREAS
87130	03.01 – 03.07

SUPPLEMENTAL INSPECTION INFORMATION

1.PROGRAM	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
2201	5	John F. Kobayashi, M.D. - RSO	574-234-9001

☒ Main Office Inspection — Next Inspection Date: June 2016

☐ Field Office Inspection _____

☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

This was a routine inspection of a private clinic that performed six diagnostic nuclear medicine procedures per day. One full time nuclear medicine technologist and one part time stress technologist performed all patient procedures Monday through Thursday. The licensee obtained licensed material as unit doses from an area nuclear pharmacy, and did not use bulk doses or molybdenum/technetium generators. The licensee performed exclusively cardiac scans, as well as occasional MUGA scans, and was not authorized to perform or administer therapeutic doses.

Performance Observations

The inspector observed one resting dose of technicium-99m being administered during the inspection. This observation, combined with interviews of the technologist and the Radiation Safety Officer, revealed an adequate level of understanding of emergency and material handling procedures and techniques. Dose calibrator constancy checks, package receipt, daily surveys, and waste handling and disposal procedures were successfully demonstrated. An outside consultant performed quarterly program audits that were adequate to oversee the program.

Licensed material was adequately secured and not readily accessible to members of the general public. The licensee possessed a radiation survey meter that was calibrated, operational, and performed well in side-by-side comparison with an NRC instrument.

Independent measurements did not indicate readings in excess of Title 10 of the Code of Federal Regulations (10 CFR) Part 20 limits in restricted or unrestricted areas. Personal whole body and extremity dosimetry were observed worn by the staff during the inspection, and records did not indicate doses in excess of 10 CFR Part 20 limits. Dosimetry records indicated that the highest annual whole body and extremity readings for the past four years were 521 millirem (mrem) and 790 mrem, respectively.

No violations were identified during this inspection.