

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

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|---|---|---|--|
| 1. LICENSEE/LOCATION INSPECTED: Cardiovascular Consultants, P.C. 10010 Donald S. Powers Drive Munster, Indiana 46321 REPORT NUMBER(S) 2019001 | | 2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352 | |
| 3. DOCKET NUMBER(S) 030-33827 | 4. LICENSE NUMBER(S) 13-26642-01 | 5. DATE(S) OF INSPECTION 9/17/19 | |

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, 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 in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.
(Violations and Corrective Actions)

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 | Robert G. Gattone, Jr. | <i>Robert G. Gattone, Jr.</i> | 10/2/19 |
| BRANCH CHIEF | Aaron T. McCraw <i>Robert Ruiz for</i> | <i>[Signature]</i> | 10/2/19 |

Docket File Information

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| 6. INSPECTION PROCEDURES USED 87130 | | 7. INSPECTION FOCUS AREAS 03.01 through 03.07 | |

SUPPLEMENTAL INSPECTION INFORMATION

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|---------------------------------|----------------------|---|---|
| 1. PROGRAM CODE(S) 02201 | 2. PRIORITY 5 | 3. LICENSEE CONTACT Wail Asfour, M.D., RSO | 4. TELEPHONE NUMBER (219) 934-4200 |
|---------------------------------|----------------------|---|---|

☒ Main Office Inspection Next Inspection Date: 09/17/2024
☐ Field Office Inspection _____
☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

This was a routine inspection of a private clinic located in Munster, Indiana, performing approximately 10 diagnostic nuclear medicine procedures per day, Monday through Friday, each week. One full-time nuclear medicine technologist (NMT), and 1 PRN NMT, performed all patient procedures. The licensee obtained licensed material as unit doses from an area nuclear pharmacy, and did not use xenon-133, bulk doses, or molybdenum-99/technetium generators. The licensee exclusively performed cardiac scans. The licensee was not authorized to perform or administer therapeutic doses. All waste was held for decay-in-storage (DIS) or returned to the nuclear pharmacy as a limited quantity shipment.

Performance Observations

The inspector: (1) observed an NMT administer technetium-99m Sestamibi to a patient while using proper personal protection equipment; (2) noted that the licensee had a radiation safety consultant; (3) reviewed selected radiation protection audit records, including leak test records, sealed source inventory records, dose calibrator calibration records, and dosimetry badge records; (4) noted that there were no medical events since the last inspection; (5) noted that there were not radioactive spills since the last inspection; (6) observed that licensed material was secured as required; (7) reviewed records showing that survey instruments were calibrated as required; (8) observed that the licensee had proper survey meters; (9) noted that the licensee did not do uptake, dilution, and excretion studies; (10) observed an NMT use proper shielding including a syringe shield, a pig, and a shielded syringe carrier; (11) observed that an NMT wore whole body and extremity dosimeter badges while handling unsealed licensed material; (12) observed an NMT use a dose calibrator to verify the dosage radioactivity prior to administering it to the patient; (13) reviewed selected dosimeter badge results and the doses were well below the occupational dose limits; (14) reviewed records regarding hazmat re-training; (15) reviewed selected records of end-of-day ambient exposure rates in the facility; (16) reviewed selected records of weekly wipe surveys in the facility; (17) observed an NMT demonstrate how she would respond to a spill of unsealed licensed material based on a scenario posed by the inspector; and (18) observed an NMT demonstrate how she received packages containing licensed material, based on a scenario posed by the inspector; and (19) observed an NMT demonstrate how she transferred packages containing licensed material to the nuclear pharmacy, based on a scenario posed by the inspector. No violations of NRC requirements were identified as a result of this inspection.