

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Cardiology Consultants of Michigan
3535 West 13 Mile Road
Royal Oak, MI 48073

REPORT NUMBER(S) 2018001

2. NRC/REGIONAL OFFICE

Region III
U. S. Nuclear Regulatory Commission
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

3. DOCKET NUMBER(S)

030-36295

4. LICENSE NUMBER(S)

21-32460-01

5. DATE(S) OF INSPECTION

July 12, 2018

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 violations(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	Ryan Craffey	<i>Ry Craffey</i>	7/12/18
BRANCH CHIEF	Aaron McCraw	<i>gzw - for AJM</i>	8/2/18

Docket File Information

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6 INSPECTION PROCEDURES USED

87130

7. INSPECTION FOCUS AREAS

All

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)

02201

2 PRIORITY

5

3. LICENSEE CONTACT

James Botti, MS - RSO

4 TELEPHONE NUMBER

(734) 662-3197

☒ Main Office Inspection

Next Inspection Date: 07/12/2023

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was an unannounced routine inspection of a cardiology practice authorized to use byproduct material for diagnostic medical purposes at its clinic on the premises of the Beaumont campus in Royal Oak, Michigan. At the time of the inspection, one nuclear medicine technologist performed around seven cardiac stress tests per week, starting on Wednesday and continuing on Thursday if necessary. The licensee used only unit doses of radiopharmaceuticals, and retained the services of a consulting medical physicist who audited the radiation safety program quarterly.

PERFORMANCE OBSERVATIONS

The inspector toured the clinic in Royal Oak to evaluate the licensee's measures for materials security, hazard communication, and exposure control. The inspector conducted independent surveys of the facility, and observed the licensee's conduct of area surveys, including the response to a small area of minor contamination identified within the restricted area. The inspector also observed the preparation of one unit dose for a cardiac stress test; however, the licensee did not administer this dose, as the patient was unable to complete the test for medical reasons. The inspector also observed the preparation of packages containing limited quantities of licensed material for return to the radiopharmacy, and the handling of radioactive waste. The inspector interviewed the licensee's staff to discuss a variety of radiation safety topics, and found the staff to be knowledgeable of licensee procedures and regulatory requirements.

The inspector also reviewed a selection of records, including consultant audits, documentation of various radiation surveys and instrument quality assurance checks, sealed source inventories and leak tests results, decay-in-storage waste disposal logs, hazmat refresher training materials, and personnel dosimetry reports, which indicated that occupational exposures to staff since the last inspection had been well below regulatory limits.

No violations of NRC requirements were identified as a result of this inspection.

GW for
ATM
8/2/18