

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Cardiac Care Associates, PC
1205 S. Main Street
Crown Point, IN 46307

REPORT NUMBER(S) 2016001

2. NRC/REGIONAL OFFICE

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

3. DOCKET NUMBER(S)

030-33947

4. LICENSE NUMBER(S)

13-26674-01

5. DATE(S) OF INSPECTION

Oct. 18, 2016

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:

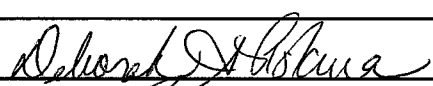
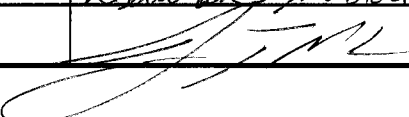
- ☒ 1. Based on the inspection findings, no violations were identified.
- ☐ 2. Previous violation(s) closed.
- ☐ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was 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	Deborah A. Piskura, Senior Health Physicist		10/18/16
BRANCH CHIEF	Aaron T. McCraw, Chief, MIB		10/28/16

Docket File Information

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6. INSPECTION PROCEDURES USED

87130

7. INSPECTION FOCUS AREAS

03.01 - 03.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)

02201

2. PRIORITY

5

3. LICENSEE CONTACT

Trent G. Orfanos, M.D., RSO

4. TELEPHONE NUMBER

(219) 662-0137

☒ Main Office Inspection

Next Inspection Date: Oct 18, 2021

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was a routine inspection of a private-practice cardiology clinic. The licensee was authorized to use licensed material permitted by 10 CFR 35.100 and 35.200. The licensee performed nuclear studies Monday through Thursday. The clinic employed one full-time technologist who performed 50-55 patient cardiac studies monthly. The licensee received unit doses from a licensed radiopharmacy. The licensee retained a consultant who audited the radiation safety program on a quarterly basis (last audit on 7/27/2016, with no findings).

This inspection consisted of interviews with licensee personnel, a review of selected records, a tour of the nuclear medicine department, and independent measurements. The inspection included observations of dose calibrator QA checks, security of licensed material, and use of personnel monitoring. The inspector observed the licensee personnel prepare, assay, and administer three unit doses for one resting study and two cardiac stress testing procedures.

No violations of NRC requirements were identified during this inspection.