

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Medical Group of Fort Wayne
d/b/a Heart Center Medical Group
Fort Wayne, IN

REPORT NUMBER(S) 2009-001

2. NRC/REGIONAL OFFICE

U.S. Nuclear Regulatory Commission
Region III
2443 Warrenville Road
Suite 210
Lisle, Illinois 60532-4351

3. DOCKET NUMBER(S)

030-34778

4. LICENSEE NUMBER(S)

13-32106-01

5. DATE(S) OF INSPECTION

Jan. 13, 2009

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.
(Violations and Corrective Actions)

Condition 15. of License No. 13-32106-01 specifies that the licensee shall conduct its program in accordance with the statements, representations & procedures in Application dated 4/25/2008. Item 10. C. of application dated 4/25/2008, "Safe Use of Unsealed Licensed Material" states that the licensee will develop and implement policies and procedures for safe use of licensed material. Item A, of "Procedures for the Security and Safe Use of Radiative material in Nuclear Medicine, States do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is used or stored. Contrary to the above, a physician authorized uses drink coffee during a cardiac stress testing procedure. The licensee will conduct an interview for the dining staff and a broadcast voice mail to the physicians, informing them of the violation, and post the cardiac stress testing area to remind staff that food and drink is prohibited in the area.

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	JO ANN JOHNSTON	JoAnn Johnston, Director of Operations	1-13-09
NRC INSPECTOR	Deborah A. Piskura	Deborah A. Piskura	1/13/2009

**SAFETY INSPECTION REPORT
AND COMPLIANCE INSPECTION**

1. LICENSEE

Medical Group of Ft. Wayne d/b/a Heart Center/Medical Group
REPORT NUMBER(S) 2009-001

2. NRC/REGIONAL OFFICE

Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532

3. DOCKET NUMBER(S)

030-34778

4. LICENSE NUMBER(S)

13-26508-01

5. DATE(S) OF INSPECTION

Jan. 13, 2009

6. INSPECTION PROCEDURES USED

87130

7. INSPECTION FOCUS AREAS

03.01 – 03.08

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)

02201

2. PRIORITY

5

3. LICENSEE CONTACT

Scott E. Mattson, D.O., RSO

4. TELEPHONE NUMBER

219-432-2297



Main Office Inspection

Next Inspection Date: Jan. 2014



Field Office

Temporary Job Site
Inspection**PROGRAM SCOPE**

This licensee was a private practice diagnostic cardiology office and authorized to use licensed material permitted by Sections 35.100 and 35.200. The nuclear medicine department was staffed with three full-time technologists who performed approximately 300 diagnostic nuclear cardiology procedures per month. The licensee received unit doses from a licensed radiopharmacy

This inspection consisted of interviews with licensee personnel, a review of select records, tour of the nuclear medicine department, and independent measurements. The inspector observed licensee personnel prepare, assay and administer a unit dosage for a cardiac stress testing procedure. The inspection included observations of security of byproduct material, use of personnel monitoring, dose calibrator QA checks, area surveys, and packaging of RAM for transportation.

While the inspector observed a pharmaceutical stress testing procedure, an authorized physician user, who was attending to the patient, was observed drinking cup of coffee in the cardiac stress testing area. License Condition 15. of License No. 13-321066-01 references the licensee's renewal application dated April 25, 2008. Item 10.C. of this application refers to the licensee's established procedures for "Safe Handling Practices for Radioactive Material." Item A states, "Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is used or stored." At the inspector's request, the physician stopped drinking his coffee and threw the coffee cup in the trash. The licensee planned to take the following corrective actions: (1) discuss policies regarding eating/drinking in RAM areas with the nuclear medicine staff during an in-service; (2) send a broadcast voicemail message to the authorized physician users informing them of the violation identified during this inspection; and (3) posting the cardiac stress testing area with signs reminding the staff that food and drink (for their consumption) is prohibited.