

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

The Heart Center of Lake County, P.C.
5800 Broadway
Merrillville, IN 46410

REPORT NUMBER(S): 11-01

2. NRC/REGIONAL OFFICE

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

3. DOCKET NUMBER(S)

030-35414

4. LICENSEE NUMBER(S)

13-32260-01

5. DATE(S) OF INSPECTION

June /7, 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:

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1. Based on the inspection findings, no violations were identified.

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2. Previous violation(s) closed.

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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.

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Non-cited violation(s) were discussed involving the following requirement(s):

(1) Title 10 of the Code of Federal Regulations (10 CFR) 20.2103(a) states, in part, that each licensee shall maintain records showing the results of surveys and calibrations required by 10 CFR 20.1501 and 20.1906(c).

(2) Title 10 CFR 35.60(c) states that a licensee shall retain a record of each instrument calibration required by this section in accordance with 10 CFR 35.2060.

Contrary to the above, between October 26 and November 6, 2009, the licensee failed to record the results of package receipt surveys and daily dose calibrator constancy calibrations, as required.

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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	<i>Andrew M. Bramnik</i>	6/17/2011
Branch Chief	Tamara E. Bloomer	<i>T. Bloomer</i>	6/22/11

Docket File Information
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5. DATE(S) OF INSPECTION
June 17, 2011

6. INSPECTION PROCEDURES
87130

7. INSPECTION FOCUS AREAS
03.01 – 03.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM
2201

2. PRIORITY
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3. LICENSEE CONTACT
Charles-Luwanga Okoro, D.O. - RSO

4. TELEPHONE NUMBER
219-884-9180

☒ 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 approximately 80 - 100 diagnostic nuclear medicine procedures per month. One full time nuclear medicine technologist and one stress technologist performed all patient procedures Monday through Friday. 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 and was not authorized to perform or administer therapeutic doses.

PERFORMANCE OBSERVATIONS

The inspector observed one resting and one stress dose of technetium-99m being administered during the inspection. These observations, combined with interviews of available staff, 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 268 millirem (mrem) and 2550 mrem, respectively.

Two Non-Cited Violations (NCVs) were identified during this inspection: On October 25, 2009, the nuclear medicine technologist went on vacation, and a temporary technologist was hired through a staffing agency. The temporary technologist received one half day of turnover with the permanent technologist on October 25, 2009. Between October 26 and November 6, 2009, the temporary technologist failed to maintain records showing the results of package receipt surveys, as required by 10 CFR 20.2103(a), and failed to retain a record of dose calibrator daily constancy checks, as required by 10 CFR 30.60(c). The permanent technologist immediately identified both issues upon her return, and brought the issues to the attention of licensee management. Immediate corrective actions taken included documenting the non-compliances, contacting the staffing agency, double-checking survey records each week, and proposing enhanced training for temporary workers. As both issues were self-identified, non-repetitive, non-willful, and corrective actions have been taken, both issues meet the criteria to be NCVs.

No additional violations were identified during this inspection.