

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Portage Heart Care, PC
One Tower Plaza
103 E. 89th Avenue
Merrville, IN 46410

REPORT NUMBER(S) 13-01

2. NRC/REGIONAL OFFICE

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

3. DOCKET NUMBER(S)

030-36408

4. LICENSE NUMBER(S)

13-32478-01

5. DATE(S) OF INSPECTION

August 13, 2013

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:

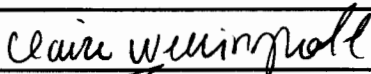
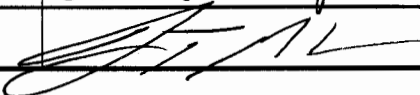
- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is 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	Claire E. Wellinghoff		8/21/13
BRANCH CHIEF	Aaron McCraw		8/22/13

Docket File Information
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6. INSPECTION PROCEDURES USED 87130	7. INSPECTION FOCUS AREAS 3.01-3.07
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SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02201	2. PRIORITY 5	3. LICENSEE CONTACT Sharon Updike, RSO	4. TELEPHONE NUMBER (219) 796-0400
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Main Office Inspection Next Inspection Date: August 13, 2018

Field Office Inspection _____

Temporary Job Site Inspection _____

PROGRAM SCOPE

The licensee had two authorized locations of use in Merrillville and Portage, IN. The Merrillville facility was open Tuesday, Thursday, and Friday; the Portage facility was open Monday, Wednesday and every third Thursday. There was one full-time, and two part-time nuclear medicine technologists (NMT) that worked at both locations. At the Portage facility, the licensee performed approximately 7 cardiac imaging studies per week, while the Merrillville facility performed approximately 10-12 cardiac imaging studies per week. The licensee primarily utilized unit doses of Tc-99m for the diagnostic imaging tests, and very rarely used thallium. Doses commonly used for the cardiac rest and stress tests were 10mCi and 30mCi respectively. The Radiation Safety Officer (RSO) for the license was an outside consultant who oversaw the radiation safety program, and conducted quarterly audits of the two authorized locations.

Performance Observations

The Merrillville facility was visited during the time of the inspection; the inspector was able to observe two patient administrations (one stress and one rest test) at that time. The inspector observed the NMT: (1) assay the dose; (2) use tongs to handle the material; (3) carry the dose in a shielded box to the patient injection area; (4) use a syringe shield during the administration; and (5) properly dispose of waste after use. The NMT demonstrated package receipt procedures, daily calibration checks, spill procedures, daily surveys, as well as performing an inventory check with no identified issues. The inspector also reviewed select licensee records including: (1) accuracy test records; (2) survey meter calibrations; (3) linearity test records; (4) daily surveys; (5) weekly wipe test results; (6) leak test records; (7) disposal logs; (8) quarterly audit reports; and (9) dosimetry reports with no issues identified. Additionally, the licensee had a calibrated, and operational survey meter in the hot lab. The inspector performed independent measurements in the hot lab and injection area; no readings above the background level were observed.