

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Community Heart and Vascular Hospital 1400 N. Ritter Ave., Suite 500 Indianapolis, IN	2. NRC/REGIONAL OFFICE Region III 2443 Warrenville Rd., Suite 210 Lisle, IL 60532 Select a location (Use keyboard arrows to select)...
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REPORT NUMBER(S) 2017-001

3. DOCKET NUMBER(S) 030-29663	4. LICENSE NUMBER(S) 13-24834-01	5. DATE(S) OF INSPECTION 12/12/17
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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)

10 CFR 20.1801 states, "The licensee shall secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas."

Contrary to the above, on 12/12/17, the licensee left the hot lab door open and unattended for about 2 minutes and the hot lab entrance was not being monitored by anyone to prevent unauthorized removal or access to Tc-99m (1 mCi), Cs-137 (0.01 mCi), and Co-57 (0.1 mCi). Corrective Actions include communication regarding the need to lock the hot lab door when it is not occupied. In addition, the licensee (See Part 2)

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	SHAO Poolman		12/18/17
NRC INSPECTOR	Robert G. Gattone, Jr.	Robert G. Gattone, Jr.	12/19/17
BRANCH CHIEF	Aaron T. McCraw		12/19/17

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1400 N. Ritter Ave, Suite 500
Indianapolis, IN

2. NRC/REGIONAL OFFICE

Region III
2443 Warrenville Rd., Suite 210
Lisle, IL 60532
Select a location ..

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12/12/17

(Continued)

ordered an automatic door closer for the hot lab door resulting in automatic door locking.

Docket File Information

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3. DOCKET NUMBER(S) 030-29663	4. LICENSE NUMBER(S) 13-24834-01	5. DATE(S) OF INSPECTION 12/12/17
6. INSPECTION PROCEDURES USED 87130	7. INSPECTION FOCUS AREAS 02.01 through 02.07	

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02121	2. PRIORITY 5	3. LICENSEE CONTACT Kiran Kireti, M.D., RSO	4. TELEPHONE NUMBER (317) 355-1234
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☒ Main Office Inspection Next Inspection Date: 12/12/2022

☐ Field Office Inspection _____

☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

The licensee received unit dosages of radiopharmaceuticals from an authorized radiopharmacy in Indianapolis, Indiana. The licensee provided cardiac diagnostic imaging. The licensee's work hours were 6:00am to 3:00pm. Two nuclear medicine technologists (NMTs) were working during the inspection.

Performance Observations

The inspector: (1) observed an NMT prepare a technetium-99m Cardiolite unit dosage, including measurement in a dose calibrator, use of personal protection equipment (PPE), including lab coats and gloves; (2) reviewed a sample of the licensee's consultant's records of its quarterly audits of the licensee's radiation protection program; (3) observed that the facility was posted as required; (4) observed that the licensee's hot lab included use of absorbent paper, L-block, and shielded containers; (5) observed that the facility was as required; (6) observed licensee staff members wearing their whole body and extremity dosimeter badges while handling unsealed licensed material; (7) observed an NMT administer a dosage to a patient, including use of dosimeter badges and PPE, syringe shield, and a unit dosage shield; (8) noted that a licensee's survey meter was calibrated as required; (9) noted that the licensee had not received any PET material, in accordance with the NRC license; (10) noted that the RSO was as authorized; (11) noted that the authorized users were as required; (12) observed an NMT properly prepare radioactive waste for return to the radiopharmacy, including required package surveys and markings; (13) conducted a side-by-side ambient exposure rate survey with an NRC owned, calibrated survey meter and the NMT used the licensee's survey instrument to survey the same surface and the licensee and the inspector measured 0.2 mR/hr at the surface of a constancy check source; (14) reviewed annual dosimetry records from 2013 through 10/31/17, and the highest whole body and extremity readings were 1736 millirem and 10,190 millirem, respectively; (15) noted that the licensee provided HAZMAT training in March 2016, and annual radiation safety training in March 2017; (16) reviewed a sample of spill reports and there were no overdoses to licensee staff or members of the public; (17) reviewed selected records regarding dose calibrator quarterly linearity tests, and annual accuracy tests; (18) reviewed selected quarterly sealed source inventory records; (19) reviewed selected sealed source leak test records; (20) observed an NMT demonstrate how she would respond to a spill based on a scenario posed by the inspector; and (21) used the NRC survey meter to conduct independent surveys of selected surfaces of the facility.