



Materials Inspection Report

1. Licensee/Location Inspected:

St. Louis Heart and Vascular, P.C.
11155 Dunn Rd.
Ste. 304E
St. Louis, MO 63136
(Location Inspected: 3550 McKelvey Rd.)

Report Number(s) 2022001

2. NRC/Regional Office

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

3. Docket Number(s)

030-35969

4. License Number(s)

24-32384-01

5. Date(s) of Inspection

October 26-27, 2022

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. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements, and were assessed at Severity Level IV, in accordance with the NRC Enforcement Policy.
- A. 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, corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy were satisfied.
(Non-cited violation(s) was/were discussed involving the following requirement(s))

B. The following violation(s) is/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.

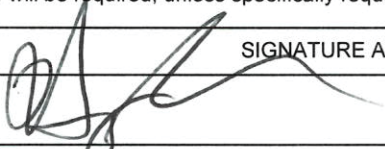

(Violations and Corrective Actions)

10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

Contrary to the above, on October 26, 2022, the licensee did not secure from unauthorized removal or limit access to approximately 45 millicuries of fluorine-18, 1.87 microcuries of cesium-137, 11.84 millicuries of (continued on Page 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 AND DATE
LICENSEE'S REPRESENTATIVE	Harvey Serota, MD CEO / Partner	 11-29-2022
NRC INSPECTOR	Jason Draper, Health Physicist	Jason D. Draper <small>Digitally signed by Jason D. Draper Date: 2022.11.22 13:13:06 -0600</small>
BRANCH CHIEF	Rhex A. Edwards	 <small>Digitally signed by Rhex A. Edwards Date: 2022.11.22 15:27:47 -0600</small>

Add Continuation Page

Materials Inspection Report (Continued)

(continued from Page 1)

cobalt-57, and 3.07 millicuries of germanium-68, located in the unlocked hot lab, which is a controlled area.

As corrective action, the licensee immediately closed the already locked door. To prevent recurrence, on November 8, 2022, the licensee installed a mechanical closer for the hot lab door to prevent anyone inadvertently leaving the door open when the hot lab is unattended.



Materials Inspection Record

1. Licensee Name: St. Louis Heart and Vascular, P.C.		2. Docket Number(s): 030-35969		3. License Number(s) 24-32384-01	
4. Report Number(s): 2022001			5. Date(s) of Inspection: October 26-27, 2022		
6. Inspector(s): Jason Draper		7. Program Code(s): 02201		8. Priority: 5	9. Inspection Guidance Used: IP 87130
10. Licensee Contact Name(s): Michael Rosenblatt, COO		11. Licensee E-mail Address: mrosenblatt@slhv.com		12. Licensee Telephone Number(s): (314) 852-1412	
13. Inspection Type: <input checked="" type="checkbox"/> Routine <input type="checkbox"/> Announced <input type="checkbox"/> Non-Routine <input checked="" type="checkbox"/> Unannounced		14. Locations Inspected: <input type="checkbox"/> Main Office <input checked="" type="checkbox"/> Field Office <input type="checkbox"/> Temporary Job Site <input type="checkbox"/> Remote		15. Next Inspection Date (MM/DD/YYYY): 10/26/2027 <input checked="" type="checkbox"/> Normal <input type="checkbox"/> Extended <input type="checkbox"/> Reduced <input type="checkbox"/> No change	
16. Location(s) Inspected List: 3550 McKelvey Rd., Bridgeton, MO					
17. Scope and Observations: <p>This was an inspection of a cardiology clinic authorized to use byproduct material for diagnostic medical purposes at its facilities in St. Louis and Bridgeton, Missouri. At the time of the inspection, one nuclear medicine technologist (NMT) performed primarily cardiac stress tests at each location (St. Louis: Tuesdays, Wednesdays, and Fridays; and Bridgeton: every weekday except every other Wednesday). A third technologist performed PET scans most weekdays at the Bridgeton location. The licensee ordered unit dosages from a local radiopharmacy, and averaged approximately 7-8 administrations per day at each location. The licensee retained the services of a medical physics consultant to perform instrument and camera quality control and to audit the implementation of the radiation safety program at each location quarterly.</p> <p>During the inspection, the inspector toured the licensee's Bridgeton location to verify licensed material was appropriately secured and performed independent surveys to verify postings were appropriate. There were no patients receiving administrations of byproduct material during the inspection, so the inspector interviewed the PET NMT on October 26 and the cardiac NMT on October 27 regarding radioactive package receipt procedures, daily checks of instrumentation, survey procedures, and radioactive waste handling. The inspector also reviewed a selection of records associated with sealed source inventories, dosimetry, instrument checks and calibrations, area radiation and contamination surveys, and routine audits and radiation safety program reviews.</p> <p>During the inspection on October 26, the inspector identified that the door to the hot lab was open when the inspector arrived, and that no licensee employee was maintaining control and constant surveillance of the room. Within the room, the licensee had one dosage of fluorine-18 (F-18) along with a variety of sealed sources (Cs-137, Co-57, and Ge-68) that were not secured from unauthorized access or removal. The licensee indicated that while the door was locked, it was left open after the radiopharmacy driver dropped off the F-18 dosage. This is contrary to 10 CFR 20.1801, which requires licensees to secure licensed material that is in storage. Using the sum of the fractions, the inspector calculated that the entirety of the material aggregated to a quantity greater than 10 times but less than 1000 times the quantities in the table in 10 CFR 20, Appendix C. Additionally, the inspector determined that the</p>					

Materials Inspection Record (Continued)

material was labeled and located in an area posted as containing radioactive materials and that the failure occurred despite the licensee having a functional program to detect and deter security violations. This is a Severity Level IV violation in accordance with the example in Section 6.7.d.6 of the enforcement policy.

The inspector determined that the cause of the violation was the licensee's failure to oversee the activities of the radiopharmacy driver to ensure material was secured when the driver left the licensee's facility. As immediate corrective action, the licensee closed the door, which was always locked. To prevent recurrence, the licensee installed a mechanical door closer on November 8, 2022, to prevent the door from being inadvertently left open.

One Severity Level IV violation was identified as a result of this inspection.

Signature and Date - Branch Chief



 Digitally signed by Rhex A. Edwards
Date: 2022.11.22 15:27:05 -06'00'