

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Venocure, PLLC 2881 Monroe Street Dearborn, Michigan REPORT NUMBER(S) 2014-001		2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352	
3. DOCKET NUMBER(S) 03038666	4. LICENSE NUMBER(S) 21-35088-01	5. DATE(S) OF INSPECTION 5/2/14	

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	Robert G. Gattone, Jr.	<i>Robert G. Gattone, Jr.</i>	5/15/14
BRANCH CHIEF	Aaron T. McCraw	<i>[Signature]</i>	5/15/14

Docket File Information

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6. INSPECTION PROCEDURES USED 87130	7. INSPECTION FOCUS AREAS 03.01, 03.02, and 03.04 through 03.07
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SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02201	2. PRIORITY 5	3. LICENSEE CONTACT Jim Botti, RSO	4. TELEPHONE NUMBER (313) 562-3232
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Main Office Inspection Next Inspection Date: 05/02/2019

Field Office Inspection

Temporary Job Site Inspection

PROGRAM SCOPE

Licensed activities were limited to doing about 7 cardiac imaging studies with unit dosages of technetium-99m radiopharmaceuticals per workday. The licensee's work hours were Tuesdays and Fridays from 8:30am to 4:40pm.

Performance Observations

The inspector: (1) observed a nuclear medicine technologist (NMT) demonstrate how she had conducted package receipt surveys and noted that the NMT's surveys were adequate; (2) observed that the NMT wore gloves, a lab coat, and her whole body and extremity dosimeters while conducting licensed activities; (3) observed the NMT prepare and administer a dosage to a patient while using time, distance and shielding to reduce her radiation exposure; (4) observed the NMT discard radioactive waste by placing it into a labeled radioactive waste container; (5) observed that the hot lab containing licensed material was secured from unauthorized access; (6) reviewed selected records of staff training; (7) observed the NMT demonstrate how she had conducted operational checks on the licensee's Ludlum Model 14C survey instrument that was last calibrated on 10/7/13 and due on 10/7/14, and the battery and constancy checks passed; (8) conducted a confirmatory survey with an NRC-owned and calibrated survey instrument, and the inspector's results were similar to the NMT's results at the surface of the constancy check source; (9) observed the NMT demonstrate how she would respond to a radioactive spill; (10) observed the NMT demonstrate how she prepared LQ packages for return to the nuclear pharmacy; (11) reviewed records showing that the licensee first received licensed material after it received its NRC license, and package receipt survey results were below regulatory limits; (12) observed the NMT demonstrate how she had done daily dose calibrator constancy checks; (13) reviewed selected area survey records; (14) reviewed the RSO's audit record dated 2/18/14, which included, in part, verification of security of licensed material; (15) reviewed dosimetry records that showed that the highest annual doses received to the whole body and extremities were well below regulatory limits; (16) reviewed records of dose calibrator linearity, accuracy, and geometrical variation tests; and (17) observed the NMT conduct a physical inventory of sealed sources. The inspector identified a minor violation of 10 CFR 20.1802 for failure to control 1 millicurie of technetium-99m in a labeled syringe during camera quality tests. The syringe was left unattended in the camera room with the doors open and unauthorized staff had access to it. Corrective actions included having the NMT maintain surveillance of the syringe to prevent unauthorized access, and verifying that the corrective actions are effective during program audits.