

**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

1. LICENSEE/LOCATION INSPECTED:

The South Bend Clinic  
211 N. Eddy Street  
South Bend, IN 46634-1755

REPORT NUMBER(S) 2015-001

2. NRC/REGIONAL OFFICE

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

3. DOCKET NUMBER(S)

030-36006

4. LICENSE NUMBER(S)

13-32393-01

5. DATE(S) OF INSPECTION

MARCH 30<sup>th</sup>, 2015

**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:

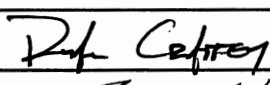
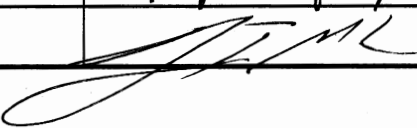
- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is 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             | Ryan Craffey |  | 3/30/15 |
| BRANCH CHIEF              | Aaron McCraw |  | 4/7/15  |

**Docket File Information**  
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|--------------------------------------|---|--|

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| 6. INSPECTION PROCEDURES USED<br><br>87131 | 7. INSPECTION FOCUS AREAS<br><br>All |
|--|--------------------------------------|

**SUPPLEMENTAL INSPECTION INFORMATION**

|                                 |                      |   |   |
|---------------------------------|----------------------|---|---|
| 1. PROGRAM CODE(S)<br><br>02200 | 2. PRIORITY<br><br>3 | 3. LICENSEE CONTACT<br><br>Sharon Updike, MHP - RSO | 4. TELEPHONE NUMBER<br><br>(574) 287-4146 |
|---------------------------------|----------------------|---|---|

Main Office Inspection      Next Inspection Date: March 2018

Field Office Inspection \_\_\_\_\_

Temporary Job Site Inspection \_\_\_\_\_

**PROGRAM SCOPE**

This was an unannounced routine inspection of a primary and specialty care clinic authorized to conduct diagnostic and therapeutic administrations of radiopharmaceuticals at its main facility in South Bend, Indiana. At the time of the inspection, one nuclear medicine technologist administered cardiac stress tests Mondays through Thursdays and other diagnostic nuclear tests on Fridays. The licensee averaged four administrations daily, using unit doses of technetium-99m. Although authorized to conduct therapeutic administrations of radiopharmaceuticals, to date the licensee had never administered any, and on March 23, 2015 submitted an amendment request to remove the authorization. The licensee retained the services of a medical physics consultant to conduct audits of the program on a quarterly basis.

**PERFORMANCE OBSERVATIONS**

The inspector toured the clinic to evaluate the licensee's measures for materials security, hazard communication and exposure control. The inspector conducted independent and confirmatory surveys of the clinic, and found no residual contamination or exposures to members of the public in excess of regulatory limits. The inspector was unable to observe the administration of any radiopharmaceuticals. However, the technologist was able to demonstrate their preparation and administration, in addition to implementation of licensee procedures for package receipt, instrument quality control, waste handling and spill response. Through these demonstrations and other discussions, the inspector found that the technologist was knowledgeable of radiation protection principles, licensee procedures, and regulatory requirements.

The inspector reviewed a selection of licensee records, including routine survey and dose calibrator quality control documentation, hazmat training materials, dosimetry, quarterly audits and sealed source inventories, the most recent of which matched the licensee's current possession of sealed sources.

No violations of NRC requirements were identified as a result of this inspection.