

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

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| 1. LICENSEE/LOCATION INSPECTED: The South Bend Clinic 211 N Eddy St. South Bend, IN 46634-1755 REPORT NUMBER(S) 2021001 | | 2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Rd, Suite 210 Lisle, IL 60532 | |
| 3. DOCKET NUMBER(S) 030-36006 | 4. LICENSE NUMBER(S) 13-32393-01 | 5. DATE(S) OF INSPECTION January 26, 2021 | |

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 | Zahid Sulaiman, Health Physicist | Zahid M. Sulaiman <small>Digitally signed by Zahid M. Sulaiman Date: 2021.02.01 13:55:21 -06'00'</small> | |
| BRANCH CHIEF | Michael Kunowski, Chief, MIB | Michael A. Kunowski <small>Digitally signed by Michael A. Kunowski Date: 2021.02.03 09:53:42 -06'00'</small> | |

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1. LICENSEE/LOCATION INSPECTED:

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

REPORT NUMBER(S) 2021001

2. NRC/REGIONAL OFFICE

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

3. DOCKET NUMBER(S)

030-36006

4. LICENSE NUMBER(S)

13-32393-01

5. DATE(S) OF INSPECTION

January 26, 2021

(Continued)

Docket File Information

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| 6. INSPECTION PROCEDURES USED 87130 | 7. INSPECTION FOCUS AREAS 03.01 - 03.07 |
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SUPPLEMENTAL INSPECTION INFORMATION

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|---------------------------------|----------------------|--|---|
| 1. PROGRAM CODE(S) 02201 | 2. PRIORITY 5 | 3. LICENSEE CONTACT Alseny Diallo, CNMT | 4. TELEPHONE NUMBER (574) 204-6329 |
|---------------------------------|----------------------|--|---|

Main Office Inspection Next Inspection Date: 01/26/2026
 Field Office Inspection _____
 Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an announced remote routine inspection of a primary and specialty care clinic authorized to conduct diagnostic administrations of radiopharmaceuticals at its main facility in South Bend, Indiana. The nuclear medicine department was staffed with a full-time nuclear medicine technologist (NMT). The NMT performed approximately 80 diagnostic procedures monthly. The diagnostic procedures included a variety of imaging procedures using technetium-99m (Tc-99m), primarily cardiac stress test, HIDA, and bone scans. The licensee retained the services of a medical physics consultant to conduct audits of the program on a quarterly basis.

PERFORMANCE OBSERVATIONS

This inspection was conducted virtually through the Microsoft Team meeting and consisted of interview with select licensee personnel, a review of select records, and an observation of security of the materials. Through Microsoft Team meeting, the inspector observed the physical inventory of sealed sources, and all sources were accounted for. The inspector had the NMT demonstrate the package receipt, instrument quality control, waste handling, spill response and daily area surveys, with no issue noted. Through these demonstrations and other discussion, 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 quarterly program audits, package receipts, waste disposal records, DOT Hazmat training, linearity and accuracy of the dose calibrator, instrument calibration, sealed source leak tests and inventory, daily area surveys, and weekly wipe tests. The inspector reviewed dosimetry records for 2018 through August 4, 2020, indicating the maximum annual dose to be 277 mrem - DDE, and 355 mrem - SDE.

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



Materials Inspection Record

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| 1. Licensee Name: The South Bend Clinic | | 2. Docket Number(s): 030-36006 | | 3. License Number(s) 13-32393-01 | |
| 4. Report Number(s): 2021001 | | | 5. Date(s) of Inspection: January 26, 2021 | | |
| 6. Inspector(s): Zahid Sulaiman, Health Physicist | | 7. Program Code(s): 2201 | 8. Priority: 5 | 9. Inspection Guidance Used: 87130 | |
| 10. Licensee Contact Name(s): Alseny Diallo, CNMT | | 11. Licensee E-mail Address: adiallo@southbendclinic.com | | 12. Licensee Telephone Number(s): (574)204-6329 | |
| 13. Inspection Type: | | 14. Locations Inspected: | | 15. Next Inspection Date (MM/DD/YYYY): | |
| <input type="checkbox"/> Initial <input checked="" type="checkbox"/> Routine <input type="checkbox"/> Announced <input type="checkbox"/> Non-Routine <input type="checkbox"/> Unannounced | | <input checked="" type="checkbox"/> Main Office <input type="checkbox"/> Field Office <input type="checkbox"/> Temporary Job Site <input checked="" type="checkbox"/> Remote | | 01/26/2026 <input checked="" type="checkbox"/> Normal <input type="checkbox"/> Extended <input type="checkbox"/> Reduced <input type="checkbox"/> No change | |

16. Scope and Observations:

This was an announced remote routine inspection of a primary and specialty care clinic authorized to conduct diagnostic administrations of radiopharmaceuticals at its main facility in South Bend, Indiana. The nuclear medicine department was staffed with a full-time nuclear medicine technologist (NMT). The NMT performed approximately 80 diagnostic procedures monthly. The diagnostic procedures included a variety of imaging procedures using technetium-99m (Tc-99m), primarily cardiac stress test, HIDA, and bone scans. The licensee retained the services of a medical physics consultant to conduct audits of the program on a quarterly basis.

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