

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Parkview Health
11050 Parkview Cir.
Fort Wayne, IN 46845

2. NRC/REGIONAL OFFICE

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

REPORT NUMBER(S) 2020-001

3. DOCKET NUMBER(S)

030-01593

4. LICENSE NUMBER(S)

13-01284-02

5. DATE(S) OF INSPECTION

January 16 & 17, 2020

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	<i>Zahid Sulaiman</i>	1/17/2020
BRANCH CHIEF	Robert Ruiz, Acting Chief, MIB	<i>Robert Ruiz</i>	1/24/20

Docket File Information

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January 16-17, 2020

6. INSPECTION PROCEDURES USED

87131, 87132

7. INSPECTION FOCUS AREAS

03.01 - 03.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)

02230

2. PRIORITY

2

3. LICENSEE CONTACT

Yuenian (Neal) Zhang, Ph.D, RSO

4. TELEPHONE NUMBER

(260) 266-9145

☒ Main Office Inspection Next Inspection Date: 01/16/2022

☒ Field Office Inspection As noted below

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was an unannounced, routine inspection of a regional medical center authorized to use byproduct material for medical purposes at its campus in Fort Wayne, Indiana, and at various satellite facilities in northeastern Indiana. The licensee was authorized to perform high dose rate remote afterloader (HDR) and temporary implant brachytherapy treatments, as well as yttrium-90 (Y-90) microspheres, radium-223 (Ra-223) Xofigo, iodine-131 (I-131 in capsules form) administration, and a full spectrum of diagnostic radiopharmaceutical administrations including fluorine-18 (FDG) at various location on its main campus. The main hospital nuclear medicine department was staffed with seven full-time, and a PRN nuclear medicine technologists (NMTs) who supported various nuclear medicine department in the main campus and its satellite facilities. The PET Fusion center was staffed with three full-time NMTs. The NMTs typically administered approximately 300 diagnostic doses monthly, 63 I-131 hyperthyroid and thyroid ablations, 16 Y-90 Sir-Spheres, and 21 Ra-223 therapy procedures annually. Licensee also performed a research study treatment procedure using lutetium-177 (Lu-177) labeled PSMA to a patient. The cancer institute was staffed with four oncologists, three authorized medical physicists (AMPs), and four dosimetrists who performed approximately 195 HDR gynecological and breast cancer treatments annually. Licensee had not performed any seeds implants since the last inspection.

PERFORMANCE OBSERVATIONS

The inspection consisted of interviews with selected licensee personnel, a review of selected records, independent measurements, and tours of the facilities at 11109 Parkview Plaza Drive, 11141 Parkview Plaza Drive, 11108 Parkview Circle Drive, and 3703 New Vision Drive in Fort Wayne, IN. The inspector observed the preparation and administration of a technetium-99m for cardiac stress test and FDG for PET imaging to a patient. The inspector: (1) observed the NMT conduct a physical inventory of sealed sources, and all sources were accounted for; (2) had the NMT demonstrate the dose calibrator constancy check, package receiving and check-in procedures, the end of the day daily and weekly area surveys, and proper handling of radioactive waste and disposal procedures. The inspector had the licensee staff demonstrate the licensee's procedures for HDR treatment planning and Y-90 Sir-Spheres preparation and administration.

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3. DOCKET NUMBER(S) 030-01593	4. LICENSE NUMBER(S) 13-01284-02	5. DATE(S) OF INSPECTION January 16-17, 2020
6. INSPECTION PROCEDURES USED 87131, 87132	7. INSPECTION FOCUS AREAS 03.01 - 03.07	

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02230	2. PRIORITY 2	3. LICENSEE CONTACT Yuenian (Neal) Zhang, Ph.D, RSO	4. TELEPHONE NUMBER (260) 266-9145
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PROGRAM SCOPE

(continued)

The inspector had the AMP demonstrate the HDR unit's: (1) security, (2) daily spot checks, (3) emergency equipment and procedures, (4) safety procedures and instructions, (5) door interlock system, (6) radiation monitoring equipment checks, and (7) full calibration measurements.

The inspector reviewed selected HDR, Y-90, Ra-223, and Lu-177 written directives and treatment plans. The inspector also reviewed the following records: radiation safety committee minutes, quarterly program audits, DOT Hazmat training, linearity and accuracy of the dose calibrator, instrument calibration, package receipts, waste disposal records, radiation safety training, and sealed source leak tests and inventory.

The inspector reviewed dosimetry records for 2018 through December 31, 2019, indicating the maximum annual dose to be 420 mrem - DDE and 1,986 mrem- SDE. The inspector conducted independent and confirmatory radiation surveys and found no residual contamination or exposures to members of the public in excess of regulatory limits. The last HDR source was exchanged on January 9, 2020.

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