

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Parkview Health
11141 Parkview Plaza Drive
Fort Wayne, IN 46845

REPORT NUMBER(S) 2018001

2. NRC/REGIONAL OFFICE

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

3. DOCKET NUMBER(S)

030-01593

4. LICENSE NUMBER(S)

13-01284-02

5. DATE(S) OF INSPECTION

March ~~5~~⁶, 2018

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 | Dennis P. O'Dowd | <i>Dennis P. O'Dowd</i> | 03/06/2018 |
| BRANCH CHIEF | Aaron T. McCraw | <i>Aaron T. McCraw</i> | 3/22/18 |

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

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| 1. LICENSEE/LOCATION INSPECTED: Parkview Health 11141 Parkview Plaza Drive Fort Wayne, IN 46845 REPORT NUMBER(S) 2018001 | 2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352 |
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| 3. DOCKET NUMBER(S) 030-01593 | 4. LICENSE NUMBER(S) 13-01284-02 | 5. DATE(S) OF INSPECTION March 5-6, 2018 |
| 6. INSPECTION PROCEDURES USED 87131, 87132 | 7. INSPECTION FOCUS AREAS All | |

SUPPLEMENTAL INSPECTION INFORMATION

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|---------------------------------|----------------------|---|---|
| 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: 03/05/2020

☒ 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 HDR and temporary implant brachytherapy treatments, as well as for Y-90 microspheres, Ra-223 Xofigo, I-131 capsule administrations and a full spectrum of diagnostic radiopharmaceutical administrations (including PET) at various locations on its main campus. The licensee performed only diagnostic administrations at its satellite facilities, though some maintained additional authorizations. The licensee retained the services of a medical physics consultant to review the content and implementation of the various facilities quarterly, and its RSC met quarterly. The RSO was based at the Cancer Center.

PERFORMANCE OBSERVATIONS: The inspector toured the facilities at 11109 Parkview Plaza Drive, 11141 Parkview Plaza Drive, 11108 Parkview Circle Drive, 3707 New Vision Drive, and 2200 Randallia Drive in Fort Wayne, to evaluate the licensee's measures for materials security, hazard communication and exposure control. The inspector observed the preparation and administration of a bone scan and several cardiac studies, package receipt, instrument quality control and waste handling by nuclear medicine staff. Licensee personnel demonstrated nuclear medicine daily checks, and daily/weekly area surveys, and described planning and administration of therapeutic procedures. No therapeutic procedures involving sealed or unsealed sources were conducted by the licensee at the time of the inspection. The inspector reviewed the licensee's procedures for HDR treatments and Y-90 Sir-Spheres administrations, and licensee staff demonstrated the implementation of licensee procedures for brachytherapy treatment planning and administration, including daily QA checks of the HDR, and for Sir-Sphere treatment planning and administration. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings. The inspector reviewed a selection of written directives and treatment plans for all modalities in use since the last inspection, documentation of daily QA checks of the HDR, implant brachytherapy sealed source inventories, routine nuclear medicine records, training records, dosimetry reports, consultant audits, and RSC meeting minutes. Review of dosimetry records indicated no exposures of regulatory concern.

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