NRC FORM 591M PART 1
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Parkview Health 11141 Parkview Plaza Drive Fort Wayne, Indiana 46845 REPORT NUMBER(S) 2013-001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-01593	13-01284-02 ~~13-01248-02~~	Sept. 23-25, 2013

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 violations(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	Geoffrey M. Warren		9/25/13
BRANCH CHIEF	Aaron T. McCraw		10/2/13

NRC FORM 591M PART 3
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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030-01593	13-01284-02	Sept. 23 - 25, 2013

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87131, 87132	03.01 - 03.08, 03.01 - 03.08

SUPPLEMENTAL INSPECTION INFORMATION

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

☑ Main Office Inspection — Next Inspection Date: September 2015

☑ Field Office Inspection — 11109 and 11123 Parkview Plaza Drive, Fort

☐ Temporary Job Site Inspection — Wayne IN and 207 N. Townline Road, Lagrange IN

PROGRAM SCOPE

This was a routine, unannounced inspection. The licensee operated a large medical campus in northern Fort Wayne, Indiana, and several smaller hospitals and clinics limited to nuclear medicine procedures in northeastern Indiana. Authorized addresses on Parkview Plaza Drive (PPD) and Parkview Circle Drive were different entrances to the main hospital. The licensee was authorized to use byproduct materials in 35.100 through 35.400 and iridium-192 in a high dose rate (HDR) remote afterloader.

The radiation oncology department was staffed with three physicists, three dosimetrists, and four authorized users who performed twelve to fifteen HDR fractions quarterly at 11141 PPD and eight temporary implant procedures quarterly using iridium-192 and cesium-137 seeds at 11109 PPD. No permanent implant procedures had been performed since 2011; the licensee would train staff before resuming such procedures.

The main campus included several nuclear medicine areas. Four full-time technologists staffed the inpatient clinic (11109 PPD) and outpatient clinic (11141 PPD); staff from the outpatient clinic performed 3 to 5 sentinel node procedures weekly at 11123 PPD. Nuclear medicine staff at the inpatient and outpatient areas performed 300 diagnostic procedures monthly, including a wide variety of procedures but excluding cardiac stress testing. In addition, these staff performed 15 iodine-131 therapy procedures quarterly, with the iodine in capsule form. Doses were received as unit doses or prepared from bulk technetium.

Two cardiology areas were operated at 11108 Parkview Circle Drive; this address was not reviewed during the inspection.

At the Lagrange facility, one part-time technologist performed 40 diagnostic nuclear medicine procedures monthly, primarily cardiac, hepatobiliary, and bone scans, using unit doses. At this site, licensed activities occurred Tuesdays through Thursdays.

(continued on Part 2)

NRC FORM 591M PART 2
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

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(Continued)

Performance Observations: The inspector observed one HDR treatment, five diagnostic administrations of licensed materials, HDR daily QC checks, kit preparation, and package receipt surveys and wipes. Licensee personnel demonstrated nuclear medicine daily checks and daily and weekly contamination surveys, and described planning and administration of therapeutic procedures. The inspector noted no concerns with these activities. The inspector reviewed written directives for radiopharmaceutical therapies, HDR treatments, and brachytherapy procedures, and identified no concerns. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. Review of dosimetry records indicated no exposures of regulatory concern except as described below. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings. Radiation Safety Committee minutes indicated appropriate membership and topics of discussion.

The licensee had reported to the NRC on April 22, 2013, that one individual's whole-body dosimeter had indicated an exposure of 13.7 rem from October 1 through December 31, 2012, exceeding the regulatory limit for annual whole-body exposure. The individual's two ring badges for the period indicated exposures of 7,032 and 55 millirem. The individual's total whole-body exposure for over 25 years exposure prior to this reading was less than 1 rem. The licensee determined that the whole-body badge showed a static exposure, indicating that the badge had not moved while receiving the exposure. Based on this and other factors, the licensee concluded that the individual had not been wearing the badges at the time of exposure and administratively assigned a typical exposure for the wearing period. The inspector reviewed the licensee's investigation and determined that the licensee sufficiently supported this conclusion.