NRC FORM 591M PART 1
(10-2011)
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 Parkview Comprehensive Care Center 11141 Parkview Plaza Drive Fort Wayne, IN 46845 REPORT NUMBER(S) 12-01	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	January 10-11, 2012

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.

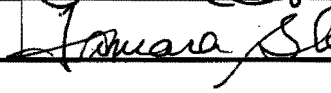
☐ 3. The violations(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, to exercise discretion, were satisfied.

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	Robert P. Hays		1/11/12
BRANCH CHIEF	Tamara E. Bloomer		1/26/12

NRC FORM 591M PART 3
(10-2011)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
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3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-01593	13-01284-02	January 10-11, 2012

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87130, 87132	03.01-03.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02230	2	Tom Kumpuris, RSO	(800) 321-2207

☑ Main Office Inspection Next Inspection Date: 01/10/2014

☑ Field Office Inspection Huntington, IN and Columbia City, IN

☐ Temporary Job Site Inspection

PROGRAM SCOPE

The licensee was a medical institution with authorization by the license to use byproduct materials for diagnostic and therapeutic medical procedures under 10 CFR 35.100, 35.200, 35.300, 35.400, and 35.600 using a Nucletron MicroSelectron remote afterloading device Model 105.999 at 12 locations in the vicinity of Ft. Wayne, IN.

During the previous inspection, the licensee's nuclear medicine, brachytherapy, and HDR afterloader radiation safety programs were reviewed with no violations or concerns identified. This inspection focused only on the licensee's Nucletron MicroSelectron-HDR Classic Remote Afterloader at the main office and two additional locations recently added to the license at Huntington, IN and Columbia, City, IN.

Performance Observations

During the HDR inspection, the licensee's medical physicists demonstrated/discussed: (1) required patient surveys; (2) package receipt and return procedures; (3) written directives and treatment plans; (4) security of licensed material; (5) electrometer, well chamber (June 2011) and survey instrument calibrations; (7) full HDR calibrations; (8) daily checks performed prior to each treatment; (9) emergency equipment and procedures; (10) annual refresher training/ emergency drills; (11) postings; (12) redundancy verifications (by authorized user) for ensuring correct step position, dwell time, and dose; (13) Prime Alert monitor tests; and (14) written procedures for HDR treatments. Surveys of the treatment device in storage indicated no dose concerns and consistent with licensee survey records and postings.

At the Huntington IN facility, the licensee is authorized for diagnostic studies as authorized by 10 CFR 35.100 and 35.200. The nuclear medicine department was staffed with one nuclear medicine technologist (NMT). The NMT administered a daily average of 3-6 diagnostic studies, with the majority being cardiac studies using myoview as ordered by the authorized user. Iodine-123 is administered for uptake studies and averaged 1 case per month.

Continued on the next page (Part 3, page 2).

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6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87130, 87132	03.01-03.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02240	2	Tom Kumpuris, RSO	(800) 321-2207

☑ Main Office Inspection Next Inspection Date: 01/09/2014

☑ Field Office Inspection Huntington, IN and Columbia City, IN

☐ Temporary Job Site Inspection

PROGRAM SCOPE

Continued from the previous page (Part 3, page 1).

The nuclear medicine department received unit doses from a Ft. Wayne, IN nuclear pharmacy. All waste was either held for decay-in-storage (DIS) or returned to the nuclear pharmacy as limited quantity shipments.

At Columbia, City, IN, the nuclear medicine department was staffed with one nuclear medicine technologist (NMT). The NMT administered a daily average of 3-5 diagnostic studies, with the majority being cardiac studies using myoview or thallium as ordered by the authorized user. Iodine-123 is administered for uptake studies and averaged from none to 1 or 2 cases per month. The nuclear medicine department also received unit doses from a Ft. Wayne, IN nuclear pharmacy. All waste was either held for decay-in-storage (DIS) or returned to the nuclear pharmacy as limited quantity shipments.

Performance Observations

During each nuclear medicine inspection, the licensee's NMT demonstrated/discussed: (1) survey instruments and required surveys; (2) package receipt and check-in procedures; (3) wipe test counting and efficiency; (4) unit dose and safe handling procedures; (5) waste handling; (6) sealed source inventories and leak tests; (7) security and storage of licensed material; (8) dose calibrator tests; (9) quarterly radiation safety program audit results; and (10) dosimetry (< 10% of annual limits). The inspector performed independent and confirmatory radiation measurements at each location, which indicated results consistent with licensee survey records and postings.