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
Porter Regional Hospital 85 East U.S. Highway 6 Valparaiso, Indiana 46383 REPORT NUMBER(S) 2017-001	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
030-12150	13-17073-01	03/01/2017

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	Dennis P. O'Dowd	Dennis P. O'Dowd	03/01/17
BRANCH CHIEF	Aaron T. McCraw		3/16/17

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

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-12150	13-17073-01	March 1, 2017

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

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02240	2	James Forde, M.D., RSO	(219) 983-8300

☑ Main Office Inspection Next Inspection Date: 03/01/2019

☑ Field Office Inspection Two Addt'l. Locations - See below

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was a routine, unannounced inspection of a licensee authorized under its NRC license to use byproduct materials for various medical uses permitted by 10 CFR Part 35 at three locations: A 300-bed main hospital located in Valparaiso, Indiana, authorized for materials and uses permitted by 35.100, 35.200, 35.300, 35.400, and 35.1000 (yttrium-90 SIR-Spheres); a cardiology center in Valparaiso, Indiana, authorized for uses of 35.100 and 35.200 materials; and a PET center in Chesterton, Indiana, authorized for uses of 35.100 and 35.200 materials. The licensee employed 7 full-time nuclear medicine technologists (NMTs), and with the exception of one NMT dedicated to the cardiology center, provided coverage at all three locations on a rotational basis. Approximately 275 diagnostic nuclear medicine procedures were performed monthly at the main hospital; approximately 200 diagnostic nuclear medicine procedures (cardiology only) were performed monthly at the cardiology center, and approximately 50 procedures using F-18 (FDG) were performed monthly at the PET center. The main hospital received both unit and bulk doses (200 mCi twice daily) from an area pharmacy; the other two locations received unit doses only. The licensee (main hospital only) performed approximately three administrations of sodium iodide I-131 per month. Nine administration of Ra-223 dichloride (Xofigo) were performed in 2016, (none in 2015 and 2017). The licensee performed three Y-90 SIR-Spheres treatments in 2015, none in 2016, and one, as of the inspection date, in 2017. No prostate seed implant procedures were conducted since the last inspection. The licensee retained a consulting physicist who audited the licensee's program on a quarterly basis.

PERFORMANCE OBSERVATIONS

The inspector observed several diagnostic administrations of byproduct material during the inspection at the licensee's main hospital, (including the delivery of Tc-99m MAA trans-arterially to a patient in the interventional radiology suite, as part of an evaluation for shunting prior to a Y-90 treatment scheduled for the following week). The inspector also observed several diagnostic nuclear cardiology administrations at the cardiology center. The inspector also conducted an onsite inspection of the licensee's PET center (although no administrations were observed). These observations,

(cont'd. on Part 2)

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(Continued)

(cont'd. from Part 3)

combined with interviews of available staff, revealed an adequate level of understanding of emergency and material handling procedures and techniques. Within each functional area, the licensee successfully discussed/demonstrated routine equipment QA/QC checks, daily package receiving and check-in procedures, daily and weekly area surveys, and waste handling and disposal procedures. The inspector confirmed that these activities were successfully and routinely completed by reviewing selected records. The inspector reviewed selected records for I-131, Ra-223 Xofigo, and Y-90 SIR-Spheres administrations requiring a written directive since the previous inspection. The licensee maintained adequate records and procedures to demonstrate that each administration was in accordance with the written directive. Licensed material was adequately secured and not readily accessible to members of the general public. The licensee possessed several survey meters that were calibrated, operational, and performed comparably to an NRC survey meter during side-by-side measurements. The inspector performed independent and confirmatory radiation measurements in each functional area that were consistent with licensee survey records and postings. Personal whole body and extremity dosimetry badges were observed being worn by the staff during the inspection, and records did not indicate doses in excess of 10 CFR Part 20 limits. Dosimetry records indicated that the maximum annual doses to be: for 2015, 324 mrem- DDE, 874 mrem- SDE; for 2016, 232 mrem- DDE, 904 mrem- SDE.

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