

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Porter Regional Hospital 85 East U.S. Highway 6 Valparaiso, Indiana 46383 REPORT NUMBER(S) 2017001	2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352
--	---

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

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

SUPPLEMENTAL INSPECTION INFORMATION

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

- Main Office Inspection Next Inspection Date: 03/01/2019
- Field Office Inspection Two Addtl. 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)

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Porter Regional Hospital 85 East U.S. Highway 6 Valparaiso, Indiana 46383 REPORT NUMBER(S) 2017001	2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352
--	---

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

(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.