

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Porter Regional Hospital
85 E. U.S. Hwy 6
Valparaiso, IN

2. NRC/REGIONAL OFFICE

Region III
2443 Warrenville Rd.
Lisle, IL 60532

Select a location (Use keyboard arrows to select) . .

REPORT NUMBER(S) 2018001

3. DOCKET NUMBER(S)

030-12150

4. LICENSE NUMBER(S)

13-17073-01

5. DATE(S) OF INSPECTION

11/30/18

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:

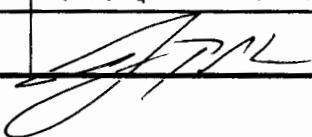
- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is 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	Robert G. Gattone, Jr.	Robert G. Gattone, Jr.	11/30/18
BRANCH CHIEF	Anna T. McCann		12/14/18

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Porter Regional Hospital 85 E. U.S. Highway 6 Valparaiso, IN 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) 030-12150	4. LICENSE NUMBER(S) 13-17073-01	5. DATE(S) OF INSPECTION 11/30/18
--------------------------------------	---	--

6. INSPECTION PROCEDURES USED 87132	7. INSPECTION FOCUS AREAS 02.01, 02.02, 02.04, 02.05, 02.06, 02.07, 02.09
--	--

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: 11/30/2020

Field Office Inspection _____

Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an unannounced, routine inspection. The licensee had 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. That PET Center is planned to be decommissioned. The new PET Center will be located at the main hospital. The licensee employed 7 full-time nuclear medicine technologists (NMTs), and with the exception of 1 NMT dedicated to the cardiology center, provided coverage at all three locations on a rotational basis. Approximately 425 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 licensee (main hospital only) performed approximately two administrations of sodium iodide I-131 per month (whole body scan, thyroid cancer treatment, and hyperthyroid treatment). The licensee last administered Ra-223 dichloride (Xofigo) on 10/4/17. The licensee performed several Y-90 SIR-Spheres treatments. The licensee had not conducted 35.400 treatments since about 2012.

Performance Observations

The inspector: (1) toured the new PET Center at the main hospital that was in the construction phase, and noted that the layout was as per the facility diagram in the licensee's letter dated 6/12/18; (2) noted that there were no therapies during the inspection; (3) observed licensed material secured and posted as required; (4) observed a nuclear medicine technologist (NMT) prepare a technetium-99m Cardiolite dosage for a cardiac stress imaging test using proper radiation safety techniques; (5) noted that the licensee's survey instruments were calibrated; (6) reviewed selected records of yttrium-90 SIR-Spheres treatments, including liver to lung shunt tests prior to yttrium-90 SIR-Spheres administration; (7) reviewed dosimeter records since the last inspection to date, and the highest annual doses of whole body and extremity were 244 millirem (mrem) and 950 mrem, respectively; and (8) reviewed selected records of iodine-131 use and a Xofigo treatment in 2017.

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